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Safety Assessment of Polyglyceryl Fatty Acid Esters as Used in Cosmetics

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Abstract

The Expert Panel for Cosmetic Ingredient Safety (Panel) assessed the safety of 274 polyglyceryl fatty acid esters. Each of the esters in this group is a polyether comprising 2 to 20 glyceryl residues, end-capped by esterification with simple carboxylic acids, such as fatty acids. Most of these ingredients are reported to function in cosmetics as skin-conditioning agents and/or surfactants. The Panel reviewed the available data and considered conclusions from their relevant previous reports, and determined that these ingredients are safe in cosmetics in the present practices of use and concentration described in this safety assessment when formulated to be non-irritating.

Keywords

polyglyceryl fatty acid esters, safety, cosmetics, personal care products, risk assessment

Introduction

This is a safety assessment of the polyglyceryl fatty acid esters as used in cosmetic formulations. Each of the esters in this report is a polyether comprising 2 to 20 glyceryl residues, end-capped by esterification with simple carboxylic acids, such as fatty acids. The 274 ingredients included in this report are listed alphabetically in Table 1. Table 2 and Table 3 present these ingredients based initially by increasing polyglyceryl chain length and second by increasing alkyl chain length; however, when there is a mixture of fatty acid constituents, those ingredients are presented by chain length for the polyglyceryl moiety and alphabetically based on the fatty acid component. Test data are presented based on increasing chain length (i.e., the order provided in Table 2 and Table 3).

According to the *International Cosmetic Ingredient Dictionary and Handbook* (*Dictionary*), most of these ingredients are reported to function in cosmetics as skin-conditioning agents and/or surfactants[1] (Table 3). Additional functions have also been reported.

In 2011, the Panel published a safety assessment of a family of ingredients that included Polyglyceryl-20 Octaisononanoate; the Panel concluded that all of the ingredients named in that report are safe in the present practices of use and concentration identified in that assessment.[2] Because Polyglyceryl-20 Octaisononanoate is a polyglyceryl fatty acid ester and is structurally related to the ingredients in this report, it is being included in this safety assessment.

The Panel has recently reviewed the safety of monoglyceryl monoesters, and concluded that the monoglyceryl monoesters are safe in cosmetics in the present practices of use and concentration described in that safety assessment.[3] Monoglyceryl monoesters and the polyglyceryl fatty acid esters both consist of the same starting materials, and they have the same potential metabolites. The difference between these two families of ingredients is that monoglyceryl monoesters are structurally constituted of the esterification products of only one equivalent of glycerin and one equivalent of a carboxylic acid, as opposed to the varying number of equivalents of glycerin and fatty acids in the polyglyceryl esters.

The Panel has previously reviewed the safety of ingredients that represent some of the starting materials of the polyglyceryl fatty acid esters that may persist as residual impurities

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Table 1. Polyglyceryl Fatty Acid Esters – Presented Alphabetically.

Adansonia Digitata Seed Oil Polyglyceryl-6 Esters	Polyglyceryl-3 Dicocoate
Almond Oil/Polyglyceryl-10 Esters	Polyglyceryl-3 Di-Hydroxystearate
Apricot Kernel Oil Polyglyceryl-3 Esters	Polyglyceryl-3 Diisostearate
Apricot Kernel Oil Polyglyceryl-4 Esters	Polyglyceryl-3 Dioleate
Apricot Kernel Oil Polyglyceryl-5 Esters	Polyglyceryl-3 Distearate
Apricot Kernel Oil Polyglyceryl-6 Esters	Polyglyceryl-3 Isostearate
Apricot Kernel Oil Polyglyceryl-10 Esters	Polyglyceryl-3 Laurate
Argan Oil Polyglyceryl-6 Esters	Polyglyceryl-3 Myristate
Astrocaryum Vulgare Oil Polyglyceryl-6 Esters	Polyglyceryl-3 Oleate
Avocado Oil Polyglyceryl-6 Esters	Polyglyceryl-3 Palmitate
Babassu Oil Polyglyceryl-4 Esters	Polyglyceryl-3 Pentacaprylate/Caprate
Babassu Oil Polyglyceryl-6 Esters	Polyglyceryl-3 Pentaolivate
Bertholletia Excelsa Seed Oil Polyglyceryl-6 Esters	Polyglyceryl-3 Pentaricinoleate
Borage Seed Oil Polyglyceryl-4 Esters	Polyglyceryl-3 Rice Branate
Borage Seed Oil Polyglyceryl-6 Esters	Polyglyceryl-3 Ricinoleate
Candelilla/Jojoba/Rice Bran Polyglyceryl-3 Esters	Polyglyceryl-3 Soyate/Shea Butterate
Caprylic/Capric Glycerides Polyglyceryl-10 Esters	Polyglyceryl-3 Stearate
Carapa Guaianensis Oil Polyglyceryl-6 Esters	Polyglyceryl-3 Stearate SE
Castor Oil Polyglyceryl-6 Esters	Polyglyceryl-3 Triisostearate
Cocoa Butter Polyglyceryl-6 Esters	Polyglyceryl-3 Triolivate
Coconut Oil Polyglyceryl-6 Esters	Polyglyceryl-4 Almondate/Shea Butterate
Coffee Seed Oil Polyglyceryl-6 Esters	Polyglyceryl-4 Caprate
Diisostearoyl Polyglyceryl-3 Dimer Dilinoleate	Polyglyceryl-4 Caprylate
Glyceryl/Polyglyceryl-6 Isostearate/Behenate Esters	Polyglyceryl-4 Caprylate/Caprate
Hazelnut Seed Oil Polyglyceryl-6 Esters	Polyglyceryl-4 Cocoate
Linseed Oil Polyglyceryl-4 Esters	Polyglyceryl-4 Dilaurate
Macadamia Seed Oil Polyglyceryl-6 Esters	Polyglyceryl-4 Distearate
Macadamia Seed Oil Polyglyceryl-6 Esters Behenate	Polyglyceryl-4 Hazelnutseedate
Mauritia Flexuosa Seed Oil Polyglyceryl-6 Esters	Polyglyceryl-4 Isostearate
Olive Oil Polyglyceryl-3 Esters	Polyglyceryl-4 Isostearate/Laurate
Olive Oil Polyglyceryl-4 Esters	Polyglyceryl-4 Laurate
Olive Oil Polyglyceryl-6 Esters	Polyglyceryl-4 Laurate/Sebacate
Palm Kernel Oil Polyglyceryl-4 Esters	Polyglyceryl-4 Laurate/Succinate
Palm Oil Polyglyceryl-3 Esters	Polyglyceryl-4 Oleate
Palm Oil Polyglyceryl-4 Esters	Polyglyceryl-4 Pentaoleate
Palm Oil Polyglyceryl-5 Esters	Polyglyceryl-4 Pentapalmitate/Stearate
Palm Oil Polyglyceryl-6 Esters	Polyglyceryl-4 Pentastearate
Parinari Curatellifolia Oil Polyglyceryl-6 Esters	Polyglyceryl-4 Punicate
Pinus Sibirica Seed Oil Polyglyceryl-6 Esters	Polyglyceryl-4 Stearate
Polyglyceryl-2 Caprate	Polyglyceryl-4 Sweet Almondate
Polyglyceryl-2 Caprylate	Polyglyceryl-4 Tristearate
Polyglyceryl-2 Diisostearate	Polyglyceryl-5 Caprate
Polyglyceryl-2 Dioleate	Polyglyceryl-5 Dicaprylate
Polyglyceryl-2 Distearate	Polyglyceryl-5 Dilaurate
Polyglyceryl-2 Isopalmitate	Polyglyceryl-5 Dioleate
Polyglyceryl-2 Isopalmitate/Sebacate	Polyglyceryl-5 Hexastearate
Polyglyceryl-2 Isostearate	Polyglyceryl-5 Isostearate
Polyglyceryl-2 Laurate	Polyglyceryl-5 Laurate
Polyglyceryl-2 Myristate	Polyglyceryl-5 Myristate
Polyglyceryl-2 Oleate	Polyglyceryl-5 Oleate
Polyglyceryl-2 Palmitate	Polyglyceryl-5 Pentamyristate
Polyglyceryl-2 Sesquicaprylate	Polyglyceryl-5 Ricinoleate
Polyglyceryl-2 Sesquiisostearate	Polyglyceryl-5 Stearate
Polyglyceryl-2 Sesquioleate	Polyglyceryl-5 Tribehenate
Polyglyceryl-2 Sesquistearate	Polyglyceryl-5 Triisostearate
Polyglyceryl-2 Stearate	Polyglyceryl-5 Trimyristate
Polyglyceryl-2 Tetrabehenate/ Macadamiate/Sebacate	Polyglyceryl-5 Trioleate
Polyglyceryl-2 Tetraisostearate	Polyglyceryl-5 Tristearate
Polyglyceryl-2 Tetraoleate	Polyglyceryl-6 Adansonia Digitata Seedate
Polyglyceryl-2 Tetrastearate	Polyglyceryl-6 Apricot Kernelate
Polyglyceryl-2 Triisostearate	Polyglyceryl-6 Argan Kernelate
Polyglyceryl-3 Beeswax	Polyglyceryl-6 Behenate
Polyglyceryl-3 Behenate	Polyglyceryl-6 Caprate
Polyglyceryl-3 Caprate	Polyglyceryl-6 Caprylate
Polyglyceryl-3 Caprylate	Polyglyceryl-6 Caprylate/Caprate
Polyglyceryl-3 Cocoate	Polyglyceryl-6 Citrullus Lanatus Seedate
Polyglyceryl-3 Dicaprate	Polyglyceryl-6 Dicaprate
Polyglyceryl-3 Dicitrate/Stearate	Polyglyceryl-6 Diisostearate

(continued)

Table 1. (continued)

Polyglyceryl-6 Dioleate
Polyglyceryl-6 Dipalmitate
Polyglyceryl-6 Distearate
Polyglyceryl-6 Heptacaprylate
Polyglyceryl-6 Hexaoleate
Polyglyceryl-6 Hexastearate
Polyglyceryl-6 Isostearate
Polyglyceryl-6 Laurate
Polyglyceryl-6 Myristate
Polyglyceryl-6 Octacaprylate
Polyglyceryl-6 Octastearate
Polyglyceryl-6 Oleate
Polyglyceryl-6 Palmitate
Polyglyceryl-6 Palmitate/Succinate
Polyglyceryl-6 Pentacaprylate
Polyglyceryl-6 Pentaoleate
Polyglyceryl-6 Pentaricinoleate
Polyglyceryl-6 Pentastearate
Polyglyceryl-6 Ricinoleate
Polyglyceryl-6 Schinziophyton Rautanenii Kernelate
Polyglyceryl-6 Sclerocarya Birrea Seedate
Polyglyceryl-6 Sesquicaprylate
Polyglyceryl-6 Sesquiisostearate
Polyglyceryl-6 Sesquistearate
Polyglyceryl-6 Stearate
Polyglyceryl-6 Tetrabehenate
Polyglyceryl-6 Tetracaprylate
Polyglyceryl-6 Tetraoleate
Polyglyceryl-6 Tricaprylate
Polyglyceryl-6 Trichilia Emetica Seedate
Polyglyceryl-6 Tristearate
Polyglyceryl-6 Undecylenate
Polyglyceryl-6 Ximenia Americana Seedate
Polyglyceryl-8 C12-20 Acid Ester
Polyglyceryl-8 Decabehenate/Caprate
Polyglyceryl-8 Decaerucate/Decaisostearate/ Decaricinoleate
Polyglyceryl-8 Oleate
Polyglyceryl-8 Stearate
Polyglyceryl-10 Apricot Kernelate
Polyglyceryl-10 Behenate/Eicosadioate
Polyglyceryl-10 Caprate
Polyglyceryl-10 Caprylate
Polyglyceryl-10 Caprylate/Caprate
Polyglyceryl-10 Cocoate
Polyglyceryl-10 Decaethylhexanoate
Polyglyceryl-10 Decahydroxystearate
Polyglyceryl-10 Decaisostearate
Polyglyceryl-10 Decalinoleate
Polyglyceryl-10 Decamacadamiate
Polyglyceryl-10 Decaoleate
Polyglyceryl-10 Decastearate
Polyglyceryl-10 Dicocoate
Polyglyceryl-10 Didecanoate
Polyglyceryl-10 Diisostearate
Polyglyceryl-10 Dilaurate
Polyglyceryl-10 Dimyristate
Polyglyceryl-10 Dioleate
Polyglyceryl-10 Dipalmitate
Polyglyceryl-10 Distearate
Polyglyceryl-10 Dodecabehenate
Polyglyceryl-10 Dodecacaprate
Polyglyceryl-10 Dodecacaprylate
Polyglyceryl-10 Dodeca-Caprylate/ Caprate
Polyglyceryl-10 Eicosanedioate/Tetradecanedioate
Polyglyceryl-10 Hepta(Behenate/Stearate)
Polyglyceryl-10 Heptahydroxystearate
Polyglyceryl-10 Heptaoleate
Polyglyceryl-10 Heptastearate
Polyglyceryl-10 Hexaerucate
Polyglyceryl-10 Hexaisostearate
Polyglyceryl-10 Hexaoleate
Polyglyceryl-10 Hydroxystearate/Stearate/Eicosadioate
Polyglyceryl-10 Isostearate
Polyglyceryl-10 Laurate
Polyglyceryl-10 Linoleate
Polyglyceryl-10 Mono/Dioleate
Polyglyceryl-10 Myristate
Polyglyceryl-10 Nonaerucate
Polyglyceryl-10 Nonaisostearate
Polyglyceryl-10 Oleate
Polyglyceryl-10 Palmate
Polyglyceryl-10 Palmitate
Polyglyceryl-10 Pentacaprylate
Polyglyceryl-10 Pentahydroxystearate
Polyglyceryl-10 Pentaisostearate
Polyglyceryl-10 Pentalaurate
Polyglyceryl-10 Pentalinoleate
Polyglyceryl-10 Pentaoleate
Polyglyceryl-10 Pentaricinoleate
Polyglyceryl-10 Pentastearate
Polyglyceryl-10 Sesquistearate
Polyglyceryl-10 Stearate
Polyglyceryl-10 Tetradecanedioate
Polyglyceryl-10 Tetralaurate
Polyglyceryl-10 Tetraoleate
Polyglyceryl-10 Tricocoate
Polyglyceryl-10 Tridecanoate
Polyglyceryl-10 Trierucate
Polyglyceryl-10 Triisostearate
Polyglyceryl-10 Trilaurate
Polyglyceryl-10 Trioleate
Polyglyceryl-10 Tristearate
Polyglyceryl-10 Undecylenate
Polyglyceryl-15 Diisostearate
Polyglyceryl-20 Docosabehenate/Isostearate
Polyglyceryl-20 Docosabehenate/Laurate
Polyglyceryl-20 Docosabehenate/Oleate
Polyglyceryl-20 Heptacaprylate
Polyglyceryl-20 Heptadecabehenate/Laurate
Polyglyceryl-20 Hexacaprylate
Polyglyceryl-20 Octadecabehenate/Laurate
Polyglyceryl-20 Octaisononanoate
Pumpkin Seed Oil Polyglyceryl-4 Esters
Pumpkin Seed Oil Polyglyceryl-4 Esters Succinate
Rice Bran Oil Polyglyceryl-3 Esters
Rosa Rubiginosa Seed Oil Polyglyceryl-6 Esters
Safflower Seed Oil Polyglyceryl-6 Esters
Schinziophyton Rautanenii Kernel Oil Polyglyceryl-6 Esters
Sclerocarya Birrea Seed Oil Polyglyceryl-6 Esters
Sclerocarya Birrea Seed Oil Polyglyceryl-10 Esters
Sesame Oil Polyglyceryl-6 Esters
Shea Butter Polyglyceryl-3 Esters
Shea Butter Polyglyceryl-4 Esters
Shea Butter Polyglyceryl-6 Esters
Soybean Oil Polyglyceryl-6 Esters
Sunflower Seed Oil Polyglyceryl-3 Esters
Sunflower Seed Oil Polyglyceryl-4 Esters
Sunflower Seed Oil Polyglyceryl-5 Esters
Sunflower Seed Oil Polyglyceryl-6 Esters
Sunflower Seed Oil Polyglyceryl-10 Esters
Sweet Almond Oil Polyglyceryl-4 Esters
Sweet Almond Oil Polyglyceryl-6 Esters
Theobroma Grandiflorum Seed Butter Polyglyceryl-6 Esters
Trichilia Emetica Seed Oil Polyglyceryl-6 Esters
Triisostearoyl Polyglyceryl-3 Dimer Dilinoleate
Watermelon Seed Oil Polyglyceryl-6 Esters
Watermelon Seed Oil Polyglyceryl-10 Esters
Ximenia Americana Seed Oil Polyglyceryl-6 Esters

in the polyglyceryl esters products, or may represent potential metabolites (e.g., from the action of esterases in the skin), such as glycerin and free fatty acids. A list of relevant ingredients that have been reviewed and the associated conclusions are provided in Table 4. (The full reports can be found on the Cosmetic Ingredient Review (CIR) website: https://www.cir-safety.org/ingredients). Other ingredients, such as dipropylene glycol and polypropylene glycols (PPGs), have also been reviewed and are also included in Table 4 because they have similar properties and functions.

Much of the toxicity data included in this safety assessment were found on the European Chemicals Agency (ECHA) website.[4] The ECHA website provides summaries of information generated by industry, and it is the summary data that are reported in this safety assessment when ECHA is cited. Also, when deemed appropriate, read-across data from ECHA are included in this

Table 2. Polyglyceryl Fatty Acid Esters – Arranged by Polyglyceryl Chain Length.

Polyglyceryl Multi-esters (i.e., not mono-esters and not "polyesters")

Polyglyceryl-2 discrete esters
Polyglyceryl-2 Caprate
Polyglyceryl-2 Caprylate
Polyglyceryl-2 Laurate
Polyglyceryl-2 Myristate
Polyglyceryl-2 Isopalmitate
Polyglyceryl-2 Palmitate
Polyglyceryl-2 Isostearate
Polyglyceryl-2 Oleate
Polyglyceryl-2 Stearate
Polyglyceryl-2 mixed esters
Polyglyceryl-2 Isopalmitate/Sebacate
Polyglyceryl-3 discrete esters
Polyglyceryl-3 Caprate
Polyglyceryl-3 Caprylate
Polyglyceryl-3 Laurate
Polyglyceryl-3 Myristate
Polyglyceryl-3 Palmitate
Polyglyceryl-3 Isostearate
Polyglyceryl-3 Oleate
Polyglyceryl-3 Stearate
Polyglyceryl-3 Stearate SE
Polyglyceryl-3 Ricinoleate
Polyglyceryl-3 Behenate
Polyglyceryl-3 mixed esters
Apricot Kernel Oil Polyglyceryl-3 Esters
Candelilla/Jojoba/Rice Bran Polyglyceryl-3 Esters
Olive Oil Polyglyceryl-3 Esters
Palm Oil Polyglyceryl-3 Esters
Polyglyceryl-3 Beeswax
Polyglyceryl-3 Cocoate
Polyglyceryl-3 Rice Branate
Polyglyceryl-3 Soyate/Shea Butterate
Rice Bran Oil Polyglyceryl-3 Esters
Shea Butter Polyglyceryl-3 Esters
Sunflower Seed Oil Polyglyceryl-3 Esters
Polyglyceryl-4 discrete esters
Polyglyceryl-4 Caprate
Polyglyceryl-4 Caprylate
Polyglyceryl-4 Laurate
Polyglyceryl-4 Isostearate
Polyglyceryl-4 Oleate
Polyglyceryl-4 Stearate
Polyglyceryl-4 mixed esters
Apricot Kernel Oil Polyglyceryl-4 Esters
Babassu Oil Polyglyceryl-4 Esters
Borage Seed Oil Polyglyceryl-4 Esters
Linseed Oil Polyglyceryl-4 Esters
Olive Oil Polyglyceryl-4 Esters
Palm Kernel Oil Polyglyceryl-4 Esters
Palm Oil Polyglyceryl-4 Esters
Polyglyceryl-4 Almondate/Shea Butterate
Polyglyceryl-4 Caprylate/Caprate
Polyglyceryl-4 Cocoate
Polyglyceryl-4 Hazelnutseedate
Polyglyceryl-4 Isostearate/Laurate
Polyglyceryl-4 Laurate/Sebacate
Polyglyceryl-4 Laurate/Succinate
Polyglyceryl-4 Punicate
Polyglyceryl-4 Sweet Almondate
Shea Butter Polyglyceryl-4 Esters
Sunflower Seed Oil Polyglyceryl-4 Esters
Sweet Almond Oil Polyglyceryl-4 Esters

Polyglyceryl-5 discrete esters
Polyglyceryl-5 Caprate
Polyglyceryl-5 Laurate
Polyglyceryl-5 Myristate
Polyglyceryl-5 Isostearate
Polyglyceryl-5 Oleate
Polyglyceryl-5 Stearate
Polyglyceryl-5 Ricinoleate
Polyglyceryl-5 mixed esters
Apricot Kernel Oil Polyglyceryl-5 Esters
Palm Oil Polyglyceryl-5 Esters
Sunflower Seed Oil Polyglyceryl-5 Esters
Polyglyceryl-6 discrete esters
Polyglyceryl-6 Caprate
Polyglyceryl-6 Caprylate
Polyglyceryl-6 Undecylenate
Polyglyceryl-6 Laurate
Polyglyceryl-6 Myristate
Polyglyceryl-6 Palmitate
Polyglyceryl-6 Isostearate
Polyglyceryl-6 Oleate
Polyglyceryl-6 Stearate
Polyglyceryl-6 Ricinoleate
Polyglyceryl-6 Behenate
Polyglyceryl-6 mixed esters
Adansonia Digitata Seed Oil Polyglyceryl-6 Esters
Apricot Kernel Oil Polyglyceryl-6 Esters
Argan Oil Polyglyceryl-6 Esters
Astrocaryum Vulgare Oil Polyglyceryl-6 Esters
Avocado Oil Polyglyceryl-6 Esters
Babassu Oil Polyglyceryl-6 Esters
Bertholletia Excelsa Seed Oil Polyglyceryl-6 Esters
Borage Seed Oil Polyglyceryl-6 Esters
Carapa Guaianensis Oil Polyglyceryl-6 Esters
Castor Oil Polyglyceryl-6 Esters
Cocoa Butter Polyglyceryl-6 Esters
Coconut Oil Polyglyceryl-6 Esters
Coffee Seed Oil Polyglyceryl-6 Esters
Glyceryl/Polyglyceryl-6 Isostearate/Behenate Esters
Hazelnut Seed Oil Polyglyceryl-6 Esters
Macadamia Seed Oil Polyglyceryl-6 Esters
Mauritia Flexuosa Seed Oil Polyglyceryl-6 Esters
Olive Oil Polyglyceryl-6 Esters
Palm Oil Polyglyceryl-6 Esters
Parinari Curatellifolia Oil Polyglyceryl-6 Esters
Pinus Sibirica Seed Oil Polyglyceryl-6 Esters
Polyglyceryl-6 Adansonia Digitata Seedate
Polyglyceryl-6 Apricot Kernelate
Polyglyceryl-6 Argan Kernelate
Polyglyceryl-6 Caprylate/Caprate
Polyglyceryl-6 Citrullus Lanatus Seedate
Polyglyceryl-6 Palmitate/Succinate
Polyglyceryl-6 Schinziophyton Rautanenii Kernelate
Polyglyceryl-6 Sclerocarya Birrea Seedate
Polyglyceryl-6 Trichilia Emetica Seedate
Polyglyceryl-6 Ximenia Americana Seedate
Rosa Rubiginosa Seed Oil Polyglyceryl-6 Esters
Safflower Seed Oil Polyglyceryl-6 Esters
Schinziophyton Rautanenii Kernel Oil Polyglyceryl-6 Esters
Sclerocarya Birrea Seed Oil Polyglyceryl-6 Esters
Sesame Oil Polyglyceryl-6 Esters
Shea Butter Polyglyceryl-6 Esters

Polyglyceryl-6 mixed esters (con't)
Soybean Oil Polyglyceryl-6 Esters
Sunflower Seed Oil Polyglyceryl-6 Esters
Sweet almond Oil Polyglyceryl-6 Esters
Theobroma Grandiflorum Seed Butter Polyglyceryl-6 Esters
Trichilia Emetica Seed Oil Polyglyceryl-6 Esters
Watermelon Seed Oil Polyglyceryl-6 Esters
Ximenia Americana Seed Oil Polyglyceryl-6 Esters
Polyglyceryl-8 discrete esters
Polyglyceryl-8 Oleate
Polyglyceryl-8 Stearate
Polyglyceryl-8 mixed esters
Polyglyceryl-8 C12-20 Acid Ester
Polyglyceryl-10 discrete esters
Polyglyceryl-10 Caprate
Polyglyceryl-10 Caprylate
Polyglyceryl-10 Undecylenate
Polyglyceryl-10 Laurate
Polyglyceryl-10 Myristate
Polyglyceryl-10 Palmitate
Polyglyceryl-10 Isostearate
Polyglyceryl-10 Linoleate
Polyglyceryl-10 Oleate
Polyglyceryl-10 Stearate
Polyglyceryl-10 mixed esters
Almond Oil/Polyglyceryl-10 Esters
Apricot Kernel Oil Polyglyceryl-10 Esters
Caprylic/Capric Glycerides Polyglyceryl-10 Esters
Polyglyceryl-10 Apricot Kernelate
Polyglyceryl-10 Behenate/Eicosadioate
Polyglyceryl-10 Caprylate/Caprate
Polyglyceryl-10 Cocoate
Polyglyceryl-10 Eicosanedioate/Tetradecanedioate
Polyglyceryl-10 Hydroxystearate/Stearate/Eicosadioate
Polyglyceryl-10 Palmate
Sclerocarya Birrea Seed Oil Polyglyceryl-10 Esters
Sunflower Seed Oil Polyglyceryl-10 Esters
Watermelon Seed Oil Polyglyceryl-10 Esters

(continued)

Table 2. (continued)

Polyglyceryl Multi-esters (i.e., not mono-esters and not "polyesters")

Polyglyceryl-2 discrete multi-esters	*Polyglyceryl-6 discrete multi-esters*	*Polyglyceryl-10 discrete multi-esters (con't)*
Polyglyceryl-2 Sesquicaprylate	Polyglyceryl-6 Sesquicaprylate	Polyglyceryl-10 Pentaricinoleate
Polyglyceryl-2 Sesquiisostearate	Polyglyceryl-6 Dicaprate	Polyglyceryl-10 Hexaoleate
Polyglyceryl-2 Diisostearate	Polyglyceryl-6 Tricaprylate	Polyglyceryl-10 Heptaoleate
Polyglyceryl-2 Triisostearate	Polyglyceryl-6 Tetracaprylate	Polyglyceryl-10 Decaoleate
Polyglyceryl-2 Tetraisostearate	Polyglyceryl-6 Pentacaprylate	Polyglyceryl-10 Distearate
Polyglyceryl-2 Dioleate	Polyglyceryl-6 Heptacaprylate	Polyglyceryl-10 Tristearate
Polyglyceryl-2 Sesquioleate	Polyglyceryl-6 Octacaprylate	Polyglyceryl-10 Pentastearate
Polyglyceryl-2 Tetraoleate	Polyglyceryl-6 Dipalmitate	Polyglyceryl-10 Pentahydroxystearate
Polyglyceryl-2 Sesquistearate	Polyglyceryl-6 Sesquiisostearate	Polyglyceryl-10 Heptahydroxystearate
Polyglyceryl-2 Distearate	Polyglyceryl-6 Diisostearate	Polyglyceryl-10 Heptastearate
Polyglyceryl-2 Tetrastearate	Polyglyceryl-6 Dioleate	Polyglyceryl-10 Decahydroxystearate
Polyglyceryl-2 mixed multi-esters	Polyglyceryl-6 Tetraoleate	Polyglyceryl-10 Decastearate
Polyglyceryl-2 Tetrabehenate/Macadamiate/Sebacate	Polyglyceryl-6 Pentaoleate	Polyglyceryl-10 Dodecabehenate
Polyglyceryl-3 discrete multi-esters	Polyglyceryl-6 Hexaoleate	Polyglyceryl-10 Trierucate
Polyglyceryl-3 Dicaprate	Polyglyceryl-6 Sesquistearate	Polyglyceryl-10 Hexaerucate
Polyglyceryl-3 Diisostearate	Polyglyceryl-6 Distearate	Polyglyceryl-10 Nonaerucate
Polyglyceryl-3 Triisostearate	Polyglyceryl-6 Tristearate	*Polyglyceryl-10 mixed multi-esters*
Polyglyceryl-3 Dioleate	Polyglyceryl-6 Pentastearate	Polyglyceryl-10 Decamacadamiate
Polyglyceryl-3 Distearate	Polyglyceryl-6 Hexastearate	Polyglyceryl-10 Dicocoate
Polyglyceryl-3 Di-Hydroxystearate	Polyglyceryl-6 Octastearate	Polyglyceryl-10 Didecanoate
Polyglyceryl-3 Pentaricinoleate	Polyglyceryl-6 Pentaricinoleate	Polyglyceryl-10 Dodeca-Caprylate/Caprate
Polyglyceryl-3 mixed multi-esters	Polyglyceryl-6 Tetrabehenate	Polyglyceryl-10 Hepta(Behenate/Stearate)
Diisostearoyl Polyglyceryl-3 Dimer Dilinoleate	*Polyglyceryl-6 mixed multi-ester*	Polyglyceryl-10 Mono/Dioleate
Polyglyceryl-3 Dicitrate/Stearate	Macadamia Seed Oil Polyglyceryl-6 Esters	Polyglyceryl-10 Sesquistearate
Polyglyceryl-3 Dicocoate	Behenate	Polyglyceryl-10 Tetradecanedioate
Polyglyceryl-3 Pentacaprylate/Caprate	*Polyglyceryl-8 mixed multi-esters*	Polyglyceryl-10 Tricocoate
Polyglyceryl-3 Pentaolivate	Polyglyceryl-8 Decabehenate/Caprate	*Polyglyceryl-15 discrete multi-ester*
Polyglyceryl-3 Triolivate	Polyglyceryl-8 Decaerucate/Decaisostearate/Decaricinoleate	Polyglyceryl-15 Diisostearate
Triisostearoyl Polyglyceryl-3 Dimer Dilinoleate	*Polyglyceryl-10 discrete multi-esters*	*Polyglyceryl-20 discrete multi-esters*
Polyglyceryl-4 discrete multi-esters	Polyglyceryl-10 Decaethylhexanoate	Polyglyceryl-20 Hexacaprylate
Polyglyceryl-4 Dilaurate	Polyglyceryl-10 Dodecacaprate	Polyglyceryl-20 Heptacaprylate
Polyglyceryl-4 Pentaoleate	Polyglyceryl-10 Pentacaprylate	Polyglyceryl-20 Octaisononanoate
Polyglyceryl-4 Distearate	Polyglyceryl-10 Dodecacaprylate	*Polyglyceryl-20 mixed multi-esters*
Polyglyceryl-4 Tristearate	Polyglyceryl-10 Tridecanoate	Polyglyceryl-20 Docosabehenate/Isostearate
Polyglyceryl-4 Pentastearate	Polyglyceryl-10 Dilaurate	Polyglyceryl-20 Docosabehenate/Laurate
Polyglyceryl-4 mixed multi-esters	Polyglyceryl-10 Trilaurate	Polyglyceryl-20 Docosabehenate/Oleate
Polyglyceryl-4 Pentapalmitate/Stearate	Polyglyceryl-10 Tetralaurate	Polyglyceryl-20 Heptadecabehenate/Laurate
Pumpkin Seed Oil Polyglyceryl-4 Esters	Polyglyceryl-10 Pentalaurate	Polyglyceryl-20 Octadecabehenate/Laurate
Pumpkin Seed Oil Polyglyceryl-4 Esters Succinate	Polyglyceryl-10 Dimyristate	
Polyglyceryl-5 discrete multi-esters	Polyglyceryl-10 Dipalmitate	
Polyglyceryl-5 Dicaprylate	Polyglyceryl-10 Diisostearate	
Polyglyceryl-5 Dilaurate	Polyglyceryl-10 Triisostearate	
Polyglyceryl-5 Trimyristate	Polyglyceryl-10 Pentaisostearate	
Polyglyceryl-5 Pentamyristate	Polyglyceryl-10 Hexaisostearate	
Polyglyceryl-5 Triisostearate	Polyglyceryl-10 Nonaisostearate	
Polyglyceryl-5 Dioleate	Polyglyceryl-10 Decaisostearate	
Polyglyceryl-5 Trioleate	Polyglyceryl-10 Pentalinoleate	
Polyglyceryl-5 Tristearate	Polyglyceryl-10 Decalinoleate	
Polyglyceryl-5 Hexastearate	Polyglyceryl-10 Dioleate	
Polyglyceryl-5 Tribehenate	Polyglyceryl-10 Trioleate	
	Polyglyceryl-10 Tetraoleate	
	Polyglyceryl-10 Pentaoleate	

report. In some ECHA dossiers, such as in 1,2,3-propanetriol, homopolymer, diisooctadecanoate, the number of polyglyceryl chains is not defined. Because the number of polyglyceryl chains is not defined, and it therefore is unclear what specific ingredient is being studied, the data are presented as potential read-across data.

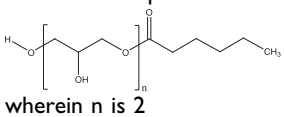
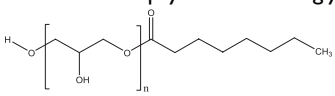
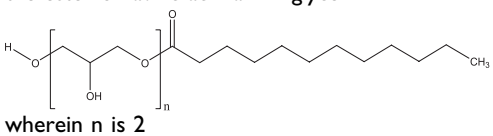
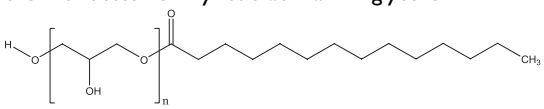
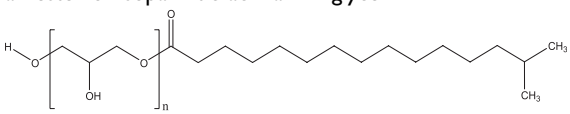
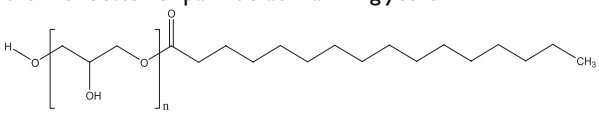
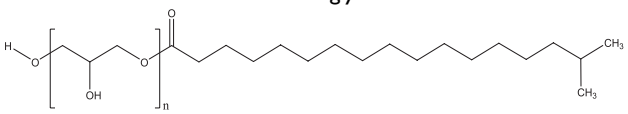
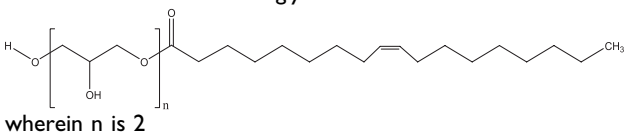
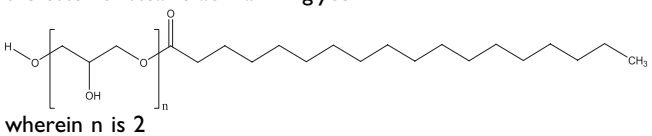
Several studies that are summarized in this safety assessment examined the toxicity of a "polyglyceryl ester." The exact composition of the test material was not identified in many of the studies and, generally, very few details were provided. However, this information is included in this safety assessment for completeness.

Chemistry

Definition and Structure

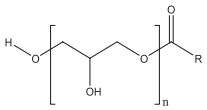
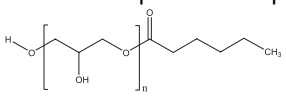
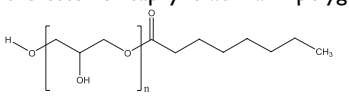
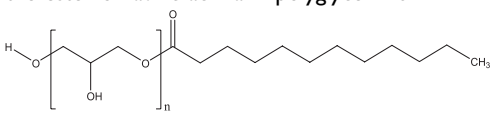
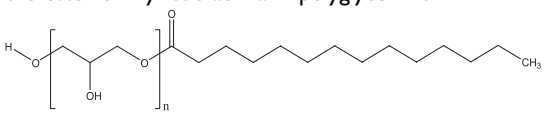
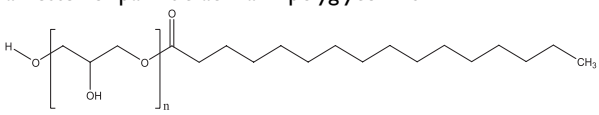
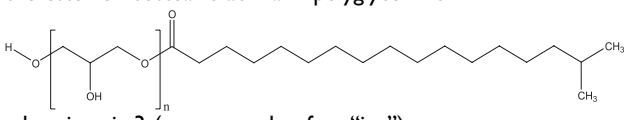
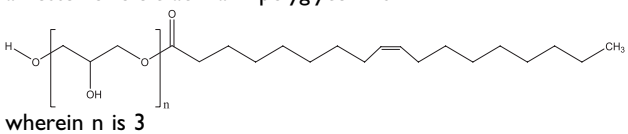
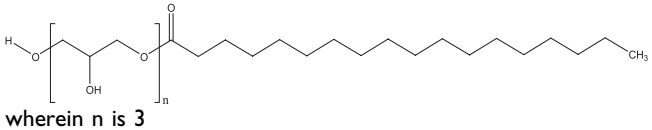
The ingredients in this report are each structurally constituted of the esterification products of polyglycerin chains and fatty acids. These ingredients vary in the number of equivalents of glycerin and fatty acids, and the length of those fatty acids (Figures 1 and 2). The definitions and idealized structures of the polyglyceryl fatty acid esters are provided in Table 3.

Table 3. Definitions, Idealized Structures, and Reported Functions1,CIR Staff.

Ingredient CAS No.	Definition & Structure	Function(s)
	Polyglyceryl Monoesters	
Polyglyceryl-2 discrete esters		
Polyglyceryl-2 Caprate 156153-06-9	the ester of capric acid and diglycerin  wherein n is 2	skin-conditioning agent – emollient; surfactant – emulsifying agent
Polyglyceryl-2 Caprylate	the ester of caprylic acid and diglycerin  wherein n is 2	skin-conditioning agent – emollient; surfactant – emulsifying agent
Polyglyceryl-2 Laurate 96499-68-2	the ester of lauric acid and diglycerin  wherein n is 2	skin-conditioning agent – emollient; surfactant – emulsifying agent
Polyglyceryl-2 Myristate	the monoester of myristic acid and diglycerol  wherein n is 2	skin-conditioning agent – emollient; surfactant – emulsifying agent
Polyglyceryl-2 Isopalmitate	an ester of isopalmitic acid and diglycerin  wherein n is 2 (one example of an "iso")	skin-conditioning agent – emollient; surfactant – emulsifying agent
Polyglyceryl-2 Palmitate	the monoester of palmitic acid and diglycerol  wherein n is 2	skin-conditioning agent – emollient; surfactant – emulsifying agent
Polyglyceryl-2 Isostearate 73296-86-3 81752-33-2	the ester of isostearic acid and diglycerin  wherein n is 2 (one example of an "iso")	skin-conditioning agent – emollient; surfactant – emulsifying agent
Polyglyceryl-2 Oleate 49553-76-6 9007-48-1 (generic)	an ester of oleic acid and diglycerin  wherein n is 2	skin-conditioning agent – emollient; surfactant – emulsifying agent
Polyglyceryl-2 Stearate 12694-22-3 9009-32-9 (generic)	the ester of stearic acid and diglycerin  wherein n is 2	skin-conditioning agent – emollient; surfactant – emulsifying agent

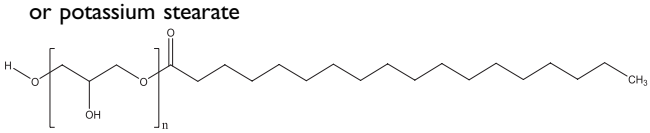
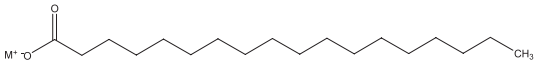
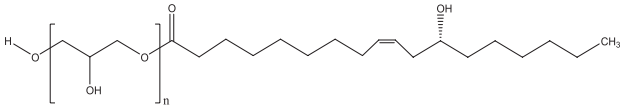
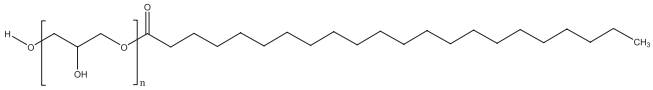
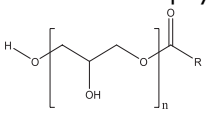
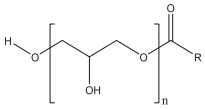
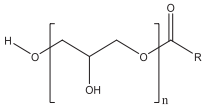
(continued)

Table 3. (continued)

Ingredient CAS No.	Definition & Structure	Function(s)
Polyglyceryl-2 mixed esters		
Polyglyceryl-2 Isopalmitate/ Sebacate	the mixed ester of isopalmitic acid, sebacic acid and diglycerin  wherein RC(O)- represents the residue of isopalmitic or sebacic acid, and n is 2	surfactant – emulsifying agent
Polyglyceryl-3 discrete esters		
Polyglyceryl-3 Caprate 133654-02-1 51033-30-8 74504-65-7	an ester of capric acid and polyglycerin-3  wherein n is 3	skin-conditioning agent – emollient; surfactant – emulsifying agent
Polyglyceryl-3 Caprylate 108777-93-1	the ester of caprylic acid and polyglycerin-3  wherein n is 3	deodorant agent; surfactants – emulsifying agent
Polyglyceryl-3 Laurate 51033-31-9	the ester of lauric acid and polyglycerin-3  wherein n is 3	skin-conditioning agent – emollient; surfactant – emulsifying agent
Polyglyceryl-3 Myristate	the ester of myristic acid and polyglycerin-3  wherein n is 3	skin-conditioning agent – emollient; surfactant – emulsifying agent
Polyglyceryl-3 Palmitate	an ester of palmitic acid and polyglycerin-3  wherein n is 3	skin-conditioning agent – emollient; surfactant – emulsifying agent
Polyglyceryl-3 Isostearate 127512-63-4	the ester of isostearic acid and polyglycerin-3  wherein n is 3 (one example of an "iso")	skin-conditioning agent – emollient; surfactant – emulsifying agent
Polyglyceryl-3 Oleate 33940-98-6 9007-48-1 (generic)	an ester of oleic acid and polyglycerin-3  wherein n is 3	skin-conditioning agent – emollient; surfactant – emulsifying agent
Polyglyceryl-3 Stearate 26855-43-6 27321-72-8 37349-34-1 (generic)	an ester of stearic acid and polyglycerin-3  wherein n is 3	skin-conditioning agent – emollient; surfactant – emulsifying agent

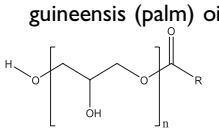
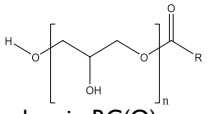
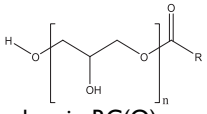
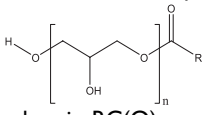
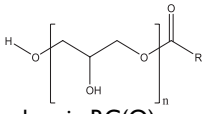
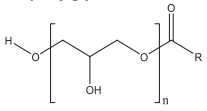
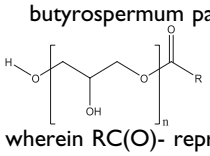
(continued)

Table 3. (continued)

Ingredient CAS No.	Definition & Structure	Function(s)
Polyglyceryl-3 Stearate SE	a self-emulsifying grade of polyglyceryl-3 stearate that contains some sodium and/or potassium stearate  wherein n is 3 and  wherein M is sodium or potassium	surfactant – emulsifying agent
Polyglyceryl-3 Ricinoleate 29894-35-7 (generic)	an ester of ricinoleic acid and polyglycerin-3  wherein n is 3	skin-conditioning agent – emollient; surfactant – emulsifying agent
Polyglyceryl-3 Behenate	the ester of behenic acid and polyglycerin-3  wherein n is 3	emulsion stabilizer; slip modifier; surface modifier
Polyglyceryl-3 mixed esters		
Apricot Kernel Oil Polyglyceryl-3 Esters	the product obtained by the transesterification of prunus armeniaca (apricot) kernel oil and polyglycerin-3  wherein RC(O)- represents the residue of fatty acids derived (via transesterification) from prunus armeniaca (apricot) kernel oil, and n is 3	skin-conditioning agent – emollient; surfactant – emulsifying agent
Candelilla/Jojoba/Rice Bran Polyglyceryl-3 Esters	a product obtained by the transesterification of polyglycerin-3 and euphorbia cerifera (candelilla) wax, and simmondsia chinensis (jojoba) seed wax and oryza sativa (rice) bran wax  wherein RC(O)- represents the residue of fatty acids derived (via transesterification) from euphorbia cerifera (candelilla) wax, and simmondsia chinensis (jojoba) seed wax and oryza sativa (rice) bran wax, and n is 3	emulsion stabilizer; surfactant – emulsifying agent
Olive Oil Polyglyceryl-3 Esters	the product obtained by the transesterification of polyglycerin-3 and olea europaea (olive) fruit oil  wherein RC(O)- represents the residue of fatty acids derived (via transesterification) from olea europaea (olive) fruit oil, and n is 3	surfactant – emulsifying agent

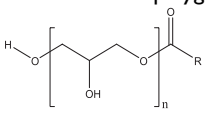
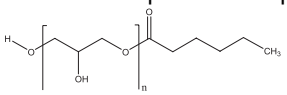
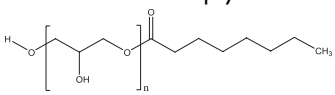
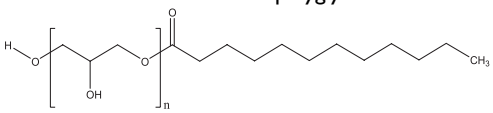
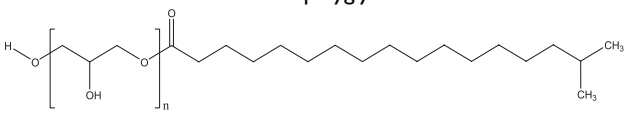
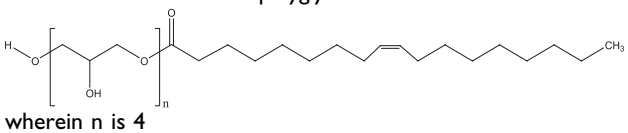
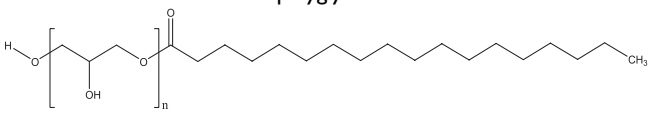
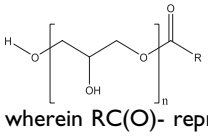
(continued)

Table 3. (continued)

Ingredient CAS No.	Definition & Structure	Function(s)
Palm Oil Polyglyceryl-3 Esters	the product obtained by the transesterification of polyglycerin-3 and elaeis guineensis (palm) oil  wherein RC(O)- represents the residue of fatty acids derived (via transesterification) from elaeis guineensis (palm) oil, and n is 3	skin-conditioning agent – emollient; surfactant – emulsifying agent
Polyglyceryl-3 Beeswax 136097-93-3	an ester of beeswax fatty acids and polyglycerin-3  wherein RC(O)- represents the residue of beeswax fatty acids, and n is 3	surfactant – emulsifying agent
Polyglyceryl-3 Cocoate	the ester of coconut acid and polyglycerin-3  wherein RC(O)- represents the residue of coconut acid, and n is 3	surfactant – emulsifying agent
Polyglyceryl-3 Rice Branate	the monoester of polyglycerin-3 and rice bran acid  wherein RC(O)- represents the residue of rice bran acid, and n is 3	surfactant – emulsifying agent
Polyglyceryl-3 Soyate/Shea Butterate	an ester of a mixture of fatty acids derived from glycine soja (soybean) oil and butyrospermum parkii (shea) butter with polyglycerin-3  wherein RC(O)- represents the residue of the fatty acids obtained from glycine soja (soybean) oil and butyrospermum parkii (shea) butter, and n is 3	surfactant – emulsifying agent
Rice Bran Oil Polyglyceryl-3 Esters	the product obtained by the transesterification of oryza sativa (rice) bran oil and polyglycerin-3  wherein RC(O)- represents the residue of fatty acids derived (via transesterification) from oryza sativa (rice) bran oil, and n is 3	surfactants – emulsifying agent
Shea Butter Polyglyceryl-3 Esters	the product obtained by the transesterification of polyglycerin-3 and butyrospermum parkii (shea) butter  wherein RC(O)- represents the residue of fatty acids derived (via transesterification) from butyrospermum parkii (shea) butter, and n is 3	emulsion stabilizer; hair conditioning agent; skin-conditioning agent – miscellaneous; surfactant – emulsifying agent; viscosity increasing agent – aqueous

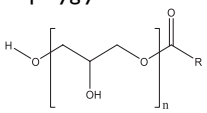
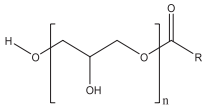
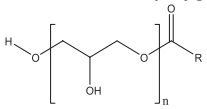
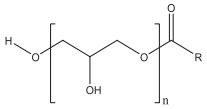
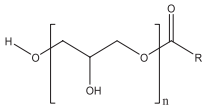
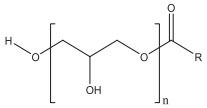
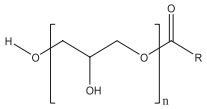
(continued)

Table 3. (continued)

Ingredient CAS No.	Definition & Structure	Function(s)
Sunflower Seed Oil Polyglyceryl-3 Esters	the product obtained by the transesterification of helianthus annuus (sunflower) seed oil and polyglycerin-3  wherein RC(O)- represents the residue of fatty acids derived (via transesterification) from helianthus annuus (sunflower) seed oil, and n is 3	skin-conditioning agent – emollient; surfactant – emulsifying agent
Polyglyceryl-4 discrete esters		
Polyglyceryl-4 Caprate 160391-93-5 74504-65-7	the ester of capric acid and polyglycerin-4  wherein n is 4	skin-conditioning agent – emollient; surfactant – emulsifying agent
Polyglyceryl-4 Caprylate	the monoester of caprylic acid and polyglycerin-4  wherein n is 4	skin-conditioning agent – emollient; surfactant – emulsifying agent
Polyglyceryl-4 Laurate 75798-42-4; 74504-64-6 (generic);	the ester of lauric acid and polyglycerin-4  wherein n is 4	skin-conditioning agent – emollient; surfactant – emulsifying agent
Polyglyceryl-4 Isostearate 63705-03-3 91824-88-3	an ester of isostearic acid and polyglycerin-4  wherein n is 4 (one example of an "iso")	skin-conditioning agent – emollient; surfactant – emulsifying agent
Polyglyceryl-4 Oleate 71012-10-7 9007-48-1 (generic)	an ester of oleic acid and polyglycerin-4  wherein n is 4	skin-conditioning agent – emollient; surfactant – emulsifying agent
Polyglyceryl-4 Stearate 26855-44-7 37349-34-1 (generic) 68004-11-5	an ester of stearic acid and polyglycerin-4  wherein n is 4	surfactant – emulsifying agent
Polyglyceryl-4 mixed esters		
Apricot Kernel Oil Polyglyceryl-4 Esters	the product obtained by the transesterification of prunus armeniaca (apricot) kernel oil and polyglycerin-4  wherein RC(O)- represents the residue of fatty acids derived (via transesterification) from prunus armeniaca (apricot) kernel oil, and n is 4	skin-conditioning agent – emollient; surfactant – emulsifying agent

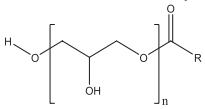
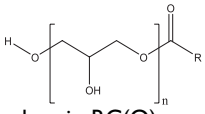
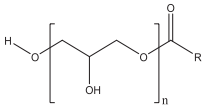
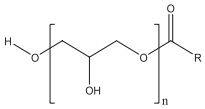
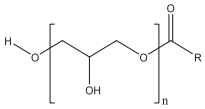
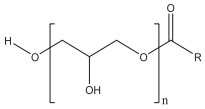
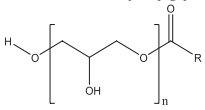
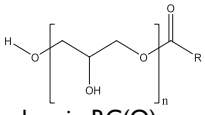
(continued)

Table 3. (continued)

Ingredient CAS No.	Definition & Structure	Function(s)
Babassu Oil Polyglyceryl-4 Esters	the product of the transesterification of orbignya oleifera seed oil and polyglycerin-4  wherein RC(O)- represents the residue of fatty acids derived (via transesterification) from orbignya oleifera seed oil, and n is 4	surfactant – solubilizing agent
Borage Seed Oil Polyglyceryl-4 Esters	the product obtained by the transesterification of borago officinalis seed oil and polyglycerin-4  wherein RC(O)- represents the residue of fatty acids derived (via transesterification) from borago officinalis seed oil, and n is 4	opacifying agent; surfactant – emulsifying agent; surfactant – solubilizing agent
Linseed Oil Polyglyceryl-4 Esters	the product obtained by the transesterification of linum usitatissimum (linseed) seed oil and polyglycerin-4  wherein RC(O)- represents the residue of fatty acids derived (via transesterification) from linum usitatissimum (linseed) seed oil, and n is 4	opacifying agent; surfactant – emulsifying agent; surfactant – solubilizing agent
Olive Oil Polyglyceryl-4 Esters	the product obtained by the transesterification of olea europaea (olive) fruit oil and polyglycerin-4  wherein RC(O)- represents the residue of fatty acids derived (via transesterification) from olea europaea (olive) fruit oil, and n is 4	surfactant – solubilizing agent
Palm Kernel Oil Polyglyceryl-4 Esters	is the product obtained by the transesterification of elaeis guineensis (palm) kernel oil and polyglycerin-4  wherein RC(O)- represents the residue of fatty acids derived (via transesterification) from elaeis guineensis (palm) kernel oil, and n is 4	opacifying agent; surfactant – emulsifying agent; surfactant – solubilizing agent
Palm Oil Polyglyceryl-4 Esters	the product obtained by the transesterification of polyglycerin-4 and elaeis guineensis (palm) oil  wherein RC(O)- represents the residue of fatty acids derived (via transesterification) from elaeis guineensis (palm) oil, and n is 4	skin-conditioning agent – emollient; surfactant – emulsifying agent
Polyglyceryl-4 Almondate/ Shea Butterate	an ester of a mixture of fatty acids derived from almond oil and butyrospermum parkii (shea) butter with polyglycerin-4  wherein RC(O)- represents the residue of fatty acids derived (via transesterification) from butyrospermum parkii (shea) butter, and n is 4	surfactant – emulsifying agent

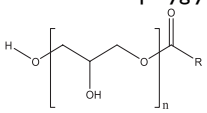
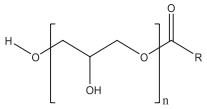
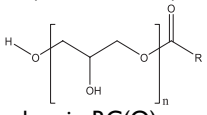
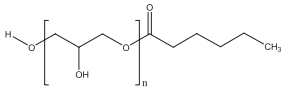
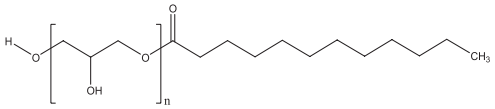
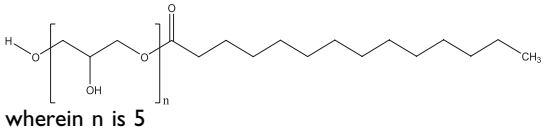
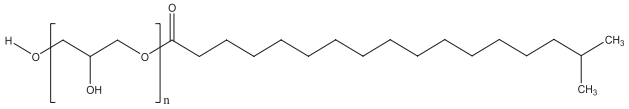
(continued)

Table 3. (continued)

Ingredient CAS No.	Definition & Structure	Function(s)
Polyglyceryl-4 Caprylate/ Caprate	the monoester of polyglycerin-4 and a mixture of caprylic and capric acids  wherein RC(O)- represents the residue of capric or caprylic acid, and n is 4	surfactant – hydrotrope; surfactant – solubilizing agent
Polyglyceryl-4 Cocoate	an ester of coconut acid and polyglycerin-4  wherein RC(O)- represents the residue of coconut acid, and n is 4	surfactant – emulsifying agent
Polyglyceryl-4 Hazelnutseedate	an ester of the fatty acids derived from corylus avellana (hazelnut) seed oil with polyglycerin-4  wherein RC(O)- represents the residue of the fatty acids derived from corylus avellana (hazelnut) seed oil, and n is 4	surfactant – emulsifying agent
Polyglyceryl-4 Isostearate/ Laurate	the ester of a mixture of isostearic and lauric acids with polyglycerin-4  wherein RC(O)- represents the residue of isostearic or lauric acid, and n is 4	dispersing agent – nonsurfactant; emulsion stabilizer; surfactant – emulsifying agent; surfactant – foam booster
Polyglyceryl-4 Laurate/ Sebacate	the monoester of polyglycerin-4 and a mixture of lauric and sebacic acids  wherein RC(O)- represents the residue of lauric or sebacic acid, and n is 4	surfactant – hydrotrope; surfactant – solubilizing agent
Polyglyceryl-4 Laurate/ Succinate	the monoester of polyglycerin-4 and a mixture of lauric and succinic acids  wherein RC(O)- represents the residue of lauric or succinic acid, and n is 4	surfactant – emulsifying agent
Polyglyceryl-4 Punicate	the ester of polyglycerin-4 and punicic acid  wherein RC(O)- represents the residue of punicic acid, and n is 4	surfactant – emulsifying agent
Polyglyceryl-4 Sweet Almondate	an ester of the fatty acids derived from sweet almond oil and polyglycerin-4  wherein RC(O)- represents the residue of the fatty acids obtained from sweet almond oil, and n is 4	skin-conditioning agent – misc; surfactant – emulsifying agent

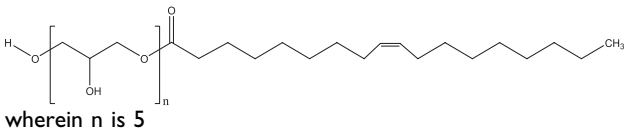
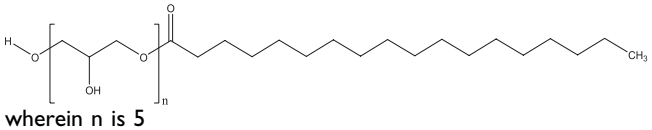
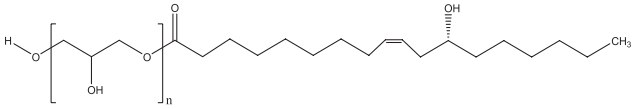
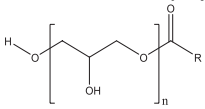
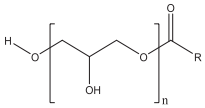
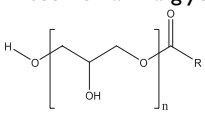
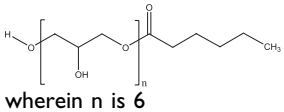
(continued)

Table 3. (continued)

Ingredient CAS No.	Definition & Structure	Function(s)
Shea Butter Polyglyceryl-4 Esters	the product obtained by the transesterification of butyrospermum parkii (shea) butter and polyglycerin-4  wherein RC(O)- represents the residue of fatty acids derived (via transesterification) from butyrospermum parkii (shea) butter, and n is 4	emulsion stabilizer; skin-conditioning agent – emollient
Sunflower Seed Oil Polyglyceryl-4 Esters	the product obtained by the transesterification of helianthus annuus (sunflower) seed oil and polyglycerin-4  wherein RC(O)- represents the residue of fatty acids derived (via transesterification) from helianthus annuus (sunflower) seed oil, and n is 4	skin-conditioning agent – emollient; surfactant – emulsifying agent
Sweet Almond Oil Polyglyceryl-4 Esters 1072006-19-9 (generic)	the product obtained by the transesterification of prunus amygdalus dulcis (sweet almond) oil and polyglycerin-4  wherein RC(O)- represents the residue of fatty acids derived (via transesterification) from prunus amygdalus dulcis (sweet almond) oil, and n is 4	surfactants – solubilizing agent
Polyglyceryl-5 discrete esters		
Polyglyceryl-5 Caprate	the monoester of capric acid and polyglycerin-5  wherein n is 5	skin-conditioning agent – emollient; surfactant – emulsifying agent
Polyglyceryl-5 Laurate 128738-83-0; 74504-64-6 (generic)	the ester of lauric acid and a glycerin polymer containing an average of 5 glycerin units  wherein n is 5	skin-conditioning agent – emollient; surfactant – emulsifying agent
Polyglyceryl-5 Myristate	the monoester of myristic acid and a glycerin polymer containing 5 units of glycerin  wherein n is 5	skin-conditioning agent – emollient; surfactant – emulsifying agent
Polyglyceryl-5 Isostearate	the ester of isostearic acid and a glycerin polymer containing an average of 5 glycerin units  wherein n is 5 (one example of an "iso")	skin-conditioning agent – emollient; surfactant – emulsifying agent

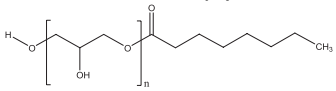
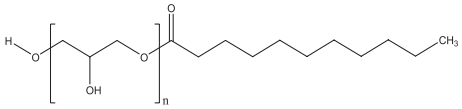
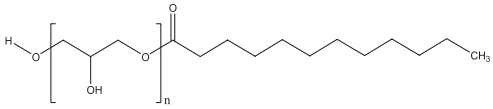
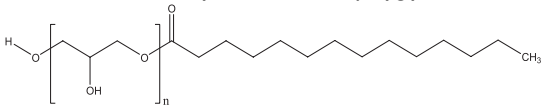
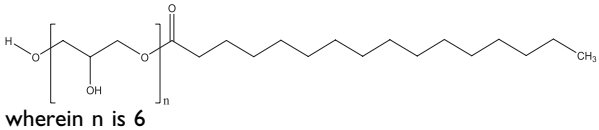
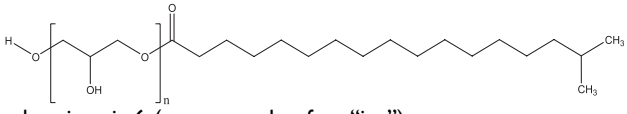
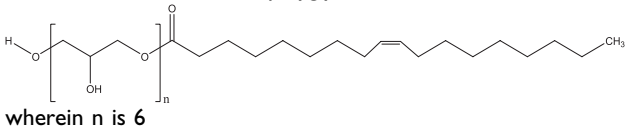
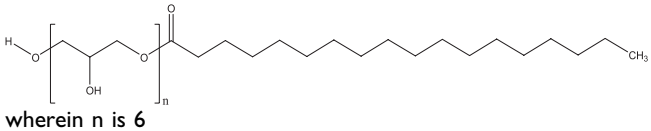
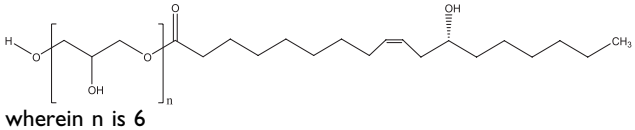
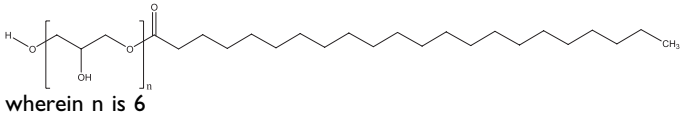
(continued)

Table 3. (continued)

Ingredient CAS No.	Definition & Structure	Function(s)
Polyglyceryl-5 Oleate 86529-98-8 9007-48-1 (generic)	the ester of oleic acid and a glycerin polymer containing an average of 5 glycerin units  wherein n is 5	skin-conditioning agent – emollient; surfactant – emulsifying agent
Polyglyceryl-5 Stearate 37349-34-1 (generic)	the monoester of stearic acid and a glycerin polymer containing 5 units of glycerin  wherein n is 5	surfactant – emulsifying agent
Polyglyceryl-5 Ricinoleate	is the product obtained by the reaction of ricinoleic acid with a glycerin polymer containing 5 glycerin units  wherein n is 5	surfactant – emulsifying agent
Polyglyceryl-5 mixed esters		
Apricot Kernel Oil Polyglyceryl-5 Esters	the product obtained by the transesterification of prunus armeniaca (apricot) kernel oil and polyglycerin-5  wherein RC(O)- represents the residue of fatty acids derived (via transesterification) from prunus armeniaca (apricot) kernel oil, and n is 5	skin-conditioning agent – emollient; surfactant – emulsifying agent
Palm Oil Polyglyceryl-5 Esters	the product obtained by the transesterification of a glycerin polymer containing 5 units of glycerin and elaeis guineensis (palm) oil  wherein RC(O)- represents the residue of fatty acids derived (via transesterification) from elaeis guineensis (palm) oil, and n is 5	skin-conditioning agent – emollient; surfactant – emulsifying agent
Sunflower Seed Oil Polyglyceryl-5 Esters	the product obtained by the transesterification of helianthus annuus (sunflower) seed oil and a glycerin polymer containing 5 units of glycerin  wherein RC(O)- represents the residue of fatty acids derived (via transesterification) from helianthus annuus (sunflower) seed oil, and n is 5	skin-conditioning agent – emollient; surfactant – emulsifying agent
Polyglyceryl-6 discrete esters		
Polyglyceryl-6 Caprate	the monoester of capric acid and polyglycerin-6  wherein n is 6	surfactant – cleansing agent; surfactant – emulsifying agent

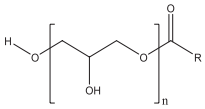
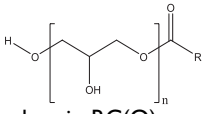
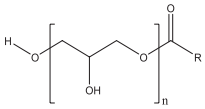
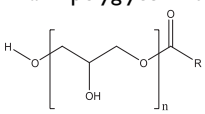
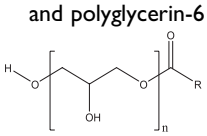
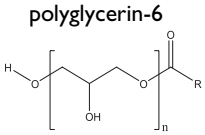
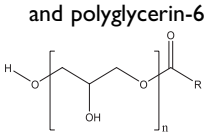
(continued)

Table 3. (continued)

Ingredient CAS No.	Definition & Structure	Function(s)
Polyglyceryl-6 Caprylate	the monoester of caprylic acid and polyglycerin-6  wherein n is 6	skin-conditioning agent – emollient; surfactant – emulsifying agent
Polyglyceryl-6 Undecylenate	an ester of undecylenic acid and polyglycerin-6  wherein n is 6	surfactant – emulsifying agent
Polyglyceryl-6 Laurate 51033-38-6; 74504-64-6 (generic)	the ester of lauric acid and polyglycerin-6  wherein n is 6	skin-conditioning agent – emollient; surfactant – emulsifying agent
Polyglyceryl-6 Myristate	the monoester of myristic acid and polyglycerin-6  wherein n is 6	skin-conditioning agent – emollient; surfactant – emulsifying agent
Polyglyceryl-6 Palmitate 99734-31-3	the ester of palmitic acid and polyglycerin-6  wherein n is 6	skin-conditioning agent – emollient; surfactant – emulsifying agent
Polyglyceryl-6 Isostearate 126928-07-2	the ester of isostearic acid and polyglycerin-6  wherein n is 6 (one example of an "iso")	skin-conditioning agent – emollient; surfactant – emulsifying agent
Polyglyceryl-6 Oleate 79665-92-2 9007-48-1 (generic)	the ester of oleic acid and polyglycerin-6  wherein n is 6	skin-conditioning agent – emollient; surfactant – emulsifying agent
Polyglyceryl-6 Stearate 95461-65-7	the ester of stearic acid and polyglycerin-6  wherein n is 6	skin-conditioning agent – emollient; surfactant – emulsifying agent
Polyglyceryl-6 Ricinoleate 107615-51-0	the ester of polyglycerin-6 and ricinoleic acid  wherein n is 6	skin-conditioning agent – emollient; surfactant – emulsifying agent
Polyglyceryl-6 Behenate	the monoester of behenic acid and polyglycerin-6  wherein n is 6	emulsion stabilizer; slip modifier; surface modifier

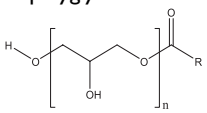
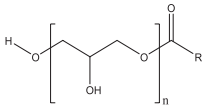
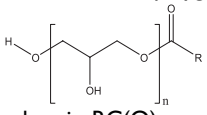
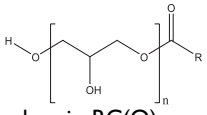
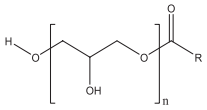
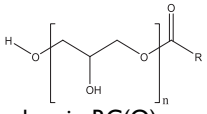
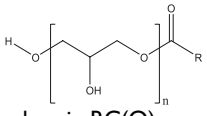
(continued)

Table 3. (continued)

Ingredient CAS No.	Definition & Structure	Function(s)
Polyglyceryl-6 mixed esters		
Adansonia Digitata Seed Oil Polyglyceryl-6 Esters	the product obtained by the transesterification of adansonia digitata seed oil and polyglycerin-6  wherein RC(O)- represents the residue of fatty acids derived (via transesterification) from adansonia digitata seed oil, and n is 6	skin-conditioning agent – emollient; surfactant – emulsifying agent
Apricot Kernel Oil Polyglyceryl-6 Esters	the product obtained by the transesterification of prunus armeniaca (apricot) kernel oil and polyglycerin-6  wherein RC(O)- represents the residue of fatty acids derived (via transesterification) from prunus armeniaca (apricot) kernel oil, and n is 6	skin-conditioning agent – emollient; surfactant – emulsifying agent
Argan Oil Polyglyceryl-6 Esters	the product obtained by the transesterification of argania spinosa kernel oil and polyglycerin-6  wherein RC(O)- represents the residue of fatty acids derived (via transesterification) from argania spinosa kernel oil, and n is 6	skin-conditioning agent – emollient; surfactant – emulsifying agent
Astrocaryum Vulgare Oil Polyglyceryl-6 Esters	the product obtained by the transesterification of astrocaryum vulgare kernel oil and polyglycerin-6  wherein RC(O)- represents the residue of fatty acids derived (via transesterification) from astrocaryum vulgare kernel oil, and n is 6	skin-conditioning agent – misc; surfactant – emulsifying agent
Avocado Oil Polyglyceryl-6 Esters	the product obtained by the transesterification of persea gratissima (avocado) oil and polyglycerin-6  wherein RC(O)- represents the residue of fatty acids derived (via transesterification) from persea gratissima (avocado) oil, and n is 6	skin-conditioning agent – emollient; surfactant – emulsifying agent
Babassu Oil Polyglyceryl-6 Esters	the product obtained by the transesterification of orbignya oleifera seed oil and polyglycerin-6  wherein RC(O)- represents the residue of fatty acids derived (via transesterification) from orbignya oleifera seed oil, and n is 6	skin-conditioning agent – emollient; surfactant – emulsifying agent
Bertholletia Excelsa Seed Oil Polyglyceryl-6 Esters	the product obtained by the transesterification of bertholletia excelsa seed oil and polyglycerin-6  wherein RC(O)- represents the residue of fatty acids derived (via transesterification) from bertholletia excelsa seed oil, and n is 6	skin-conditioning agent – emollient; surfactant – emulsifying agent

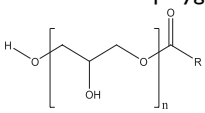
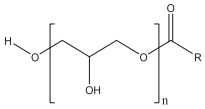
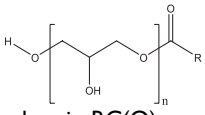
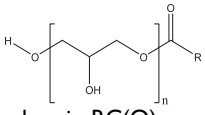
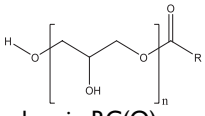
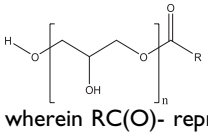
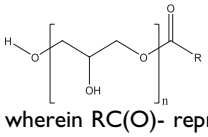
(continued)

Table 3. (continued)

Ingredient CAS No.	Definition & Structure	Function(s)
Borage Seed Oil Polyglyceryl-6 Esters	the product obtained by the transesterification of borago officinalis seed oil and polyglycerin-6  wherein RC(O)- represents the residue of fatty acids derived (via transesterification) from borago officinalis seed oil, and n is 6	skin-conditioning agent – emollient; surfactant – emulsifying agent
Carapa Guaianensis Oil Polyglyceryl-6 Esters	the product obtained by the transesterification of carapa guaianensis seed oil and polyglycerin-6  wherein RC(O)- represents the residue of fatty acids derived (via transesterification) from carapa guaianensis seed oil, and n is 6	skin-conditioning agent – emollient
Castor Oil Polyglyceryl-6 Esters	the product obtained by the transesterification of ricinus communis (castor) seed oil and polyglycerin-6  wherein RC(O)- represents the residue of fatty acids derived (via transesterification) from ricinus communis (castor) seed oil, and n is 6	skin-conditioning agent – emollient; skin conditioning agent – misc; surfactant – emulsifying agent
Cocoa Butter Polyglyceryl-6 Esters	the product obtained by the transesterification of theobroma cacao (cocoa) seed butter and polyglycerin-6  wherein RC(O)- represents the residue of fatty acids derived (via transesterification) from theobroma cacao (cocoa) seed butter, and n is 6	skin-conditioning agent – emollient
Coconut Oil Polyglyceryl-6 Esters	the product obtained by the transesterification of cocos nucifera (coconut) oil with polyglycerin-6  wherein RC(O)- represents the residue of fatty acids derived (via transesterification) from cocos nucifera (coconut) oil, and n is 6	skin-conditioning agent – emollient; surfactant – emulsifying agent
Coffee Seed Oil Polyglyceryl-6 Esters	the product obtained by the transesterification of polyglycerin-6 and coffea arabica (coffee) seed oil  wherein RC(O)- represents the residue of fatty acids derived (via transesterification) from coffea arabica (coffee) seed oil, and n is 6	skin-conditioning agent – emollient; surfactant – emulsifying agent
Glyceryl/Polyglyceryl-6 Isostearate/Behenate Esters	the mixture of esters formed by the reaction of glycerin and polyglycerin-6 with isostearic acid and behenic acid  wherein RC(O)- represents the residue of isostearic or behenic acid, and n is 1 or 6	skin-conditioning agent – emollient

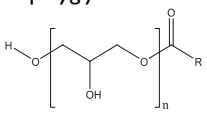
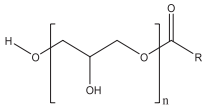
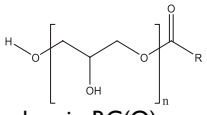
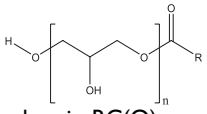
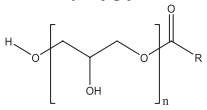
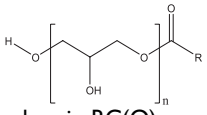
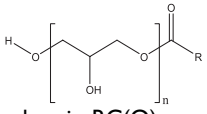
(continued)

Table 3. (continued)

Ingredient CAS No.	Definition & Structure	Function(s)
Hazelnut Seed Oil Polyglyceryl-6 Esters	the product obtained by the transesterification of corylus avellana (hazelnut) seed oil and polyglycerin-6  wherein RC(O)- represents the residue of fatty acids derived (via transesterification) from corylus avellana (hazelnut) seed oil, and n is 6	skin-conditioning agent – emollient; surfactant – emulsifying agent
Macadamia Seed Oil Polyglyceryl-6 Esters	the product obtained by the transesterification of macadamia ternifolia seed oil and polyglycerin-6  wherein RC(O)- represents the residue of fatty acids derived (via transesterification) from macadamia ternifolia seed oil, and n is 6	skin-conditioning agent – emollient; surfactant – emulsifying agent
Mauritia Flexuosa Seed Oil Polyglyceryl-6 Esters	the product obtained by the transesterification of the oil obtained from the seeds of *Mauritia flexuosa* and polyglycerin-6  wherein RC(O)- represents the residue of fatty acids derived (via transesterification) from the seeds of *Mauritia flexuosa*, and n is 6	skin-conditioning agent – emollient; surfactant – emulsifying agent
Olive Oil Polyglyceryl-6 Esters	the product obtained by the transesterification of olea europaea (olive) fruit oil and polyglycerin-6  wherein RC(O)- represents the residue of fatty acids derived (via transesterification) from olea europaea (olive) fruit oil, and n is 6	skin-conditioning agent – emollient; surfactant – emulsifying agent
Palm Oil Polyglyceryl-6 Esters	the product obtained by the transesterification of polyglycerin-6 and elaeis guineensis (palm) oil  wherein RC(O)- represents the residue of fatty acids derived (via transesterification) from elaeis guineensis (palm) oil, and n is 6	skin-conditioning agent – emollient; surfactant – emulsifying agent
Parinari Curatellifolia Oil Polyglyceryl-6 Esters	the product of the transesterification of the oil obtained from the seeds of *Parinari curatellifolia* and polyglycerin-6  wherein RC(O)- represents the residue of fatty acids derived (via transesterification) from the seeds of *Parinari curatellifolia*, and n is 6	skin-conditioning agent – emollient; surfactant – emulsifying agent
Pinus Sibirica Seed Oil Polyglyceryl-6 Esters	the product obtained by the transesterification of pinus sibirica seed oil and polyglycerin-6  wherein RC(O)- represents the residue of fatty acids derived (via transesterification) from pinus sibirica seed oil, and n is 6	surfactant – emulsifying agent

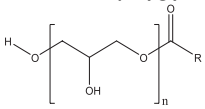
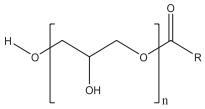
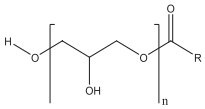
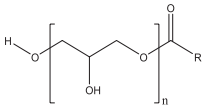
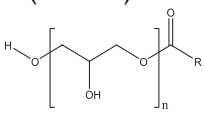
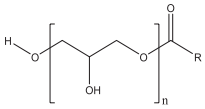
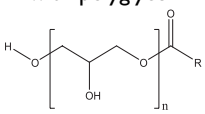
(continued)

Table 3. (continued)

Ingredient CAS No.	Definition & Structure	Function(s)
Polyglyceryl-6 Adansonia Digitata Seedate	the ester of the fatty acids obtained from adansonia digitata seed oil and polyglycerin-6  wherein RC(O)- represents the residue of fatty acids derived (via transesterification) from adansonia digitata seed oil, and n is 6	skin-conditioning agent – emollient; surfactant – emulsifying agent
Polyglyceryl-6 Apricot Kernelate	the ester of the fatty acids derived from prunus armeniaca (apricot) kernel oil and polyglycerin-6  wherein RC(O)- represents the residue of fatty acids derived (via transesterification) from prunus armeniaca (apricot) kernel oil, and n is 6	skin-conditioning agent – emollient; surfactant – emulsifying agent
Polyglyceryl-6 Argan Kernelate	the ester of polyglycerin-6 and the fatty acids obtained from argania spinosa kernel oil  wherein RC(O)- represents the residue of fatty acids derived (via transesterification) from argania spinosa kernel oil, and n is 6	skin-conditioning agent – emollient; surfactant – emulsifying agent
Polyglyceryl-6 Caprylate/ Caprate	the monoester of polyglycerin-6 and a mixture of caprylic and capric acids  wherein RC(O)- represents the residue of capric or caprylic acid, and n is 6	surfactant – hydrotrope; surfactant – solubilizing agent
Polyglyceryl-6 Citrullus Lanatus Seedate	the ester of the fatty acids derived from citrullus lanatus (watermelon) seed oil and polyglycerin-6  wherein RC(O)- represents the residue of fatty acids derived (via transesterification) from citrullus lanatus (watermelon) seed oil, and n is 6	skin-conditioning agent – emollient; surfactant – emulsifying agent
Polyglyceryl-6 Palmitate/ Succinate	the monoester of polyglycerin-6 and a mixture of palmitic and succinic acids  wherein RC(O)- represents the residue of palmitic or succinic acid, and n is 6	surfactant – emulsifying agent
Polyglyceryl-6 Schinziophyton Rautanenii Kernelate	the ester of polyglycerin-6 and the fatty acids obtained from schinziophyton rautanenii kernel oil  wherein RC(O)- represents the residue of the fatty acids obtained from schinziophyton rautanenii kernel oil, and n is 6	skin-conditioning agent – emollient; surfactant – emulsifying agent

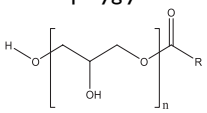
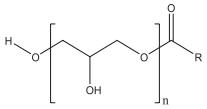
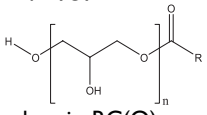
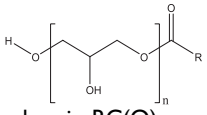
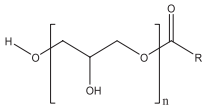
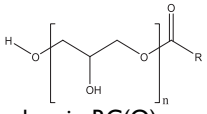
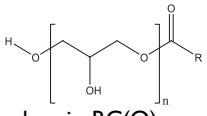
(continued)

Table 3. (continued)

Ingredient CAS No.	Definition & Structure	Function(s)
Polyglyceryl-6 Sclerocarya Birrea Seedate	the ester of polyglycerin-6 and the fatty acids obtained sclerocarya birrea seed oil  wherein RC(O)- represents the residue of the fatty acids obtained from sclerocarya birrea seed oil, and n is 6	skin-conditioning agent – emollient; surfactant – emulsifying agent
Polyglyceryl-6 Trichilia Emetica Seedate	the ester of polyglycerin-6 and the fatty acids obtained from trichilia emetica seed butter  wherein RC(O)- represents the residue of the fatty acids obtained from trichilia emetica seed butter, and n is 6	skin-conditioning agent – emollient; surfactant – emulsifying agent
Polyglyceryl-6 Ximenia Americana Seedate	the ester of polyglycerin-6 and the fatty acids obtained from ximenia americana seed oil  wherein RC(O)- represents the residue of the fatty acids obtained from ximenia americana seed oil, and n is 6	skin-conditioning agent – emollient; surfactant – emulsifying agent
Rosa Rubiginosa Seed Oil Polyglyceryl-6 Esters	the product obtained by the transesterification of rosa rubiginosa seed oil and polyglycerin-6  wherein RC(O)- represents the residue of fatty acids derived (via transesterification) from rosa rubiginosa seed oil, and n is 6	skin-conditioning agent – emollient; skin-conditioning agent – miscellaneous; surfactant – emulsifying agent
Safflower Seed Oil Polyglyceryl-6 Esters	the product obtained by the transesterification of carthamus tinctorius (safflower) seed oil and polyglycerin-6  wherein RC(O)- represents the residue of fatty acids derived (via transesterification) from carthamus tinctorius (safflower) seed oil, and n is 6	skin-conditioning agent – emollient; surfactant – emulsifying agent
Schinziophyton Rautanenii Kernel Oil Polyglyceryl-6 Esters	the product formed by the transesterification of schinziophyton rautanenii kernel oil and polyglycerin-6  wherein RC(O)- represents the residue of fatty acids derived (via transesterification) from schinziophyton rautanenii kernel oil, and n is 6	skin-conditioning agent – emollient; surfactant – emulsifying agent
Sclerocarya Birrea Seed Oil Polyglyceryl-6 Esters	the product obtained by the transesterification of sclerocarya birrea seed oil with polyglycerin-6  wherein RC(O)- represents the residue of fatty acids derived (via transesterification) from sclerocarya birrea seed oil, and n is 6	skin-conditioning agent – emollient; surfactant – emulsifying agent

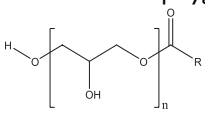
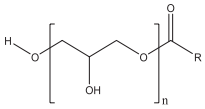
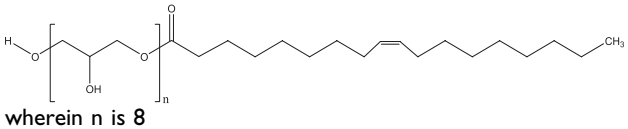
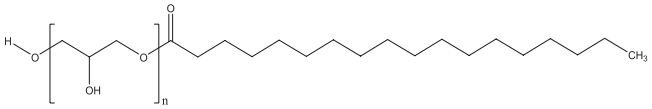
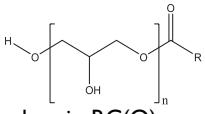
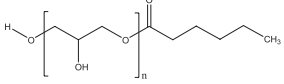
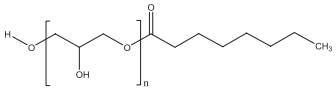
(continued)

Table 3. (continued)

Ingredient CAS No.	Definition & Structure	Function(s)
Sesame Oil Polyglyceryl-6 Esters	the product obtained by the transesterification of sesamum indicum (sesame) oil and polyglycerin-6  wherein RC(O)- represents the residue of fatty acids derived (via transesterification) from sesamum indicum (sesame) oil, and n is 6	skin-conditioning agent – emollient; surfactant – emulsifying agent
Shea Butter Polyglyceryl-6 Esters	the product obtained by the transesterification of butyrospermum parkii (shea) butter and polyglycerin-6  wherein RC(O)- represents the residue of fatty acids derived (via transesterification) from butyrospermum parkii (shea) butter, and n is 6	skin-conditioning agent – emollient; surfactant – emulsifying agent
Soybean Oil Polyglyceryl-6 Esters	the product of the transesterification of glycine soja (soybean) oil and polyglycerin-6  wherein RC(O)- represents the residue of fatty acids derived (via transesterification) from glycine soja (soybean) oil, and n is 6	skin-conditioning agent – emollient; surfactant – emulsifying agent
Sunflower Seed Oil Polyglyceryl-6 Esters	the product obtained by the transesterification of helianthus annuus (sunflower) seed oil and polyglycerin-6  wherein RC(O)- represents the residue of fatty acids derived (via transesterification) from helianthus annuus (sunflower) seed oil, and n is 6	skin-conditioning agent – emollient; surfactant – emulsifying agent
Sweet Almond Oil Polyglyceryl-6 Esters	the product obtained by the transesterification of prunus amygdalus dulcis (sweet almond) oil and polyglycerin-6  wherein RC(O)- represents the residue of fatty acids derived (via transesterification) from prunus amygdalus dulcis (sweet almond) oil, and n is 6	skin-conditioning agent – emollient; surfactant – emulsifying agent
Theobroma Grandiflorum Seed Butter Polyglyceryl-6 Esters	the product obtained by the transesterification of theobroma grandiflorum seed butter and polyglycerin-6  wherein RC(O)- represents the residue of fatty acids derived (via transesterification) from theobroma grandiflorum seed butter, and n is 6	skin-conditioning agent – emollient; surfactant – emulsifying agent
Trichilia Emetica Seed Oil Polyglyceryl-6 Esters	the product obtained by the transesterification of trichilia emetica seed butter and polyglycerin-6  wherein RC(O)- represents the residue of fatty acids derived (via transesterification) from trichilia emetica seed butter, and n is 6	skin-conditioning agent – emollient; surfactant – emulsifying agent

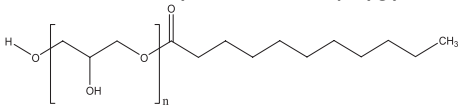
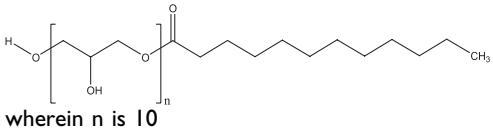
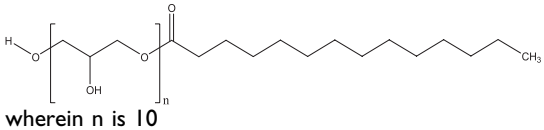
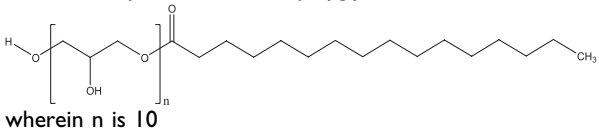
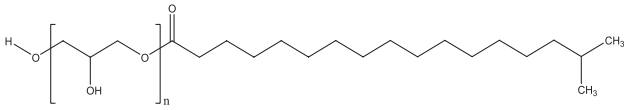
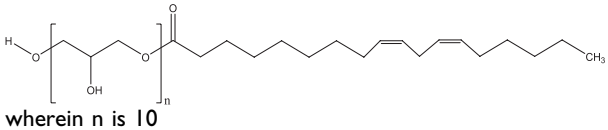
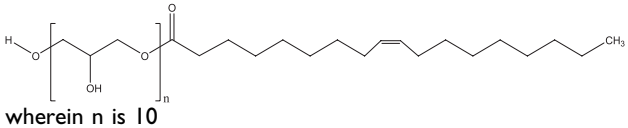
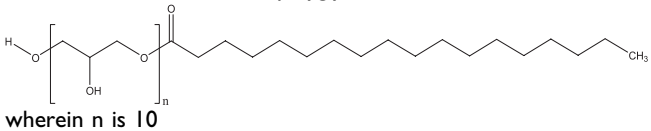
(continued)

Table 3. (continued)

Ingredient CAS No.	Definition & Structure	Function(s)
Watermelon Seed Oil Polyglyceryl-6 Esters	the product obtained by the transesterification of citrullus lanatus (watermelon) seed oil with polyglycerin-6  wherein RC(O)- represents the residue of fatty acids derived (via transesterification) from citrullus lanatus (watermelon) seed oil, and n is 6	skin-conditioning agent – emollient; surfactant – emulsifying agent
Ximenia Americana Seed Oil Polyglyceryl-6 Esters	the product obtained by the transesterification of ximenia americana seed oil and polyglycerin-6  wherein RC(O)- represents the residue of fatty acids derived (via transesterification) from ximenia americana seed oil, and n is 6	skin-conditioning agent – emollient; surfactant – emulsifying agent
Polyglyceryl-8 discrete esters		
Polyglyceryl-8 Oleate 75719-56-1 9007-48-1 (generic)	an ester of oleic acid and a glycerin polymer containing an average of 8 glycerin units  wherein n is 8	skin-conditioning agent – misc.; surfactant – emulsifying agent
Polyglyceryl-8 Stearate 37349-34-1 (generic) 75719-57-2	an ester of stearic acid and a glycerin polymer containing an average of 8 glycerin units  wherein n is 8	surfactant – emulsifying agent
Polyglyceryl-8 mixed esters		
Polyglyceryl-8 C12-20 Acid Ester	the ester of a glycerin polymer containing 8 units of glycerin and a synthetic mixture of saturated acids containing 12 to 20 carbons in the alkyl chain  wherein RC(O)- represents the residue of a fatty acid containing 12 to 20 carbons in the alkyl chain, and n is 8	surfactant – emulsifying agent
Polyglyceryl-10 discrete esters		
Polyglyceryl-10 Caprate	the ester of capric acid and polyglycerin-10  wherein n is 10	skin-conditioning agent – emollient; surfactant – emulsifying agent
Polyglyceryl-10 Caprylate 51033-41-1	the monoester of caprylic acid and polyglycerin-10  wherein n is 10	surfactant – emulsifying agent

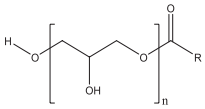
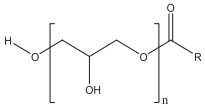
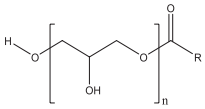
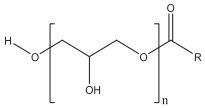
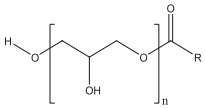
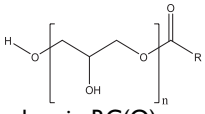
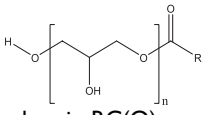
(continued)

Table 3. (continued)

Ingredient CAS No.	Definition & Structure	Function(s)
Polyglyceryl-10 Undecylenate	an ester of Undecylenic Acid and polyglycerin-10  wherein n is 10	surfactant – emulsifying agent
Polyglyceryl-10 Laurate 34406-66-1 74504-64-6 (generic)	an ester of lauric acid and polyglycerin-10  wherein n is 10	skin-conditioning agent – misc; surfactant – emulsifying agent
Polyglyceryl-10 Myristate 87390-32-7	an ester of myristic acid and polyglycerin-10  wherein n is 10	skin-conditioning agent – emollient; surfactant – emulsifying agent
Polyglyceryl-10 Palmitate 79777-31-4	the ester of palmitic acid and polyglycerin-10  wherein n is 10	skin-conditioning agent – emollient; surfactant – emulsifying agent
Polyglyceryl-10 Isostearate 133738-23-5	the ester of isostearic acid and polyglycerin-10  wherein n is 10 (one example of an "iso")	skin-conditioning agent – emollient; surfactant – emulsifying agent
Polyglyceryl-10 Linoleate	the monoester of linoleic acid and polyglycerin-10  wherein n is 10	skin-conditioning agent – emollient; surfactant – emulsifying agent
Polyglyceryl-10 Oleate 79665-93-3 9007-48-1 (generic)	an ester of oleic acid and polyglycerin-10  wherein n is 10	skin-conditioning agent – misc; surfactant – emulsifying agent
Polyglyceryl-10 Stearate 79777-30-3 9009-32-9 (generic)	an ester of stearic acid and polyglycerin-10  wherein n is 10	skin-conditioning agent – misc; surfactant – emulsifying agent

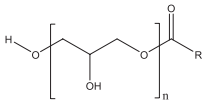
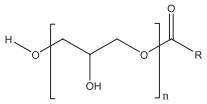
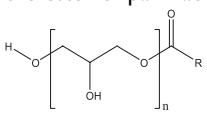
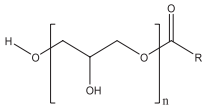
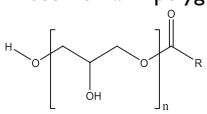
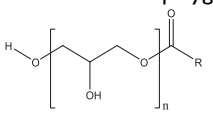
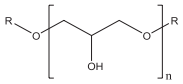
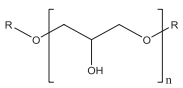
(continued)

Table 3. (continued)

Ingredient CAS No.	Definition & Structure	Function(s)
Polyglyceryl-10 mixed esters		
Almond Oil/Polyglyceryl-10 Esters	the product obtained by the transesterification of prunus amygdalus dulcis (sweet almond) oil and polyglycerin-10  wherein RC(O)- represents the residue of fatty acids derived (via transesterification) from prunus amygdalus dulcis (sweet almond) oil, and n is 10	surfactant – emulsifying agent
Apricot Kernel Oil Polyglyceryl-10 Esters	the product obtained by the transesterification of prunus armeniaca (apricot) kernel oil and polyglycerin-10  wherein RC(O)- represents the residue of fatty acids derived (via transesterification) from prunus armeniaca (apricot) kernel oil, and n is 10	skin-conditioning agent – emollient; surfactant – emulsifying agent
Caprylic/Capric Glycerides Polyglyceryl-10 Esters	the product obtained by the transesterification of caprylic/capric glycerides with polyglycerin-10  wherein RC(O)- represents the residue of caprylic or capric acid, and n is 10	skin-conditioning agent – emollient; surfactant – emulsifying agent; surfactant – solubilizing agent
Polyglyceryl-10 Apricot Kernelate	the ester of the fatty acids derived from prunus armeniaca (apricot) kernel oil and polyglycerin-10  wherein RC(O)- represents the residue of fatty acids derived (via transesterification) from prunus armeniaca (apricot) kernel oil, and n is 10	skin-conditioning agent – emollient; skin-conditioning agent – miscellaneous; surfactant – emulsifying agent
Polyglyceryl-10 Behenate/ Eicosadioate	the monoester of polyglycerin-10 and a blend of behenic and eicosadioic acids  wherein RC(O)- represents the residue of behenic or eicosadioic acid, and n is 10	skin-conditioning agent – emollient; surfactant – emulsifying agent
Polyglyceryl-10 Caprylate/ Caprate	the monoester of polyglycerin-10 and a blend of caprylic and capric acids  wherein RC(O)- represents the residue of capric or caprylic acid, and n is 10	emulsion stabilizer; solvent; surfactant – emulsifying agent
Polyglyceryl-10 Cocoate	the ester of coconut acid and polyglycerin-10  wherein RC(O)- represents the residue of coconut acid, and n is 10	surfactant-cleansing agent; surfactant-emulsifying agent

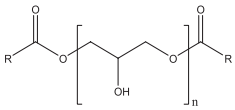
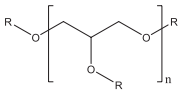
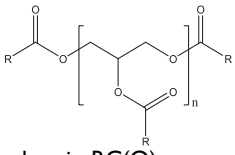
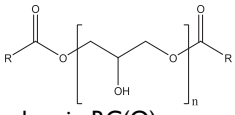
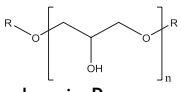
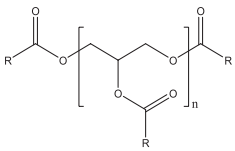
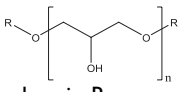
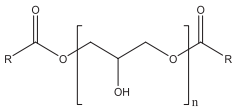
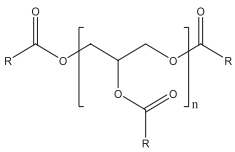
(continued)

Table 3. (continued)

Ingredient CAS No.	Definition & Structure	Function(s)
Polyglyceryl-10 Eicosanedioate/ Tetradecanedioate	the ester of polyglycerin-10 with a mixture of eicosanedioic and tetradecanedioic acids  wherein RC(O)- represents the residue of eicosanedioic or tetradecanedioic acid, and n is 10	hair conditioning agent; skin conditioning agent – occlusive
Polyglyceryl-10 Hydroxystearate/ Stearate/Eicosadioate	the monoester of polyglycerin-10 with a blend of hydroxystearic, stearic and eicosandioic acids  wherein RC(O)- represents the residue of hydroxystearic, stearic and eicosandioic acids, and n is 10	skin-conditioning agent – emollient
Polyglyceryl-10 Palmate	the ester of palm acid and polyglycerin-10  wherein RC(O)- represents the residue of palm acid, and n is 10	skin-conditioning agent – misc; surfactant – emulsifying agent
Sclerocarya Birrea Seed Oil Polyglyceryl-10 Esters	the product obtained by the transesterification of sclerocarya birrea seed oil with polyglycerin-10  wherein RC(O)- represents the residue of fatty acids derived (via transesterification) from sclerocarya birrea seed oil, and n is 10	skin-conditioning agent – emollient; surfactant – emulsifying agent
Sunflower Seed Oil Polyglyceryl-10 Esters	the product obtained by the transesterification of helianthus annuus (sunflower) seed oil and polyglycerin-10  wherein RC(O)- represents the residue of fatty acids derived (via transesterification) from helianthus annuus (sunflower) seed oil, and n is 10	skin-conditioning agent – emollient; surfactant – emulsifying agent
Watermelon Seed Oil Polyglyceryl-10 Esters	the product obtained by the transesterification of citrullus lanatus (watermelon) seed oil with polyglycerin-10  wherein RC(O)- represents the residue of fatty acids derived (via transesterification) from citrullus lanatus (watermelon) seed oil, and n is 10	skin-conditioning agent – emollient; surfactant – emulsifying agent
	Polyglyceryl Multi-esters (i.e., not mono-esters and not "polyesters")	
Polyglyceryl-2 discrete multi-esters		
Polyglyceryl-2 Sesquicaprylate	a mixture of mono- and diesters of caprylic acid and diglycerin  wherein R- represents hydrogen or the residue of caprylic acid, and n is 2	skin-conditioning agent – emollient; surfactant – emulsifying agent
Polyglyceryl-2 Sesquiisostearate 170211-20-8	a mixture of mono and diesters of isostearic acid and diglycerin  wherein R- represents hydrogen or the residue of isostearic acid, and n is 2	skin-conditioning agent – emollient; surfactant – emulsifying agent

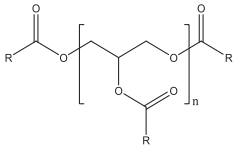
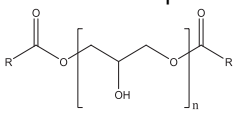
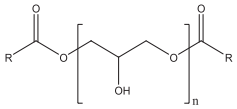
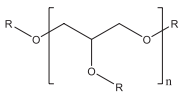
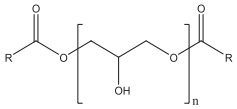
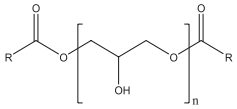
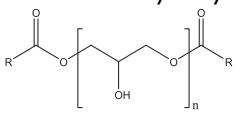
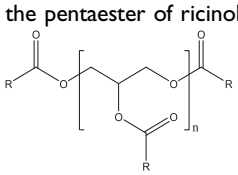
(continued)

Table 3. (continued)

Ingredient CAS No.	Definition & Structure	Function(s)
Polyglyceryl-2 Diisostearate 63705-03-3 (generic) 67938-21-0	the diester of isostearic acid and diglycerin  wherein RC(O)- represents the residue of isostearic acid, and n is 2	skin-conditioning agent – emollient; surfactant – emulsifying agent
Polyglyceryl-2 Triisostearate 120486-24-0	the triester of isostearic acid and diglycerin  wherein R- represents hydrogen or the residue of isostearic acid, and n is 2	skin-conditioning agent – emollient; surfactant – emulsifying agent
Polyglyceryl-2 Tetraisostearate 121440-30-0	the tetraester of isostearic acid and a dimer of glycerin  wherein RC(O)- represents the residue of isostearic acid, and n is 2	skin-conditioning agent – emollient; surfactant – emulsifying agent
Polyglyceryl-2 Dioleate 60219-68-3 67965-56-4	a diester of oleic acid and diglycerin  wherein RC(O)- represents the residue of oleic acid, and n is 2	skin-conditioning agent – emollient; surfactant – emulsifying agent
Polyglyceryl-2 Sesquioleate	a mixture of mono and diesters of oleic acid and diglycerin  wherein R- represents hydrogen or the residue of oleic acid, and n is 2	skin-conditioning agent – emollient; surfactant – emulsifying agent
Polyglyceryl-2 Tetraoleate	the tetraester of oleic acid and diglycerin  wherein RC(O)- represents the residue of oleic acid, and n is 2	skin-conditioning agent – misc; surfactant – emulsifying agent
Polyglyceryl-2 Sesquistearate 9009-32-9 (generic)	a mixture of mono- and diesters of stearic acid and diglycerin  wherein R- represents hydrogen or the residue of stearate acid, and n is 2	skin-conditioning agent – emollient; surfactant – emulsifying agent
Polyglyceryl-2 Distearate 61725-93-7 9009-32-9 (generic)	the diester of stearic acid and diglycerin  wherein RC(O)- represents the residue of stearic acid, and n is 2	surfactant – emulsifying agent
Polyglyceryl-2 Tetrastearate 72347-89-8 9009-32-9 (generic)	the tetraester of stearic acid and diglycerin  wherein RC(O)- represents the residue of stearic acid, and n is 2	skin-conditioning agent – emollient; surfactant – emulsifying agent

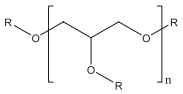
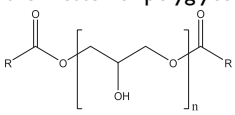
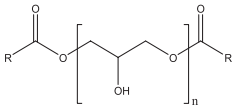
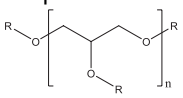
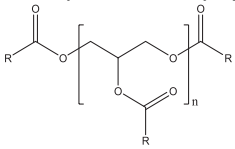
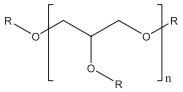
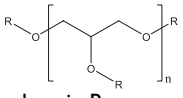
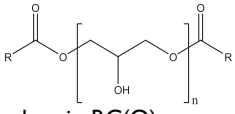
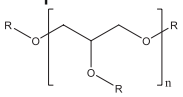
(continued)

Table 3. (continued)

Ingredient CAS No.	Definition & Structure	Function(s)
Polyglyceryl-2 mixed multi-esters		
Polyglyceryl-2 Tetrabehenate/ Macadamiate/Sebacate	the tetraester of a mixture of behenic, sebacic and macadamia acids with a dimer of glycerin  wherein RC(O)- represents the residue of behenic, sebacic, or macadamia acid, and n is 2	skin-conditioning agent – emollient
Polyglyceryl-3 discrete multi-esters		
Polyglyceryl-3 Dicaprate	the diester of capric acid and polyglycerin-3  wherein RC(O)- represents the residue of capric acid, and n is 3	skin-conditioning agent – emollient; surfactant – emulsifying agent
Polyglyceryl-3 Diisostearate 63705-03-3 (generic) 66082-42-6	a diester of isostearic acid and polyglycerin-3  wherein RC(O)- represents the residue of isostearic acid, and n is 3	skin-conditioning agent – emollient; surfactant – emulsifying agent
Polyglyceryl-3 Triisostearate 66082-43-7	the triester of isostearic acid and polyglycerin-3  wherein R- represents hydrogen or the residue of isostearic acid, and n is 3	skin-conditioning agent – emollient; surfactant – emulsifying agent
Polyglyceryl-3 Dioleate 79665-94-4	a diester of oleic acid and polyglycerin-3  wherein RC(O)- represents the residue of oleic acid, and n is 3	skin-conditioning agent – emollient; surfactant – emulsifying agent
Polyglyceryl-3 Distearate 94423-19-5 9009-32-9 (generic) 61725-93-7 (generic)	the diester of stearic acid and polyglycerin-3  wherein RC(O)- represents the residue of stearic acid, and n is 3	skin-conditioning agent – emollient; surfactant – emulsifying agent
Polyglyceryl-3 Di-Hydroxystearate	the diester of hydroxystearic acid and polyglycerin-3  wherein RC(O)- represents the residue of hydroxystearic acid, and n is 3	skin-conditioning agent – emollient; surfactant – emulsifying agent
Polyglyceryl-3 Pentaricinoleate	the pentaester of ricinoleic acid and polyglycerin-3  wherein RC(O)- represents the residue of ricinoleic acid, and n is 3	skin-conditioning agent – emollient; surfactant – emulsifying agent

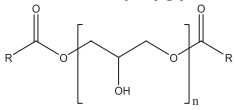
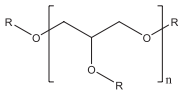
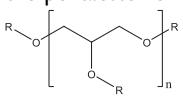
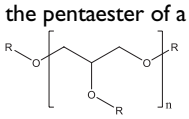
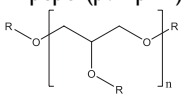
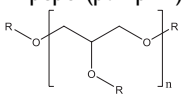
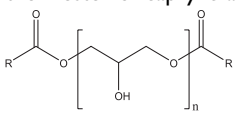
(continued)

Table 3. (continued)

Ingredient CAS No.	Definition & Structure	Function(s)
Polyglyceryl-3 mixed multi-esters		
Diisostearoyl Polyglyceryl-3 Dimer Dilinoleate	the diester of dilinoleic acid and Polyglyceryl-3 Diisostearate  wherein R- represents the residue of isostearic acid or dilinoleic acid, and n is 3	skin-conditioning agent – emollient
Polyglyceryl-3 Dicitrate/ Stearate	the diester of polyglycerin-3 with a mixture of citric acid and stearic acid  wherein RC(O)- represents the residue of citric or stearic acid, and n is 3	surfactant – emulsifying agent
Polyglyceryl-3 Dicocoate	the diester of coconut acid and polyglycerin-3  wherein RC(O)- represents the residue of coconut acid, and n is 3	skin-conditioning agent – emollient; surfactant – emulsifying agent
Polyglyceryl-3 Pentacaprylate/Caprate	the pentaester of a mixture of caprylic acid and capric acid with polyglycerin-3  wherein R- represents hydrogen or the residue of capric or caprylic acid, and n is 3	skin-conditioning agent – emollient; surfactant – emulsifying agent; surfactant – solubilizing agent
Polyglyceryl-3 Pentaolivate	is the pentaester of polyglycerin-3 and olive acid  wherein RC(O)- represents the residue of olive acid, and n is 3	skin-conditioning agent – emollient; surfactant – emulsifying agent
Polyglyceryl-3 Triolivate	the triester of polyglycerin-3 and olive acid  wherein R- represents hydrogen or the residue of olive acid, and n is 3	surfactant – emulsifying agent
Triisostearoyl Polyglyceryl-3 Dimer Dilinoleate	the diester of dilinoleic acid and polyglyceryl-3 triisostearate  wherein R- represents the residue of isostearic acid or dilinoleic acid, and n is 3	skin-conditioning agent – emollient
Polyglyceryl-4 discrete multi-esters		
Polyglyceryl-4 Dilaurate	the diester of lauric acid and polyglycerin-4  wherein RC(O)- represents the residue of lauric acid, and n is 4	skin-conditioning agent – emollient; surfactant – emulsifying agent
Polyglyceryl-4 Pentaoleate 103230-29-1	the pentaester of oleic acid and polyglycerin-4  wherein R- represents hydrogen or the residue of oleic acid, and n is 4	skin-conditioning agent – emollient; surfactant – emulsifying agent

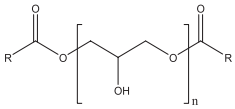
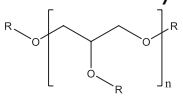
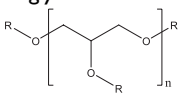
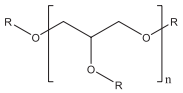
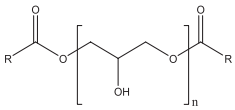
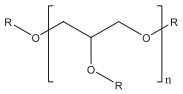
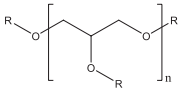
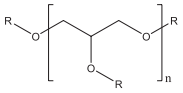
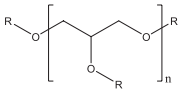
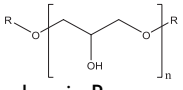
(continued)

Table 3. (continued)

Ingredient CAS No.	Definition & Structure	Function(s)
Polyglyceryl-4 Distearate	a diester of polyglycerin-4 with stearic acid  wherein RC(O)- represents the residue of stearic acid, and n is 4	surfactant – emulsifying agent
Polyglyceryl-4 Tristearate 99734-29-9	the triester of stearic acid and polyglycerin-4  wherein R- represents hydrogen or the residue of stearic acid, and n is 4	skin-conditioning agent – emollient; surfactant – emulsifying agent
Polyglyceryl-4 Pentastearate 99570-00-0	the pentaester of stearic acid and polyglycerin-4  wherein R- represents hydrogen or the residue of stearic acid, and n is 4	skin-conditioning agent – emollient; surfactant – emulsifying agent
Polyglyceryl-4 mixed multi-esters		
Polyglyceryl-4 Pentapalmitate/Stearate	the pentaester of a mixture of palmitic acid and stearic acid with polyglycerin-4  wherein R- represents hydrogen or the residue of palmitic or stearic acid, and n is 4	surfactant – emulsifying agent
Pumpkin Seed Oil Polyglyceryl-4 Esters	the complex mixture of esters formed by the transesterification of cucurbita pepo (pumpkin) seed oil and polyglycerin-4  wherein R- represents hydrogen or the residue of the fatty acids derived from cucurbita pepo (pumpkin) seed oil (via transesterification), and n is 4	emulsion stabilizer; surfactant – emulsifying agent
Pumpkin Seed Oil Polyglyceryl-4 Esters Succinate	the complex mixture of esters formed by the transesterification of cucurbita pepo (pumpkin) seed oil and polyglycerin-4 reacted with succinic acid  wherein R- represents hydrogen or the residue of succinic acid or the fatty acids derived from cucurbita pepo (pumpkin) seed oil (via transesterification), and n is 4	emulsion stabilizer; surfactant – emulsifying agent
Polyglyceryl-5 discrete multi-esters		
Polyglyceryl-5 Dicaprylate 108777-93-1 (generic)	the diester of caprylic acid with a glycerin polymer containing 5 glycerin units  wherein RC(O)- represents the residue of caprylic acid, and n is 5	skin-conditioning agent – emollient; surfactant – cleansing agent; surfactant – emulsifying agent

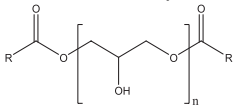
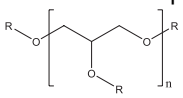
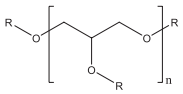
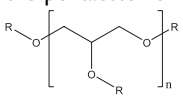
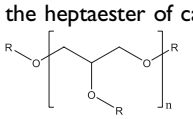
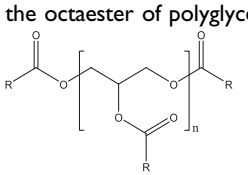
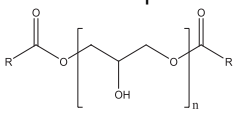
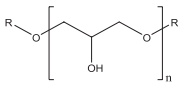
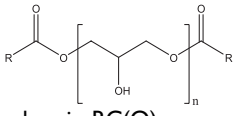
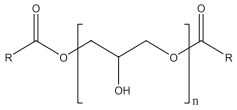
(continued)

Table 3. (continued)

Ingredient CAS No.	Definition & Structure	Function(s)
Polyglyceryl-5 Dilaurate	the diester of lauric acid and a glycerin polymer containing 5 units of glycerin  wherein RC(O)- represents the residue of lauric acid, and n is 5	surfactant – emulsifying agent
Polyglyceryl-5 Trimyristate	the triester of myristic acid and a glycerin polymer containing 5 units of glycerin  wherein R- represents hydrogen or the residue of myristic acid, and n is 5	skin-conditioning agent – emollient; surfactant – emulsifying agent
Polyglyceryl-5 Pentamyristate	the pentaester of myristic acid and a glycerin polymer containing 5 units of glycerin  wherein R- represents hydrogen or the residue of myristic acid, and n is 5	skin-conditioning agent – emollient; surfactant – emulsifying agent
Polyglyceryl-5 Triisostearate	the triester of isostearic acid and a glycerin polymer containing 5 units of glycerin  wherein R- represents hydrogen or the residue of isostearic acid, and n is 5	surfactant – cleansing agent; surfactant – dispersing agent; surfactant – emulsifying agent
Polyglyceryl-5 Dioleate	the diester of oleic acid and a glycerin polymer containing 5 units of glycerin  wherein RC(O)- represents the residue of oleic acid, and n is 5	surfactant – emulsifying agent
Polyglyceryl-5 Trioleate	the triester of oleic acid and a glycerin polymer containing 5 units of glycerin  wherein R- represents hydrogen or the residue of oleic acid, and n is 5	skin-conditioning agent – emollient; surfactant – emulsifying agent
Polyglyceryl-5 Tristearate 9009-32-9 (generic)	the triester of stearic acid and a glycerin polymer containing 5 units of glycerin  wherein R- represents hydrogen or the residue of stearic acid, and n is 5	surfactant – cleansing agent; surfactant – dispersing agent; surfactant – emulsifying agent
Polyglyceryl-5 Hexastearate	the hexaester of stearic acid and a glycerin polymer containing 5 units of glycerin  wherein R- represents hydrogen or the residue of stearic acid, and n is 5	skin-conditioning agent – emollient; surfactant – emulsifying agent
Polyglyceryl-5 Tribehenate	the triester of behenic acid and a glycerin polymer containing 5 units of glycerin  wherein R- represents hydrogen or the residue of behenic acid, and n is 5	skin-conditioning agent – emollient; surfactant – emulsifying agent
Polyglyceryl-6 discrete multi-esters		
Polyglyceryl-6 Sesquicaprylate 108777-93-1 (generic) 946492-22-4 (generic) 946492-23-5 (generic)	a mixture of mono- and diesters of caprylic acid and polyglycerin-6  wherein R- represents hydrogen or the residue of caprylic acid, and n is 6	skin-conditioning agent – emollient; surfactant – cleansing agent; surfactant – emulsifying agent

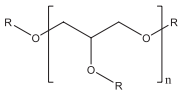
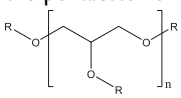
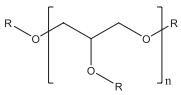
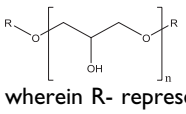
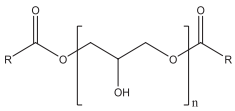
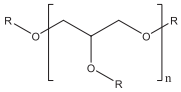
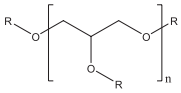
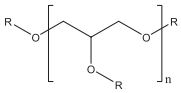
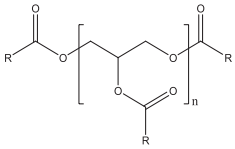
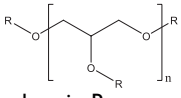
(continued)

Table 3. (continued)

Ingredient CAS No.	Definition & Structure	Function(s)
Polyglyceryl-6 Dicaprate	the diester of capric acid and polyglycerin-6  wherein RC(O)- represents the residue of capric acid, and n is 6	skin-conditioning agent – emollient; surfactant – emulsifying agent
Polyglyceryl-6 Tricaprylate	the triester of caprylic acid and polyglycerin-6  wherein R- represents hydrogen or the residue of caprylic acid, and n is 6	surfactant – cleansing agent
Polyglyceryl-6 Tetracaprylate	the tetraester of caprylic acid and polyglycerin-6  wherein R- represents hydrogen or the residue of caprylic acid, and n is 6	surfactant – cleansing agent
Polyglyceryl-6 Pentacaprylate	the pentaester of caprylic acid and polyglycerin-6  wherein R- represents hydrogen or the residue of caprylic acid, and n is 6	surfactant – cleansing agent
Polyglyceryl-6 Heptacaprylate	the heptaester of caprylic acid and polyglycerin-6  wherein R- represents hydrogen or the residue of caprylic acid, and n is 6	surfactant – emulsifying agent
Polyglyceryl-6 Octacaprylate	the octaester of polyglycerin-6 and caprylic acid  wherein RC(O)- represents the residue of caprylic acid, and n is 6	skin-conditioning agent – emollient
Polyglyceryl-6 Dipalmitate	the diester of palmitic acid and polyglycerin-6  wherein RC(O)- represents the residue of palmitic acid, and n is 6	skin-conditioning agent – emollient; surfactant – emulsifying agent
Polyglyceryl-6 Sesquiisostearate	a mixture of mono- and diesters of isostearic acid and polyglycerin-6  wherein R- represents hydrogen or the residue of isostearic acid, and n is 6	surfactant – emulsifying agent
Polyglyceryl-6 Diisostearate	the diester of isostearic acid and polyglycerin-6  wherein RC(O)- represents the residue of isostearic acid, and n is 6	skin-conditioning agent – emollient; surfactant – emulsifying agent
Polyglyceryl-6 Dioleate 76009-37-5	a diester of oleic acid and polyglycerin-6  wherein RC(O)- represents the residue of oleic acid, and n is 6	skin-conditioning agent – emollient; surfactant – emulsifying agent

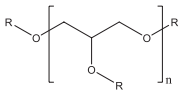
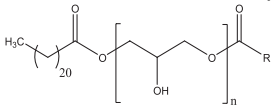
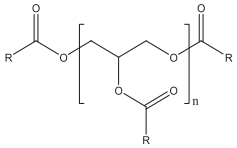
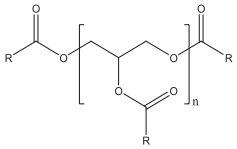
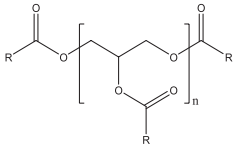
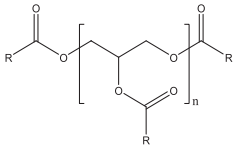
(continued)

Table 3. (continued)

Ingredient CAS No.	Definition & Structure	Function(s)
Polyglyceryl-6 Tetraoleate 128774-95-8	the tetraester of Oleic Acid and polyglycerin-6  wherein R- represents hydrogen or the residue of oleic acid, and n is 6	skin-conditioning agent – emollient; surfactant – emulsifying agent
Polyglyceryl-6 Pentaoleate 104934-17-0	the pentaester of oleic acid and polyglycerin-6  wherein R- represents hydrogen or the residue of oleic acid, and n is 6	skin-conditioning agent – emollient; surfactant – emulsifying agent
Polyglyceryl-6 Hexaoleate 95482-05-6	a hexaester of oleic acid and polyglycerin-6  wherein R- represents hydrogen or the residue of oleic acid, and n is 6	skin-conditioning agent – emollient; surfactant – emulsifying agent
Polyglyceryl-6 Sesquistearate 112939-69-2	a mixture of mono- and diesters of stearic acid and polyglycerin-6  wherein R- represents hydrogen or the residue of stearic acid, and n is 6	surfactant – emulsifying agent
Polyglyceryl-6 Distearate 34424-97-0 9009-32-9 (generic)	a diester of stearic acid and polyglycerin-6  wherein RC(O)- represents the residue of stearic acid, and n is 6	skin-conditioning agent – emollient; surfactant – emulsifying agent
Polyglyceryl-6 Tristearate 71185-87-0 9009-32-9 (generic)	the triester of stearic acid and polyglycerin-6  wherein R- represents hydrogen or the residue of stearic acid, and n is 6	surfactant – emulsifying agent
Polyglyceryl-6 Pentastearate 9009-32-9 (generic) 99734-30-2	the pentaester of stearic acid and polyglycerin-6  wherein R- represents hydrogen or the residue of stearic acid, and n is 6	skin-conditioning agent – emollient; surfactant – emulsifying agent
Polyglyceryl-6 Hexastearate	the hexaester of stearic acid and polyglycerin-6  wherein R- represents hydrogen or the residue of stearic acid, and n is 6	skin-conditioning agent – emollient; surfactant – emulsifying agent
Polyglyceryl-6 Octastearate	the octaester of stearic acid and polyglycerin-6  wherein RC(O)- represents the residue of stearic acid, and n is 6	skin-conditioning agent – emollient; surfactant – emulsifying agent
Polyglyceryl-6 Pentaricinoleate	the pentaester of ricinoleic acid and polyglycerin-6  wherein R- represents hydrogen or the residue of ricinoleic acid, and n is 6	skin-conditioning agent – emollient; surfactant – emulsifying agent

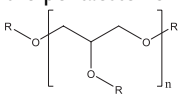
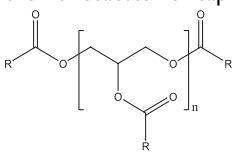
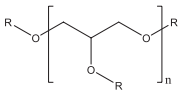
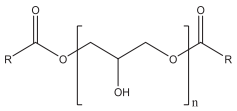
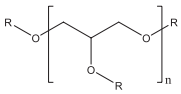
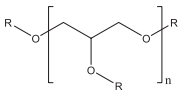
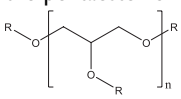
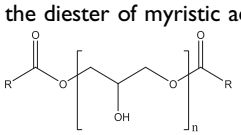
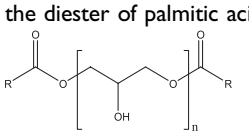
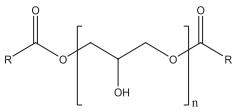
(continued)

Table 3. (continued)

Ingredient CAS No.	Definition & Structure	Function(s)
Polyglyceryl-6 Tetrabehenate	the tetraester of behenic acid and polyglycerin-6  wherein R- represents hydrogen or the residue of behenic acid, and n is 6	skin-conditioning agent – emollient; surfactant – emulsifying agent
Polyglyceryl-6 mixed multi-ester		
Macadamia Seed Oil Polyglyceryl-6 Esters Behenate	the behenic acid ester of the product obtained by the transesterification of macadamia seed oil and polyglycerin-6  wherein RC(O)- represents the residue of fatty acids derived (via transesterification) from macadamia ternifolia seed oil, and n is 6	skin-conditioning agent – emollient
Polyglyceryl-8 mixed multi-esters		
Polyglyceryl-8 Decabehenate/Caprate	the decaester of a mixture of behenic acid and capric acid with a glycerin polymer containing 8 units of glycerin  wherein RC(O)- represents the residue of capric or behenic acid, and n is 8	viscosity increasing agent – nonaqueous
Polyglyceryl-8 Decaerucate/ Decaisostearate/ Decaricinoleate	the decaester of a glycerin polymer containing 8 units of glycerin with a mixture of erucic acid, isostearic acid and ricinoleic acid  wherein RC(O)- represents the residue of erucic, isostearic, or ricinoleic acid, and n is 8	skin-conditioning agent – emollient
Polyglyceryl-10 discrete multi-esters		
Polyglyceryl-10 Decaethylhexanoate	the decaester of 2-ethylhexanoic acid and polyglycerin-10  wherein RC(O)- represents the residue of 2-ethylhexanoic acid, and n is 10	skin conditioning agent – humectant
Polyglyceryl-10 Dodecacaprate	the dodecaester of capric acid and polyglycerin-10  wherein RC(O)- represents the residue of capric acid, and n is 10	skin-conditioning agent – emollient; surfactant – emulsifying agent

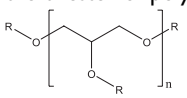
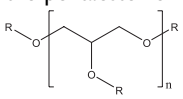
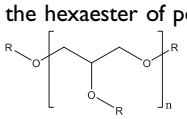
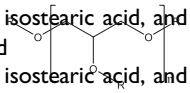
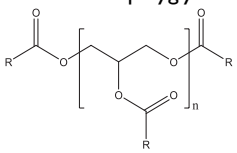
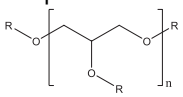
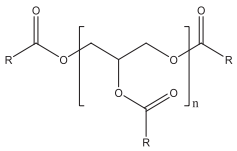
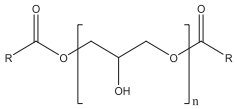
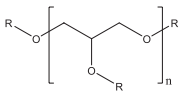
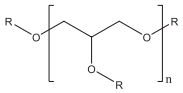
(continued)

Table 3. (continued)

Ingredient CAS No.	Definition & Structure	Function(s)
Polyglyceryl-10 Pentacaprylate	the pentaester of caprylic acid and polyglycerin-10  wherein R- represents hydrogen or the residue of caprylic acid, and n is 10	surfactant – cleansing agent; surfactant – emulsifying agent; surfactant – solubilizing agent
Polyglyceryl-10 Dodecacaprylate	the dodecaester of caprylic acid and polyglycerin-10  wherein RC(O)- represents the residue of caprylic acid, and n is 10	skin-conditioning agent – emollient; surfactant – emulsifying agent
Polyglyceryl-10 Tridecanoate 217782-56-4	the triester of decanoic acid and polyglycerin-10  wherein R- represents hydrogen or the residue of decanoic acid, and n is 10	skin-conditioning agent – emollient; surfactant – emulsifying agent
Polyglyceryl-10 Dilaurate	the diester of lauric acid and polyglycerin-10  wherein RC(O)- represents the residue of lauric acid, and n is 10	surfactant – cleansing agent
Polyglyceryl-10 Trilaurate	the triester of lauric acid and polyglycerin-10  wherein R- represents hydrogen or the residue of lauric acid, and n is 10	surfactant – cleansing agent
Polyglyceryl-10 Tetralaurate	the tetraester of lauric acid and polyglycerin-10  wherein R- represents hydrogen or the residue of lauric acid, and n is 10	surfactant – cleansing agent
Polyglyceryl-10 Pentalaurate	the pentaester of lauric acid and polyglycerin-10  wherein R- represents hydrogen or the residue of lauric acid, and n is 10	skin-conditioning agent – emollient; surfactant – emulsifying agent
Polyglyceryl-10 Dimyristate	the diester of myristic acid and polyglycerin-10  wherein RC(O)- represents the residue of myristic acid, and n is 10	surfactant – emulsifying agent
Polyglyceryl-10 Dipalmitate	the diester of palmitic acid and polyglycerin-10  wherein RC(O)- represents the residue of palmitic acid, and n is 10	skin-conditioning agent – emollient; surfactant – emulsifying agent
Polyglyceryl-10 Diisostearate 102033-55-6 63705-03-3 (generic)	a diester of isostearic acid and polyglycerin-10  wherein RC(O)- represents the residue of isostearic acid, and n is 10	skin-conditioning agent – emollient; surfactant – emulsifying agent

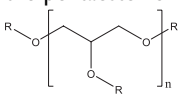
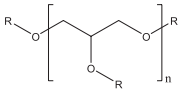
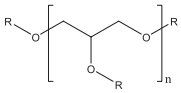
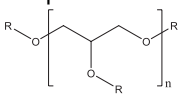
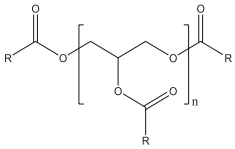
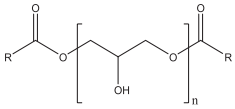
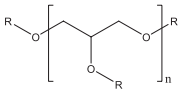
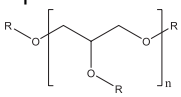
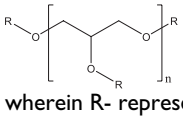
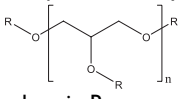
(continued)

Table 3. (continued)

Ingredient CAS No.	Definition & Structure	Function(s)
Polyglyceryl-10 Triisostearate	the triester of polyglycerin-10 and isostearic acid  wherein R- represents hydrogen or the residue of isostearic acid, and n is 10	surfactant – emulsifying agent
Polyglyceryl-10 Pentaisostearate	the pentaester of isostearic acid and polyglycerin-10  wherein R- represents hydrogen or the residue of isostearic acid, and n is 10	skin-conditioning agent – emollient; surfactant – emulsifying agent
Polyglyceryl-10 Hexaisostearate	the hexaester of polyglycerin-10 and isostearic acid  wherein R- represents hydrogen or the residue of isostearic acid, and n is 10	skin-conditioning agent – emollient; surfactant – emulsifying agent
Polyglyceryl-10 Nonaisostearate	the nonaester of polyglycerin-10 and isostearic acid  wherein R- represents hydrogen or the residue of isostearic acid, and n is 10	skin-conditioning agent – emollient
Polyglyceryl-10 Decaisostearate	the ester of polyglycerin-10 and isostearic acid  wherein RC(O)- represents the residue of isostearic acid, and n is 10	skin-conditioning agent – emollient
Polyglyceryl-10 Pentalinoleate	the pentaester of linoleic acid and polyglycerin-10  wherein R- represents hydrogen or the residue of linoleic acid, and n is 10	skin-conditioning agent – emollient; surfactant – emulsifying agent
Polyglyceryl-10 Decalinoleate 68900-96-9	a decaester of linoleic acid and polyglycerin-10  wherein RC(O)- represents the residue of linoleic acid, and n is 10	skin-conditioning agent – emollient; surfactant – emulsifying agent
Polyglyceryl-10 Dioleate 33940-99-7	a diester of oleic acid and polyglycerin-10  wherein RC(O)- represents the residue of oleic acid, and n is 10	skin-conditioning agent – emollient; surfactant – emulsifying agent
Polyglyceryl-10 Trioleate 102051-00-3	the triester of oleic acid and polyglycerin-10  wherein R- represents hydrogen or the residue of oleic acid, and n is 10	surfactant – emulsifying agent
Polyglyceryl-10 Tetraoleate 34424-98-1	a tetraester of oleic acid and polyglycerin-10  wherein R- represents hydrogen or the residue of oleic acid, and n is 10	skin-conditioning agent – emollient; surfactant – emulsifying agent

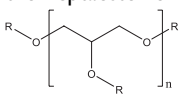
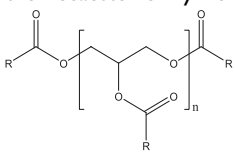
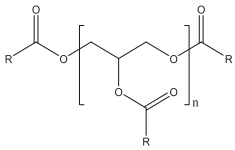
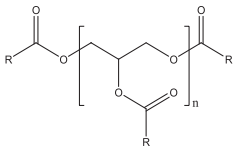
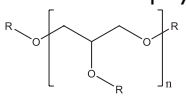
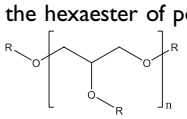
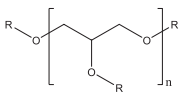
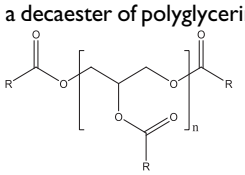
(continued)

Table 3. (continued)

Ingredient CAS No.	Definition & Structure	Function(s)
Polyglycery-1 Pentaoleate 86637-84-5	the pentaester of oleic acid and polyglycerin-10  wherein R- represents hydrogen or the residue of oleic acid, and n is 10	skin-conditioning agent – emollient; surfactant – emulsifying agent
Polyglyceryl-10 Pentaricinoleate	the pentaester of ricinoleic acid and polyglycerin-10  wherein R- represents hydrogen or the residue of ricinoleic acid, and n is 10	skin-conditioning agent – emollient; surfactant – emulsifying agent
Polyglyceryl-10 Hexaoleate 65573-03-7	the hexaester of oleic acid and polyglycerin-10  wherein R- represents hydrogen or the residue of oleic acid, and n is 10	skin-conditioning agent – emollient; surfactant – emulsifying agent
Polyglyceryl-10 Heptaoleate 103175-09-3	a heptaester of oleic acid and polyglycerin-10  wherein R- represents hydrogen or the residue of oleic acid, and n is 10	skin-conditioning agent – emollient; surfactant – emulsifying agent
Polyglyceryl-10 Decaoleate 11094-60-3	a decaester of oleic acid and polyglycerin-10  wherein RC(O)- represents the residue of oleic acid, and n is 10	skin-conditioning agent – emollient; surfactant – emulsifying agent
Polyglyceryl-10 Distearate 12764-60-2 9009-32-9 (generic)	the diester of stearic acid and polyglycerin-10  wherein RC(O)- represents the residue of stearic acid, and n is 10	skin-conditioning agent – emollient; surfactant – emulsifying agent
Polyglyceryl-10 Tristearate 12709-64-7 9009-32-9 (generic)	the triester of stearic acid and polyglycerin-10  wherein R- represents hydrogen or the residue of stearic acid, and n is 10	skin-conditioning agent – emollient; surfactant – emulsifying agent
Polyglyceryl-10 Pentastearate 9009-32-9 (generic) 95461-64-6	a pentaester of stearic acid and polyglycerin-10  wherein R- represents hydrogen or the residue of stearic acid, and n is 10	skin-conditioning agent – emollient; surfactant – emulsifying agent
Polyglyceryl-10 Pentahydroxystearate	the pentaester of hydroxystearic acid and polyglycerin-10  wherein R- represents hydrogen or the residue of hydroxystearic acid, and n is 10	skin-conditioning agent – emollient; surfactant – emulsifying agent
Polyglyceryl-10 Heptahydroxystearate	a heptaester of hydroxystearic acid and polyglycerin-10  wherein R- represents hydrogen or the residue of hydroxystearic acid, and n is 10	skin-conditioning agent – emollient; surfactant – emulsifying agent

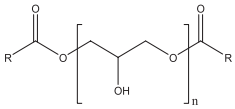
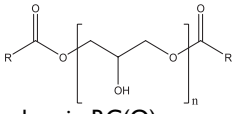
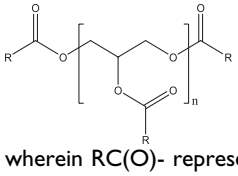
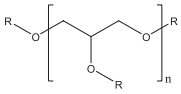
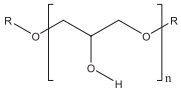
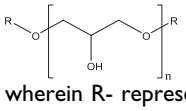
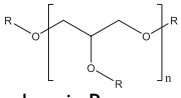
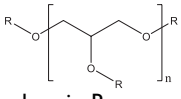
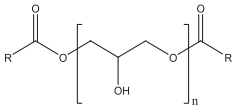
(continued)

Table 3. (continued)

Ingredient CAS No.	Definition & Structure	Function(s)
Polyglyceryl-10 Heptastearate 99126-54-2 9009-32-9 (generic)	the heptaester of stearic acid and polyglycerin-10  wherein R- represents hydrogen or the residue of stearic acid, and n is 10	skin-conditioning agent – emollient; surfactant – emulsifying agent
Polyglyceryl-10 Decahydroxystearate	the decaester of hydroxystearic acid and polyglycerin-10  wherein RC(O)- represents the residue of hydroxystearic acid, and n is 10	skin-conditioning agent – emollient; surfactant – emulsifying agent
Polyglyceryl-10 Decastearate 39529-26-5	a decaester of stearic acid and polyglycerin-10  wherein RC(O)- represents the residue of stearic acid, and n is 10	skin-conditioning agent – emollient; surfactant – emulsifying agent
Polyglyceryl-10 Dodecabehenate	the dodecaester of behenic acid and polyglycerin-10  wherein RC(O)- represents the residue of behenic, and n is 10	surfactant – emulsifying agent
Polyglyceryl-10 Trierucate	the triester of polyglycerin-10 and erucic acid  wherein R- represents hydrogen or the residue of erucic acid, and n is 10	surfactant – dispersing agent; surfactant – emulsifying agent
Polyglyceryl-10 Hexaerucate	the hexaester of polyglycerin-10 and erucic acid  wherein R- represents hydrogen or the residue of erucic acid, and n is 10	surfactant – dispersing agent; surfactant – emulsifying agent
Polyglyceryl-10 Nonaerucate 155808-79-0	the nonaester of erucic acid and polyglycerin-10  wherein R- represents hydrogen or the residue of erucic acid, and n is 10	skin-conditioning agent – emollient; surfactant – emulsifying agent
Polyglyceryl-10 mixed multi-esters		
Polyglyceryl-10 Decamacadamiate	a decaester of polyglycerin-10 and the fatty acids derived from macadamia nut oil  wherein RC(O)- represents the residue of the fatty acids derived from macadamia nut oil, and n is 10	skin-conditioning agent – emollient; surfactant – emulsifying agent

(continued)

Table 3. (continued)

Ingredient CAS No.	Definition & Structure	Function(s)
Polyglyceryl-10 Dicocoate	the diester of coconut acid and polyglycerin-10  wherein RC(O)- represents the residue of coconut acid, and n is 10	surfactant – cleansing agent; surfactant – emulsifying agent
Polyglyceryl-10 Didecanoate 182015-59-4	the diester of decanoic acid andppolyglycerin-10  wherein RC(O)- represents the residue of decanoic acid, and n is 10	skin-conditioning agent – emollient; surfactant – emulsifying agent
Polyglyceryl-10 Dodeca-Caprylate/Caprate	the dodecaester of a mixture of caprylic and capric acids with polyglycerin-10  wherein RC(O)- represents the residue of capric or caprylic acid, and n is 10	skin-conditioning agent – occlusive
Polyglyceryl-10 Hepta(Behenate/ Stearate)	the heptaester of polyglycerin-10 with a mixture of behenic acid and stearic acid  wherein R- represents hydrogen or the residue of behenic acid and stearic acid, and n is 10	surfactant – emulsifying agent
Polyglyceryl-10 Mono/ Dioleate	a mixture of mono- and diesters of oleic acid and polyglycerin-10  wherein R- represents hydrogen or the residue of oleic acid, and n is 10	skin-conditioning agent – emollient; surfactant – emulsifying agent
Polyglyceryl-10 Sesquistearate	a mixture of mono- and diesters of stearic acid and polyglycerin-10  wherein R- represents hydrogen or the residue of stearate acid, and n is 10	surfactant – emulsifying agent
Polyglyceryl-10 Tetradecanedioate	the ester of tetradecanedioic acid and polyglycerin-10  wherein R- represents hydrogen or the residue of tetradecanedioic acid, and n is 10	hair conditioning agent; skin conditioning agent – humectant
Polyglyceryl-10 Tricocoate	the triester of coconut acid and polyglycerin-10  wherein R- represents hydrogen or the residue of coconut acid, and n is 10	surfactant – cleansing agent; surfactant – emulsifying agent
Polyglyceryl-15 discrete multi-ester		
Polyglyceryl-15 Diisostearate	a diester of isostearic acid and a glycerin polymer containing 15 glycerin units  wherein RC(O)- represents the residue of isostearic acid, and n is 15	hair conditioning agent; surfactant – cleansing agent; surfactant – emulsifying agent

(continued)

Table 3. (continued)

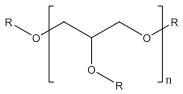
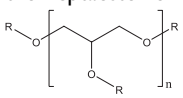
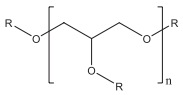
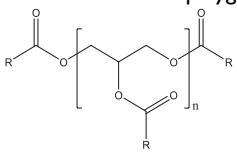
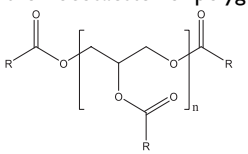
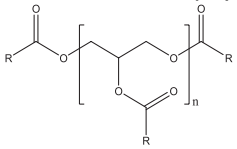
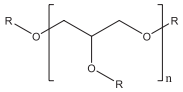
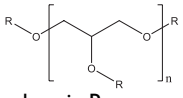
Ingredient CAS No.	Definition & Structure	Function(s)
Polyglyceryl-20 discrete multi-esters		
Polyglyceryl-20 Hexacaprylate	the hexaester of caprylic acid and polyglycerin-20  wherein R- represents hydrogen or the residue of caprylic acid, and n is 20	surfactant – cleansing agent; surfactant – emulsifying agent; surfactant – solubilizing agent
Polyglyceryl-20 Heptacaprylate	the heptaester of caprylic acid and polyglycerin-20  wherein R- represents hydrogen or the residue of caprylic acid, and n is 20	surfactant – cleansing agent; surfactant – emulsifying agent; surfactant – solubilizing agent
Polyglyceryl-20 Octaisononanoate	the octaester of isononanoic acid and polyglycerin-20  wherein R- represents hydrogen or the residue of isononanoic acid, and n is 20	surfactant – cleansing agent; surfactant – emulsifying agent; surfactant – solubilizing agent
Polyglyceryl-20 mixed multi-esters		
Polyglyceryl-20 Docosabehenate/ Isostearate	the docosaester of polyglycerin-20 with a mixture of behenic and isostearic acids  wherein RC(O)- represents the residue of behenic or isostearic acid, and n is 20	skin-conditioning agent – emollient; surfactant – emulsifying agent
Polyglyceryl-20 Docosabehenate/ Laurate	the docosaester of polyglycerin-20 with a mixture of behenic and lauric acids  wherein RC(O)- represents the residue of behenic or lauric acid, and n is 20	skin-conditioning agent – emollient; surfactant – emulsifying agent
Polyglyceryl-20 Docosabehenate/Oleate	the docosaester of polyglycerin-20 with a mixture of behenic and oleic acids  wherein RC(O)- represents the residue of behenic or oleic acid, and n is 20	skin-conditioning agent – emollient; surfactant – emulsifying agent
Polyglyceryl-20 Heptadecabehenate/ Laurate	the heptadecaester of polyglycerin-20 with a mixture of behenic and lauric acids  wherein R- represents hydrogen or the residue of behenic or lauric acid, and n is 20	skin-conditioning agent – emollient; surfactant – emulsifying agent
Polyglyceryl-20 Octadecabehenate/ Laurate	the octadecaester of polyglycerin-20 and a mixture of behenic and lauric acids  wherein R- represents hydrogen or the residue of behenic or lauric acid, and n is 20	skin-conditioning agent – emollient; surfactant – emulsifying agent

Table 4. Previously Reviewed Components and Related Ingredients.

Component	Conclusion	Reference
Glycerin	safe in cosmetics in the present practices of use and concentration (was used in 15,654 formulations, 10,046 of which were leave-ons; the maximum use concentrations were 79.2% in leave-on products, 99.4% in rinse-off products, and 47.9% in products diluted for the bath	115
Dipropylene Glycol	safe as used	116,117
Tripropylene Glycol	safe in the present practices of use and concentration when formulated to be non-irritating	118
Polypropylene Glycols (and PPG≥3)	safe in the present practices of use and concentration when formulated to be non-irritating	118
Monoglyceryl Monoesters	safe in the present practices of use and concentration	3
Glyceryl Alginate	safe in the present practices of use and concentration	119
Glyceryl Isostearate/Myristate	safe in the present practices of use and concentration	120
Glyceryl Myristate		
Citric Acid	safe in the present practices of use and concentration	121
Coconut Acid	safe for use as a cosmetic ingredient	122
Hydroxystearic Acid	safe as a cosmetic ingredient in the present practices of use	123
Isostearic Acid	safe as a cosmetic ingredient in the present practices of use	124
Lauric Acid	safe in the present practices of use and concentration	125
Myristic Acid	safe in the present practices of use and concentration	120
Oleic Acid	safe in the present practices of use and concentration	125
Olive Acid	safe in the present practices of use and concentration	126
Palm Acid	safe in the present practices of use and concentration	126
Palmitic Acid	safe in the present practices of use and concentration	125
Rice Bran Acid	safe in the present practices of use and concentration	126
Ricinoleic Acid	safe in the present practices of use and concentration	127
Sebacic Acid	safe in the present practices of use and concentration	128
Stearic Acid	safe in the present practices of use and concentration	125
Potassium Stearate		129,130
Sodium Stearate		129,130
Adansonia Digitata Seed Oil	safe in the present practices of use and concentration	126
Argania Spinosa Kernel Oil	safe in the present practices of use and concentration	126
Beeswax	safe in the present practices of use and concentration	131,132
Bertholletia Excelsa Seed Oil	safe in the present practices of use and concentration	126
Borago Officinalis Seed Oil	safe in the present practices of use and concentration	126
Butyrospermum Parkii (Shea) Butter	safe in the present practices of use and concentration	126
Caprylic/Capric/Coco Glycerides	safe for use as a cosmetic ingredient	122
Carthamus Tinctorius (Safflower) Seed Oil	safe in the present practices of use and concentration	126
Citrullus Lanatus (Watermelon) Seed Oil	safe in the present practices of use and concentration	126
Cocos Nucifera (Coconut) Oil	safe for use as a cosmetic ingredient	122
Cocoglycerides		
Hydrogenated Coco-Glycerides		
Corylus Avellana (Hazelnut) Seed Oil	safe in the present practices of use and concentration	126
Cucurbita Pepo (Pumpkin) Seed Oil	safe in the present practices of use and concentration	126
Elaeis Guineensis (Palm) Oil	safe in the present practices of use and concentration	126
Elaeis Guineensis (Palm) Kernel Oil		
Euphorbia Cerifera (Candelilla) Wax	safe in the present practices of use and concentration	131,132
Glycine Soja (Soybean) Oil	safe in the present practices of use and concentration	126
Hydrogenated Soybean Oil		
Helianthus Annuus (Sunflower) Seed Oil	safe in the present practices of use and concentration	126
Helianthus Annuus (Sunflower) Seed Wax		
Linum Usitatissimum (Linseed) Seed Oil	safe in the present practices of use and concentration	126
Macadamia Integrifolia Seed Oil	safe in the present practices of use and concentration	126
Macadamia Ternifolia Seed Oil		

(continued)

Table 4. (continued)

Component	Conclusion	Reference
Olea Europaea (Olive) Fruit Oil Orbignya Oleifera Seed Oil	safe in the present practices of use and concentration	126
Oryza Sativa (Rice) Bran Oil Oryza Sativa (Rice) Bran Wax	safe in the present practices of use and concentration	133
Persea Gratissima (Avocado) Oil	safe in the present practices of use and concentration	126
Prunus Amygdalus Dulcis (Sweet Almond) Oil	safe in the present practices of use and concentration	126
Prunus Armeniaca (Apricot) Kernel Oil	safe in the present practices of use and concentration	126
Ricinus Communis (Castor) Seed Oil Hydrogenated Castor Oil	safe in the present practices of use and concentration	127
Schinziophyton Rautanenii Kernel Oil	safe in the present practices of use and concentration	126
Sclerocarya Birrea Seed Oil	safe in the present practices of use and concentration	126
Simmondsia Chinensis (Jojoba) Seed Wax	safe in the present practices of use and concentration	134
Sesamum Indicum (Sesame) Seed Oil	safe in the present practices of use and concentration	126
Theobroma Cacao (Cocoa) Seed Butter	safe in the present practices of use and concentration	126
Theobroma Grandiflorum Seed Butter	safe in the present practices of use and concentration	126

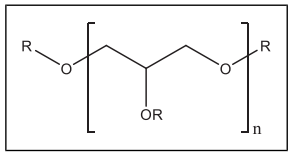


Figure 1. Generic structure of polyglyceryl esters, wherein R represents hydrogen or the residue of certain fatty acids, and n varies from 2 to 20.

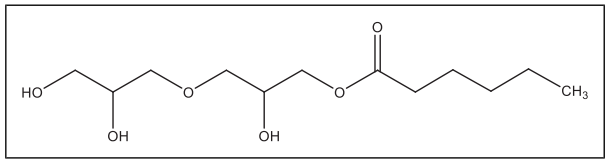


Figure 2. Polyglyceryl-2 caprate (wherein R, in the general structure in Figure 1, is hydrogen in 3 instances and caprate in 1 instance; and n is 2).

The polymerization process used to produce polyglycerol yields a distribution of different oligomers that have a primarily linear structure.[5] In addition to the linear configuration, a significant part of the polyglycerol is of the branched types, e.g., originating from 1,2- and 2,2-*O*-ether linkages.

Polyglyceryl esters of fatty acids have a hydrophilic polyglycerol group that consists of a finite number of hydroxyethers of glycerol and a hydrophobic fatty acid chain within the same compound.[6] These ingredients are non-ionic compounds, and a range of polarities is possible because of the variation of the degree of polymerization and number of fatty acids per headgroup.

Physical and Chemical Properties

The physical properties and appearance of polyglyceryl esters of fatty acids mainly depends on their molecular structure. Typically, the physical form of those with a higher degree of polymerization and shorter or unsaturated fatty acid chains ranges from viscous liquids to plastic pastes, and the polyglyceryl esters with a lower degree of polymerization and longer, saturated fatty acid chains are generally powders, flakes or small beads.[6] The color of the esters is dependent on the source of the fatty acids, but the polyglycerol will contribute to the color.[5] The solubility of polyglyceryl esters in organic solvents depends on the nature of the solvent and the polarity of the ester but, generally, the esters will show best solubility in protic and polar aprotic solvents, such as lower alcohols and dimethyl sulfoxide (DMSO).

Polyglyceryl esters of fatty acids are polar or amphiphilic lipids, and the amphiphilic properties in water exhibit mesomorphic activities forming lyotropic liquid crystals.[6] The polyglyceryl ester as a polar emulsifier will form aggregated bodies, such as micelles, at low concentrations in water. Polyglyceryl esters of fatty acids become unstable with water and high temperatures, and the instability is enhanced in the presence of alkaline substances. The presence of an alkali or acid results in the partial hydrolysis of fatty acids and the formation of free polyglycerol.

Polyglyceryl esters are comparable to monoglycerides with respect to hydrolysis. In enzymatic systems, lipases will hydrolyze the polyglyceryl ester, as seen in the case of other glycerides.[5]

The average fatty acid compositions (when available) are described in Table 5, and the physical and chemical properties of many of the ingredients included in this safety assessment are presented in Table 6.

Method of Manufacture

The synthesis of polyglyceryl esters of fatty acids is achieved by the polymerization of a hydrophilic headgroup, and then esterification of the headgroup with the hydrophobic tails.[6]

Table 5. Average Fatty Acid Composition of Polyglyceryl Fatty Acid Esters (%).

Fatty Acids	Adansonia Digitata Seed Oil Polyglyceryl-6 Esters[135]	Apricot Kernel Oil Polyglyceryl-6 Esters[136]	Apricot Kernel Oil Polyglyceryl-10 Esters[137]	Argan Oil Polyglyceryl-6 Esters[138,138]	Babassu Oil Polyglyceryl-6 Esters[139]	Bertholletia Excelsa Seed Oil Polyglyceryl-6 Esters[140]	Caprylic/Capric Glycerides Polyglyceryl-10 Esters[141]
Caproic (C6)							<2
Caprylic (C8)					2-8		50-65
Capric (C10)					1-8		30-50
Lauric (C12)*					35-55		<3
Myristic (C14)					10-30		<1
Myristoleic (C14:1)							
Palmitic (C16)	18-30	3.0-9.0	4.6-7.6	10-15	5-15	10-20	
Palmitoleic (C16:1)		<1.5					
Heptadecanoic (C17:0)							
Stearic (C18)	2-9	0.5-4.0	0.2-1.3	4-7	1-8	5-15	
Oleic (C18:1)	30-45	55.0-75.0	60-74	40-55	9-20	25-40	
Linoleic (C18:2)	20-40	20.0-35.0	20-34	25-40	1-7	30-55	
Linolenic (C18:3)	1-3			<0.5		<1	
Arachidic (C20)	< 2	<1.0		<1		<1	
Eicosenoic (C20:1)		<1.0		<1			
Behenic (C22)							
Erucic (C22:1)							
Lignoceric (C24)							
Others							

	Cocoa Butter Polyglyceryl-6 Esters[142]	Coconut oil Polyglyceryl-6 Esters[143]	Hazelnut Seed Oil Polyglyceryl-6 Esters[144]	Macadamia Seed Oil Polyglyceryl 6 Esters[145]	Olive Oil Polyglyceryl-6 Esters[146]	Polyglyceryl-10 Decaoleate[37]	Safflower Seed Oil Polyglyceryl-6 Esters[147]
Caproic (C6)		<1					
Caprylic (C8)		4-10					
Capric (C10)		4-11					
Lauric (C12)*		42-52				4.2	
Myristic (C14)		13-21				2.6	
Myristoleic (C14:1)							
Palmitic (C16)	20-35	6-12	4.5-9.	7-11	7.5-20	16.6	6-7
Palmitoleic (C16:1)	<1			16-30	<3.5		
Heptadecanoic (C17:0)							
Stearic (C18)	25-40	1-4	1-4	2-7	0.5-5	14.4	0.9-9.7
Oleic (C18:1)	25-40	3-12	66-86.2	50-67	55-85	5.3	10-20
Linoleic (C18:2)	2-5	0.5-4	8-10.4	1-5	3.5-20	55.8	68-83
Linolenic (C18:3)	<0.5		<0.6		<1.5		<0.2
Arachidic (C20)	0.5-2			1-4	<1		
Eicosenoic (C20:1)				1-3	<1		
Behenic (C22)							
Erucic (C22:1)							
Lignoceric (C24)							
Others						Total fatty acids are 83.1%	

Fatty Acids	Schinziophyton Rautanenii Kernel Oil Polyglyceryl-6 Esters[148]	Sclerocarya Birrea Seed Oil Polyglyceryl-6 Esters[149]	Sesame Oil Polyglyceryl-6 Esters[150]	Shea Butter Polyglyceryl-6 Esters[151]	Soybean Oil Polyglyceryl-6 Esters[152]	Sunflower Seed Oil Polyglyceryl-6 Esters (high oleic acid)[153]	Sunflower Seed Oil Polyglyceryl-10 Esters[154]
Caproic (C6)							
Caprylic (C8)							
Capric (C10)							
Lauric (C12)*							
Myristic (C14)		<0.2					
Myristoleic (C14:1)							
Palmitic (C16)	6-10	9-13	5-15	3-7	8-13	2-6	3-5.5
Palmitoleic (C16:1)		<0.2					
Heptadecanoic (C17:0)							
Stearic (C18)	4-8	4-8	2-8	35-47	2-7	1-5	2-5
Oleic (C18:1)	10-20	70-80	35-55	33-50	17-28.5	70-90	74-82

(continued)

Table 5. (continued)

Fatty Acids	Schinziophyton Rautanenii Kernel Oil Polyglyceryl-6 Esters[148]	Sclerocarya Birrea Seed Oil Polyglyceryl- 6 Esters[149]	Sesame Oil Polyglyceryl-6 Esters[150]	Shea Butter Polyglyceryl-6 Esters[151]	Soybean Oil Polyglyceryl-6 Esters[152]	Sunflower Seed Oil Polyglyceryl-6 Esters (high oleic acid)[153]	Sunflower Seed Oil Polyglyceryl-10 Esters[154]
Linoleic (C18:2)	30-54	4-9	34-55	3-8	46-62	5-20	8-15.5
Linolenic (C18:3)	30-32	<0.7	<1.1	<2	4-10	<1	<0.2
Arachidic (C20)		<1	<1.2	<2.5		<1	
Eicosenoic (C20:1)				<0.5		<0.5	
Behenic (C22)						<1	
Erucic (C22:1)							
Lignoceric (C24)						<1	
Others							

	Sweet Almond Oil Polyglyceryl-6 Esters[155]	Trichilia Emetica Seed Oil Polyglyceryl-6 Esters[156]
Caproic (C6)		
Caprylic (C8)		
Capric (C10)		
Lauric (C12)*		
Myristic (C14)		
Myristoleic (C14:1)		
Palmitic (C16)	4-9	30-40
Palmitoleic (C16:1)		
Heptadecanoic (C17:0)	<1	
Stearic (C18)	<3	1.5-4
Oleic (C18:1)	62-86	45-55
Linoleic (C18:2)		8-13
Linolenic (C18:3)	20-30	<1.5
Arachidic (C20)	<1	
Eicosenoic (C20:1)		
Behenic (C22)		
Erucic (C22:1)		
Lignoceric (C24)		
Others		

Polyglycerols are generally prepared from an alkaline condensation of glycerol molecules at elevated temperature, with the removal of water. Because one glycerol molecule possesses 3 reactive sites (1 secondary alcohol (center position) and 2 primary alcohols (terminal positions)), several kinds of diglycerol molecules can be formed. If the polymerization proceeds to tri-, tetra-, or higher glycerols, then the number of possible linear or branched isomers increases exponentially. Moreover, once a dimer is formed, cyclic products can result from intra-molecular ring-closure reactions (Figure 3).

Polyglycerols can be used as produced, or they may be stripped of excess glycerol and cyclic glycerols by steam distillation at reduced pressure.[7] Alternatively, stripping processes have been developed using mesoporous and zeolite catalysts under milder conditions.

Other possible processes for production of a polyglycerol use reactive petrochemical substances such as epichlorohydrin (1-chloro-2,3-dihydroxypropane), which is allowed to react with glycerol in an etherification process. However, epichlorohydrin is a hazardous material, and the purification of the polyglycerol complicates the process.[5] Glycidol is also used for the production of polyglycerol, and the oxirane group easily reacts with glycerol or epichlorohydrin, depending on the conditions of the reaction and the type of polyglycerol required. However, these processes use chemicals that make the process non-competitive in relation to a glycerol-based process.

According to the World Health Organization (WHO) Food and Agriculture Organization (FAO), polyglyceryl esters of fatty acids (as used in foods) are formed by reacting polymerized glycerols with edible fats, oils (edible fats and oils are primarily triglycerides), or fatty acids.[8] The degree of polymerization varies, and is specified by a number (such as tri-) that is related to the average number of glycerol residues per polyglycerol molecule.

Polyglyceryl esters of fatty acids also can be prepared by direct esterification between polyolethers and fatty acids at elevated temperatures (T > 200°C) with the removal of water.[5,6] The esterification is normally carried out under alkaline conditions and can be stopped by simply adding an acid and lowering the reaction temperature. To obtain a large amount of mono- and diesters, the synthesis is generally carried out with an excess of polyglycerol. Some unreacted polyglycerol can be removed by simple gravimetric settling, and the remaining fraction by extraction with water combined with salts in a charge-wise separation process. Alternatively, polyglyceryl esters can be prepared by an inter-esterification (or transesterification) between polyglycerols and

Table 6. Physical and Chemical Properties.

Property	Adansonia Digitata Seed Oil Polyglyceryl-6 Esters[135]	Apricot Kernel Oil Polyglyceryl-6 Esters[136]	Apricot Kernel Oil Polyglyceryl-10 Esters[137]	Argan Oil Polyglyceryl-6 Esters[138,138]	Babassu Oil Polyglyceryl-6 Esters[139]	Bertholletia Excelsa Seed Oil Polyglyceryl-6 Esters[140]	Borage Seed Oil Polyglyceryl-6 Esters[157]
physical characteristics	soft paste amber in color	amber liquid (20oC)	amber (physical state not specified)	amber liquid	soft paste with amber color	soft paste with amber color	oil
molecular wt							
solubility	water dispersible	water dispersible	water soluble	water dispersible	water dispersible	water dispersible	water dispersible
melting point (°C)							
density (g/ml)	<1	<1	>1		<1	<1	
specific gravity (g/ml)							
pH							
refractive index (20oC)	approx. 1.47	approx. 1.47	approx. 1.47	approx. 1.47	approx. 1.47	approx. 1.47	
saponification value	150 – 170	125-155		125-155	175-205	125-155	
acid value (mg KOH/g)	< 5	<5	<5	<5	<5	< 5	
hydroxyl value (mg KOH/g)							
peroxide value (meq of active oxygen/Kg)	<10	<10	<10	<10	<10	<10	
iodine value (gI_2/100g)		75-90		75-90	10-25	75-90	
polarity	non-ionic, amphiphilic	non-ionic, amphiphilic	non-ionic, amphiphilic	non-ionic, amphiphilic	non-ionic, amphiphilic	non-ionic, amphiphilic	non-ionic, amphiphilic
HLB							

	Caprylic/Capric Glycerides Polyglyceryl-10 Esters[141]	Cocoa Butter Polyglyceryl-6 Esters[142]	Coconut Oil Polyglyceryl-6 Esters[143]	Diisostearoyl Polyglyceryl-3 Dimer Dilinoleate	Glyceryl/Polyglyceryl-6 Isostearate/Behenate Esters	Hazelnut Seed Oil Polyglyceryl-6 Esters[144]	Macadamia Seed Oil Polyglyceryl-6 Esters[145]
physical characteristics	amber in color	beige solid	soft paste, with amber color	viscous liquid[158] yellow liquid[159]	white waxy solid[45]	amber	amber liquid
molecular wt				~6000			
solubility		water dispersible	water dispersible			water dispersible	water dispersible
melting point (°C)		40-50	40-50				
density (g/ml)	>1	<1	<1			<1	<1
specific gravity (g/ml)							
pH							
refractive index (20oC)	approx. 1.47	approx. 1.47	approx. 1.47			approx.. 1.47	~1.47
saponification value		145-165	180-220	140-160[158]			140-160
acid value (mg KOH/g)	<5	< 5	< 5	10.0 max[158]		<5	<5
hydroxyl value (mg KOH/g)							

(continued)

Table 6. (continued)

peroxide value (meq of active oxygen/Kg)	<10	<10	<10			<10	<10
iodine value (gI_2/100g)		20-35	3-10	10.0 max[158]			
polarity	non-ionic, amphiphilic	non-ionic, amphiphilic	non-ionic, amphiphilic			non-ionic, amphiphilic	non-ionic, amphiphilic
HLB				~5[159]			
	Macadamia Seed Oil Polyglyceryl-6 Esters Behenate	Olive Oil Polyglyceryl-6 Esters[146]	Palm Kernel Oil Polyglyceryl-4 Esters[160]	Polyglyceryl-3 Beeswax[161]	Polyglyceryl-2 Caprate[162]	Polyglyceryl-4 Caprate	Polyglyceryl-3 Caprylate[163]
physical characteristics	white waxy solid[51]	amber liquid		white to off-white		transparent, pale, yellow liquid with faint odor[164] colorless to yellow, clear to slightly turbid, viscous liquid[165]	high viscosity liquid
molecular wt					320.42		
solubility		water dispersible	water- and oil- soluble			soluble in water, ethanol, 1,2-propanediol, esters oil; insoluble in paraffin oi, isopropyl myristate, vegetable oil[165]	
melting point (°C)				63-73			
density (g/ml)		<1			1.083 g/cm^3		
specific gravity (g/ml)							
pH							
refractive index (20oC)		~1.47			1.481		
saponification value		125-155		80-94		50-70[164]	
acid value (mg KOH/g)		<5		2 max		5 max[164]	
hydroxyl value (mg KOH/g)							
peroxide value (meq of active oxygen/Kg)		<10					
iodine value (gI_2/100g)		60-75					
polarity		non-ionic, amphiphilic					
HLB						14.5[164]; ~14[165]	

(continued)

Table 6. (continued)

	Polyglyceryl-10 Caprylate/ Caprate[24,166]	Polyglyceryl-8 Decabehenate/ Caprate	Polyglyceryl-8 Decaerucate/ Decaisostearate/ Decaricinoleate	Polyglyceryl-10 Decaethylhexanoate	Polyglyceryl-10 Decaisostearate[167]	Polyglyceryl-10 Decaoleate	Polyglyceryl-3 Di-Hydroxystearate
physical characteristics	amber, viscous liquid	pale yellow solid[168]	pale yellow viscous liquid[53,169]	pale yellow viscous liquid[170]	faint yellow liquid		solid
molecular wt							
solubility					insoluble in water		slightly soluble in water
melting point (°C)							
density (g/ml)							
specific gravity (g/ml)					0.956 (25°C)		
pH							
refractive index (20oC)							
saponification value	85-105	150.6[168]	157[169]			170.9[36]; 177.5[37]	
acid value (mg KOH/g)	7.0 max	3.9[168]	1.3[169]	0.1[170]		14.0[36]	
hydroxyl value (mg KOH/g)						23.0[37]; 40.0[36]	
peroxide value (meq of active oxygen/Kg)	5.0 max					3.4[37]	
iodine value (gI_2/100g)	2.0 max					66.2[37]	
polarity							
HLB	14						

	Polyglyceryl-2 Diisostearate	Polyglyceryl-3 Diisostearate)[27]	Polyglyceryl-6 Diisostearate[171]	Polyglyceryl-3 Dioleate[28,172]	Polyglyceryl-6 Dioleate[173]	Polyglyceryl-10 Dipalmitate[174,174]	Polyglyceryl-3 Distearate[175]
physical characteristics	clear pale yellow, homogenous liquid[38]	slightly yellowish, viscous liquid	pale yellow liquid	viscous yellow liquid		beads or waxy solids	white or slightly yellowish powder
molecular wt				766.13[176]	991.38		
solubility		< 0.15 mg/L (water)		dispersible in water; soluble in many organic solvents			at 20oC: forms liquid crystals in water, ethanol, and glycerin; insoluble in propylene glycol; forms a solid wax with wheat germ, avocado, and paraffin oils, and squalene; at 65oC: dispersible in water, clearly soluble in ethanol, in wheat germ, avocado, and paraffin oils, and squalene; turbid solubility in glycerin; insoluble in propylene glycol
melting point (°C)	-10[38]						
density (g/ml)	0.941 g/cm³ [38]						
specific gravity (g/ml)				0.99			

(continued)

Table 6. (continued)

pH							
refractive index (20oC)		8.129 (predicted)					
saponification value							140-180
acid value (mg KOH/g)							
hydroxyl value (mg KOH/g)							
peroxide value (meq of active oxygen/Kg)							≤1.0
iodine value (gI_2/100g)							≤1.0
polarity							
HLB		1.4 (predicted)	8	3		11	
	Polyglyceryl-6 Distearate	Polyglyceryl-10 Distearate[177]	Polyglyceryl-2 Isopalmitate/ Sebacate[178]	Polyglyceryl-2 Isostearate[179]	Polyglyceryl-4 Isostearate[180]	Polyglyceryl-10 Isostearate	Polyglyceryl-3 Laurate[181]
physical characteristics	waxy solid[174]	yellow waxy solid	liquid		yellow liquid	pale yellow, extremely viscous liquid[182]	viscous liquid
molecular weight	995.43[183]			450.65			422 (average)
solubility			slightly soluble to soluble in water				
melting point (°C)		50-58					
density (g/ml)							
specific gravity (g/ml)							
pH							
refractive index (20oC)							
saponification value		105-125				64.4[182]	128-144
acid value (mg KOH/g)		2.0				0.4[182]	6 max
hydroxyl value (mg KOH/g)							
peroxide value (meq of active oxygen/Kg)							
iodine value (gI_2/100g)		3.0					
polarity							
HLB	6 [184]; 8 [174]	~11			~5		
	Polyglyceryl-4 Laurate	Polyglyceryl-10 Laurate	Polyglyceryl-10 Myristate[185]	Polyglyceryl-10 Nonaisostearate	Polyglyceryl-3 Oleate	Polyglyceryl-10 Oleate	Polyglyceryl-10 Palmate[186]
physical characteristics	viscous liquid[187]	light yellow viscous liquid[6]	pale yellow viscous liquid[188]	pale yellow viscous liquid[189]	yellow liquid[190]	waxy solid[25]	liquid
molecular wt		349.48[176]				1203.41[191]	
solubility							slightly soluble to soluble in water

(continued)

Table 6. (continued)

melting point (°C)							
density (g/ml)							
specific gravity (g/ml)							
pH							
refractive index (20oC)							
saponification value		63-83;[6]; 70.6[192]	60-70;[185] 62.8[188]	159.6[189]	115[36]	92.1[36]	
acid value (mg KOH/g)		0.2[103]	0.6;[188] 5 max[185]	0.4[189]	1.5[36]	4.2[36]	
hydroxyl value (mg KOH/g)						337[36]	
peroxide value (meq of active oxygen/Kg)							
iodine value (gI_2/100g)							
polarity	non-ionic[187]				lipophilic[190]		
HLB	~11				~5[190]	13[193]	
	Polyglyceryl-6 Pentacaprylate[194]	Polyglyceryl-3 Pentacaprylate/ Caprate[195]	Polyglyceryl-10 Pentaisostearate	Polyglyceryl-3 Pentaoleate[196]	Polyglyceryl-10 Pentaoleate[197,198]	Polyglyceryl-4 Pentastearate[199]	Polyglyceryl-6 Pentastearate[200,201]
physical characteristics	liquid	liquid	pale yellow liquid[202]	amber viscous liquid	pale yellow to red-yellow viscous liquid	white to pale yellow pellet	pale yellow waxy solid
molecular wt							
solubility	slightly soluble in water						easy to soluble in oil and organic solvent, and disperse into hot water
melting point (°C)							53-60
density (g/ml)							
specific gravity (g/ml)							
pH							
refractive index (20oC)							
saponification value			143.1[202]	170-200			125-140
acid value (mg KOH/g)			0.07[202]	5.0 max			2.0
hydroxyl value (mg KOH/g)							
peroxide value (meq of active oxygen/Kg)							
iodine value (gI_2/100g)							3.0
polarity				non-ionic[196]			
HLB		3.0			3.5		~7.0
	Polyglyceryl-10 Pentastearate[203,204]	Polyglyceryl-3 Rice Branate[205]	Polyglyceryl-3 Ricinoleate[206]	Polyglyceyl-2 Sesquicaprylate	Polyglyceryl-2 Sesquioleate[207]	Polyglyceryl-3 Soyate/ Shea Butterate[208]	Polyglyceryl-3 Stearate[174]
physical characteristics	white to pale yellow solid	light ivory (waxy solid (flakes)		yellow, transparent liquid[209]	highly viscous liquid	liquid	granules

(continued)

Table 6. (continued)

molecular wt	2091.15						
solubility		dispersible in water; miscible in oils		insoluble in water, soluble in castor oil, ethanol, mineral oil[209]		slightly soluble to soluble in water	
melting point (°C)							
density (g/ml)		>1 g/ml (25oC)					
specific gravity (g/ml)							0.89-0.92 (25oC)
pH							
refractive index (20oC)							
saponification value							
acid value (mg KOH/g)							
hydroxyl value (mg KOH/g)							
peroxide value (meq of active oxygen/Kg)							
iodine value (gI_2/100g)							
polarity		non-ionic		hydrophobic; non-ionic[209]			
HLB	3.5		4		~4		

	Polyglyceryl-4 Stearate	Polyglyceryl-10 Stearate[176,210]	Polyglyceryl-2 Tetraisostearate[209]	Polyglyceryl-10 Tetraoleate[211]	Polyglyceryl-2 Tetrastearate[212]	Polyglyceryl-10 Tricocoate[213]	Polyglyceryl-10 Tridecanoate[214]
physical characteristics		pale yellow to light yellow liquid or solid	yellow liquid	viscous amber to brown liquid		pale yellow viscous liquid	liquid
molecular wt	580.79[176]	432.64			1095.97		
solubility			soluble in low and high polar esters and in vegetable oil, castor oil, and mineral oil; insoluble in water and ethanol	insoluble in water		insoluble in water	slightly soluble in water
melting point (°C)							
density (g/ml)							
specific gravity (g/ml)			0.926	1.01			
pH							
refractive index (20oC)			1.466				
saponification value							
acid value (mg KOH/g)							
hydroxyl value (mg KOH/g)							
peroxide value (meq of active oxygen/Kg)							

(continued)

Table 6. (continued)

iodine value (gI_2/100g)							
polarity		hydrophilic					
HLB		12.0					
	Polyglyceryl-10 Triisostearate[215,216]	Polyglyceryl-10 Trioleate[217]	Polyglyceryl-10 Tristearate[218]	Rice Brain Oil Polyglyceryl-3 Esters	Safflower Seed Oil Polyglyceryl-6 Esters[147]	Schinziophyton Rautanenii Kernel Oil Polyglyceryl-6 Esters[148]	Sclerocarya Birrea Seed Oil Polyglyceryl-6 Esters[149]
physical characteristics	pale yellow liquid	light yellow to red-yellow viscous liquid	white to pale yellow waxy substance	oily limpid liquid[219] clear, oily, amber-colored liquid[220]	amber (physical state not specified)	brown liquid	amber liquid
molecular wt							
solubility	insoluble in water			dispersible in water; miscible in oils[219]	water dispersible	water dispersible	water dispersible
melting point (°C)							
density (g/ml)				>1	<1	<1	<1
specific gravity (g/ml)							
pH							
refractive index (20oC)					approx. 1.47	approx. 1.47	approx.. 1.47
saponification value						145-165	145-165
acid value (mg KOH/g)					< 5	< 5	<5
hydroxyl value (mg KOH/g)							
peroxide value (meq of active oxygen/Kg)					<10	<10	<10
iodine value (gI_2/100g)						95-110	50-65
polarity				non-ionic		non-ionic, amphiphilic	non-ionic, amphiphilic
HLB	8	7.0	7.5				
	Sesame Oil Polyglyceryl-6 Esters[150]	Shea Butter Polyglyceryl-6 Esters[151]	Soybean Oil Polyglyceryl-6 Esters[152]	Sunflower Seed Oil Polyglyceryl-10 Esters[154]	Sweet Almond Oil Polyglyceryl-6 Esters[155]	Trichilia Emetica Seed Oil Polyglyceryl-6 Esters[156]	Triisostearoyl Polyglyceryl-3 Dimer Dilinoleate[56,221,222]
physical characteristics	amber liquid	beige solid	dark orange liquid	amber viscous liquid	amber liquid	dark brown soft paste	hazy, viscous liquid
molecular wt							>1000
solubility	water dispersible	water dispersible	water dispersible	water dispersible	water dispersible	water dispersible	
melting point (°C)		35-45					
density (g/ml)	<1	<1	<1	>1	<1	<1	
specific gravity (g/ml)							
pH							
refractive index (20oC)	approx.. 1.47	approx.. 1.47	approx. 1.47	approx. 1.47	approx.. 1.47	approx.. 1.47	
saponification value	140-160	135-165	145-165	115-135	130-160	140-160	160-180
acid value (mg KOH/g)	<5	<5		< 5	<5	<5	≤10

(continued)

Table 6. (continued)

hydroxyl value (mg KOH/g)							
peroxide value (meq of active oxygen/Kg)	<10	<10		<10	<10	<10	
iodine value (gI_2/100g)	75-90	45-60	90-105	50-60	70-85	50-65	≤10
polarity	non-ionic, amphiphilic	non-ionic, amphiphilic	non-ionic, amphiphilic	non-ionic, amphiphilic	non-ionic, amphiphilic	non-ionic, amphiphilic	
HLB							

	Ximenia Americana Seed Oil Polyglyceryl-6 Esters[223]
physical characteristics	oil
molecular wt	
solubility	hydrodispersible – water soluble
melting point (°C)	
density (g/ml)	
specific gravity (g/ml)	
pH	
refractive index (20oC)	
saponification value	
acid value (mg KOH/g)	
hydroxyl value (mg KOH/g)	
peroxide value (meq of active oxygen/Kg)	
iodine value (gI_2/100g)	
polarity	
HLB	

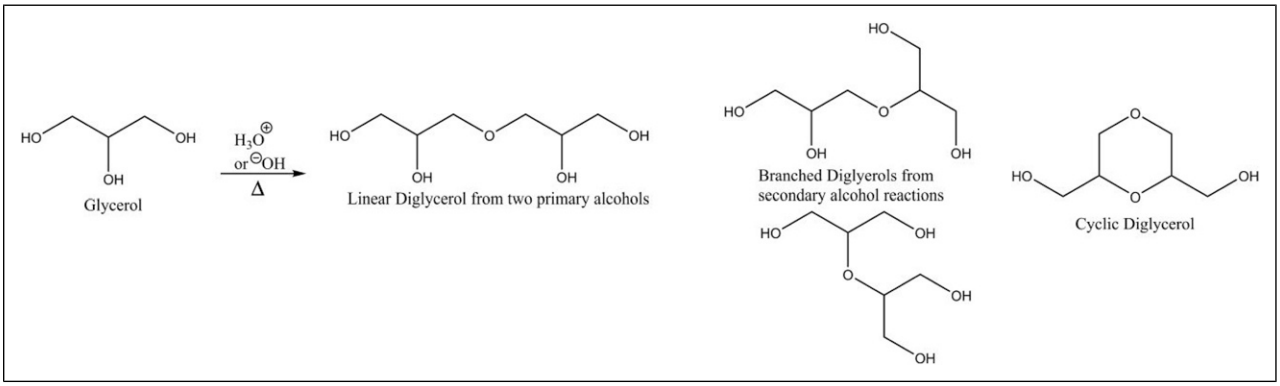


Figure 3. Polymerization of glycerol.[7]

triglycerides; this is a reaction carried out at a high temperature and under conditions similar to direct esterification, but the degree of polymerization is not as high as obtained with direct esterification. Transesterification between polyglycerol and alcohol esters of fatty acids is another possible method of synthesis; using this process, methanol is continuously removed from the reactor, and the process includes a second step to reduce the remaining unreacted oxirane oxygen.

Composition and Impurities

Joint FAO/WHO Expert Committee on Food Additives (JECFA) specifications for polyglyceryl esters of fatty acids used in foods state "the polyglycerol moiety shall be composed of not less than 70% of di-, tri-, and tetraglycerols and shall contain not more than 10% of polyglycerols equal to or higher than heptaglycerol"; that acids other than fatty acids shall not be detectable; and that not more than 2 mg/kg lead is detectable.[8] Minor amounts of mono-, di-, and triglycerides, free glycerol and polyglycerols, free fatty acids, and sodium salts of fatty acids may be present.

Trace amounts of unreacted glycerol and fatty acid soaps can be found in polyglyceryl esters of fatty acids.[6] Specifications, impurities or constituents of some of the ingredients included in this report are provided in Table 7.

Use

Cosmetic

The safety of the cosmetic ingredients included in this safety assessment is evaluated based on data received from the US Food and Drug Administration (FDA) and the cosmetics industry on the expected use of these ingredients in cosmetics. Use frequencies of individual ingredients in cosmetics are collected from manufacturers and reported by cosmetic product category in FDA's Voluntary Cosmetic Registration Program (VCRP) database. Use concentration data are submitted by Industry in response to surveys, conducted by the Personal Care Products Council (Council), of maximum reported use concentrations by product category.

Based on 20156 VCRP data and the results of the Council surveys, 77 of the 274 ingredients included in this report are reported to be in use. According to 2016 VCRP registration data, Polyglyceryl-3 Diisostearate has the most reported uses of the ingredients included in this report; of the 371 reported uses, 363 are in leave-on formulations, 216 of which are in lipsticks[9] (Table 8). Polyglyceryl-4 Isostearate has the second highest number of reported uses; of the 280 uses, all but one is in leave-on products. The results of the concentration of use surveys conducted by the Council indicate Polyglyceryl-2 Triisostearate and Polyglyceryl-3 Diisostearate have the highest concentration of use in a leave-on formulation; these ingredients are used at 40% and 39% in lipsticks, respectively[10-14] (Table 8). Additionally, supplier-recommended use concentrations are provided; most of the recommended use levels are ≤ 10% (Table 9).

Use concentrations were reported for several ingredients that were not reported as used in the VCRP; it should be presumed there is at least one use in every category for which a concentration is reported. Additionally, several ingredients have uses reported in the VCRP, but concentration of use data were not received. The 197 ingredients with no reported uses in both the VCRP and industry survey are listed in Table 10.

Of the polyglyceryl fatty acid esters used in cosmetic formulations, many are used in products applied to the eye area, that can result in incidental ingestion, or that come into contact with mucous membranes. The highest reported concentrations of use for these types of exposures are 24.1% Polyglyceryl-4 Isostearate in "other" eye make-up preparations and 40% Polyglyceryl-2 Triisostearate in lipstick formulations (resulting in incidental ingestion and mucous membrane exposure).[11] A few of the polyglyceryl fatty acid esters are reported to be used in baby products; Polyglyceryl-3 Diisostearate has the highest reported use in a baby product, i.e., 2% in baby lotions, oils, and creams.

Table 7. Specifications, Impurities, and/or Constituents.

Ingredient	Specifications/Impurities/Constituents	Reference
Diisostearoyl Polyglyceryl-3 Dimer Dilinoleate	PEG-free	159
Polyglyceryl-4 Caprate	PEG-free	164
Polyglyceryl-6 Distearate	100% vegetable-derived ; PEG-free	184,224
Polyglyceryl-10 Distearate	arsenic = 0.002; heavy meals = 0.005	177
Polyglyceryl-4 Laurate	PEG-free	187
Polyglyceryl-4 Oleate	100 ppm D,L-tocopherol; <1% volatiles	225
Polyglyceryl-10 Myristate	2 ppm arsenic; 20 ppm heavy metals	185

Abbreviations: PEG – polyethylene glycol

Additionally, some of the polyglyceryl fatty acid esters are used in cosmetic sprays and could possibly be inhaled; for example, Polyglyceryl-3 Distearate is reported to be used at 3% in spray body and hand creams. In practice, most droplets/particles released from cosmetic sprays have aerodynamic equivalent diameters > 10 μm, with propellant sprays yielding a greater fraction of droplets/particles < 10 μm compared with pump sprays.[15,16] Therefore, most droplets/particles incidentally inhaled from cosmetic sprays would be deposited in the nasopharyngeal and thoracic regions of the respiratory tract and would not be respirable (i.e., they would not enter the lungs) to any appreciable amount.[17,18]

All of the polyglyceryl fatty acids named in this report are listed in the European Union inventory of cosmetic ingredients, and none of the listed ingredients are restricted from use in any way under the rules governing cosmetic products in the European Union.[19] In Australia, according to a National Industrial Chemicals Notification and Assessment Scheme (NICNAS), Polyglyceryl-10 Laurate (~60% pure, with ~40% polyglycerin-10 and ~2% sodium laurate) is not considered to pose an unreasonable risk to public health when used in the proposed manner (i.e., ≤3% in skin lotions), and cannot be classified according to the *Globally Harmonised System for the Classification and Labelling of Chemicals* or the *Approved Criteria for Classifying Hazardous Substances*.[20]

Non-Cosmetic

Polyglyceryl esters of fatty acids, up to and including the decaglycerol esters, are permitted as multipurpose direct food additives when (1) they are prepared from corn oil, cottonseed oil, lard, palm oil from fruit, peanut oil, safflower oil, sesame oil, soybean oil, and tallow and the fatty acids derived from these substances (hydrogenated and non-hydrogenated) and/or oleic acid derived from tall oil fatty acids; (2) they are used as emulsifiers in food, in amounts not greater than that required to produce the intended physical or technical effect; (3) polyglyceryl esters of a mixture of stearic, oleic, and coconut fatty acids are used as a cloud inhibitor in vegetable and salad oils when use is not precluded by standards of identity, and oleic acid derived from tall oil fatty acids may be used as a substitute for, or together with, the oleic acid; and (4) polyglyceryl esters of butter oil fatty acids are used as emulsifiers in combination with other approved emulsifiers in dry, whipped topping base, when used at a level not in excess of the amount required to perform their emulsifying effect. [21CFR172.854]

JECFA established an acceptable daily intake (ADI) of 0-25 mg/kg bw for polyglyceryl esters of fatty acids having an average chain length of up to 3 glycerol units,[21] and an ADI of 0-7.5 mg/kg bw for polyglyceryl esters of interesterified ricinoleic acid.[22] In the EU, the esters are listed as food additives at concentrations between 5000 and 10,000 mg/kg in certain foods, and up to 7% free glycerol/polyglycerol is allowed (i.e., 700 mg/kg).[23] Polyglyceryl-10 Caprylate/Caprate[24] and Polyglyceryl-10 Oleate[25] are polysorbate replacers, dispersing agents, and emulsifiers in foods.

Several polyglyceryl oleates are allowed for use as inactive ingredients in approved drug products.[26] Polyglyceryl-3 Oleate is approved as an inactive ingredient in topical, oral, and vaginal drug products. In oral products, maximum potency is 0.87 mg in gelatin-coated capsules, 330.7 mg in soft gelatin capsules, and 310 mg/ml in oral solutions; in vaginal products maximum potency is 2.7% in regular and sustained-release emulsions and creams. Approved dermal use is in topical sustained release creams; a maximum potency was not specified. Polyglyceryl-4 Oleate is approved as an inactive ingredient in vaginal emulsions and creams at a maximum potency of 2.71%. Polyglyceryl-10 Oleate is approved for use in oral soft gelatin capsules and in oral solutions; maximum potency is 199.9 mg and 190 mg/ml, respectively.

Polyglyceryl-10 Oleate is used as an internal lubricant for polyvinyl chloride (PVC) sheet and film and as an anti-fog agent in plasticized PVC film formulations.[25]

Toxicokinetics

Penetration Enhancement

Polyglyceryl-3 Diisostearate. Polyglyceryl-3 Diisostearate was not a penetration enhancer in a study that evaluated the skin penetration enhancing effects of several excipients on the hydrophilic drug 5-fluorouracil (Figure 4).[27]

Table 8. Frequency and Concentration of Use According to Duration and Type Of Exposure.

	# of Uses[9]	Max Conc of Use (%)[10-14]	# of Uses[9]	Max Conc of Use(%)[10-14]	# of Uses[9]	Max Conc of Use (%)[10-14]
	Babassu Oil Polyglyceryl-4 Esters		Candelilla/Jojoba/Rice Bran Polyglyceryl-3 Esters		Caprylic/Capric Glycerides Polyglyceryl-10 Esters	
Totals*	18	2.3	20	0.5-2	6	NR
Duration of Use						
Leave-On	NR	NR	19	0.5-2	4	NR
Rinse-Off	18	2.3	1	NR	2	NR
Diluted for (Bath) Use	NR	NR	NR	NR	0	NR
Exposure Type						
Eye Area	NR	NR	8	NR	0	NR
Incidental Ingestion	NR	NR	1	NR	0	NR
Incidental Inhalation-Spray	NR	NR	5[a]; 3[b]	NR	1[a]; 3[b]	NR
Incidental Inhalation-Powder	NR	NR	3[b]	NR	3[b]	NR
Dermal Contact	1	2.3	19	0.5-2	6	NR
Deodorant (underarm)	NR	NR	NR	aerosol: 0.5	NR	NR
Hair – Non-Coloring	17	NR	NR	NR	NR	NR
Hair-Coloring	NR	NR	NR	NR	NR	NR
Nail	NR	NR	NR	NR	NR	NR
Mucous Membrane	NR	NR	1	NR	NR	NR
Baby Products	NR	NR	1	1.5	NR	NR
	Coconut Oil Polyglyceryl-6 Esters		Diisostearoyl Polyglyceryl-3 Dimer Dilinoleate		Glyceryl/Polyglyceryl-6 Isostearate/Behenate Esters	
Totals*	2	NR	4	2-4	10	2
Duration of Use						
Leave-On	*NR*	*NR*	*4*	*2-4*	*10*	*2*
Rinse Off	*2*	*NR*	*NR*	*NR*	*NR*	*NR*
Diluted for (Bath) Use	*NR*	*NR*	*NR*	*NR*	*NR*	*NR*
Exposure Type						
Eye Area	NR	NR	1	NR	2	NR
Incidental Ingestion	NR	NR	NR	NR	2	NR
Incidental Inhalation-Spray	NR	NR	3[a]	NR	1[b]	NR
Incidental Inhalation-Powder	NR	NR	NR	NR	NR	2[c]
Dermal Contact	2	NR	4	2-4	8	2
Deodorant (underarm)	NR	NR	NR	NR	NR	NR
Hair – Non-Coloring	NR	NR	NR	NR	NR	NR
Hair-Coloring	NR	NR	NR	NR	NR	NR
Nail	NR	NR	NR	NR	NR	NR
Mucous Membrane	1	NR	NR	NR	2	NR
Baby Products	NR	NR	NR	NR	NR	NR
	Macadamia Seed Oil Polyglyceryl-6 Esters Behenate		Palm Oil Polyglyceryl-4 Esters		Polyglyceryl-2 Caprate	
	5	2-25	1	NR	6	NR
Duration of Use						
Leave-On	*5*	*2-25*	*1*	*NR*	*6*	*NR*
Rinse-Off	NR	*NR*	*NR*	*NR*	*NR*	*NR*
Diluted for (Bath) Use	NR	*NR*	*NR*	*NR*	*NR*	*NR*
Exposure Type						
Eye Area	3	2-3	NR	NR	NR	NR
Incidental Ingestion	NR	25	NR	NR	NR	NR
Incidental Inhalation-Spray	1[a]	NR	1[b]	NR	1; 1[a]; 4[b]	NR
Incidental Inhalation-Powder	NR	NR	1[b]	NR	4[b]	NR
Dermal Contact	4	2	1	NR	6	NR
Deodorant (underarm)	NR	NR	NR	NR	NR	NR
Hair – Non-Coloring	NR	NR	NR	NR	NR	NR
Hair-Coloring	NR	NR	NR	NR	NR	NR
Nail	NR	NR	NR	NR	NR	NR
Mucous Membrane	NR	25	NR	NR	NR	NR
Baby Products	NR	NR	NR	NR	NR	NR
	Polyglyceryl-2 Diisostearate		Polyglyceryl-2 Isopalmitate		Polyglyceryl-2 Isostearate	
Totals	86	0.1-18.8	9	NR	8	1-19.3
Duration of Use						
Leave-On	*84*	*0.1-18.8*	*9*	*NR*	*7*	*1.6-19.3*

(continued)

Table 8. (continued)

	# of Uses[9]	Max Conc of Use (%)[10-14]	# of Uses[9]	Max Conc of Use(%)[10-14]	# of Uses[9]	Max Conc of Use (%)[10-14]
Rinse Off	*2*	*0.88-5*	*NR*	*NR*	*1*	*1*
Diluted for (Bath) Use	*NR*	*NR*	*NR*	*NR*	*NR*	*NR*
Exposure Type						
Eye Area	6	1.5-4	NR	NR	NR	NR
Incidental Ingestion	39	4-18.8	9	NR	1	2.3-19.3
Incidental Inhalation-Spray	7[a]; 14[b]	0.25-0.5; 15[a]	NR	NR	NR	NR
Incidental Inhalation-Powder	14[b]	0.1; 0.14-2[c]	NR	NR	2	2.1[c]
Dermal Contact	45	0.1-5	NR	NR	7	1-2.5
Deodorant (underarm)	NR	0.1 (not spray)	NR	NR	NR	NR
Hair – Non-Coloring	NR	0.25-15	NR	NR	NR	NR
Hair-Coloring	NR	NR	NR	NR	NR	NR
Nail	NR	NR	NR	NR	NR	NR
Mucous Membrane	39	4-18.8	9	NR	2	2.3-19.3
Baby Products	NR	NR	NR	NR	NR	NR
	Polyglyceryl-2 Laurate		Polyglyceryl-2 Oleate		Polyglyceryl-2 Sesquiisostearate	
Totals*	9	2-4.6	4	0.09-2.4	11	1.1-7.6
Duration of Use						
Leave-On	6	2	4	0.09-2.4	9	2.1-7.6
Rinse-Off	3	4.6	NR	2.4	2	1.1
Diluted for (Bath) Use	NR	NR	NR	NR	NR	NR
Exposure Type						
Eye Area	1	NR	NR	0.27-2.4	NR	2.1
Incidental Ingestion	NR	NR	NR	2.4	2	7.6
Incidental Inhalation-Spray	3[a]; 1[b]	2[b]	1[a]; 2[b]	NR	2[a]; 2[b]	NR
Incidental Inhalation-Powder	1[b]	NR	2[b]	0.09[c]	2[b]	4.4[c]
Dermal Contact	8	NR	4	0.09-2.4	8	1.1-4.4
Deodorant (underarm)	NR	NR	NR	NR	NR	NR
Hair – – Non-Coloring	1	2-4.6	NR	NR	NR	NR
Hair-Coloring	NR	NR	NR	NR	NR	NR
Nail	NR	NR	NR	NR	1	NR
Mucous Membrane	NR	NR	NR	2.4	2	7.6
Baby Products	NR	NR	NR	NR	NR	NR
	Polyglyceryl-2 Sesquistearate		Polyglyceryl-2 Stearate		Polyglyceryl-2 Tetraisostearate	
Totals*	NR	0.9	NR	0.16-2.2	30	0.5-7
Duration of Use						
Leave-On	*NR*	*NR*	*NR*	*0.16-2.2*	*30*	*0.5-7*
Rinse-Off	*NR*	*0.9*	*NR*	*0.2*	*NR*	*NR*
Diluted for (Bath) Use	*NR*	*NR*	*NR*	*NR*	*NR*	*NR*
Exposure Type						
Eye Area	NR	NR	NR	0.2-1	NR	NR
Incidental Ingestion	NR	NR	NR	0.2	27	7
Incidental Inhalation-Spray	NR	NR	NR	NR	NR	NR
Incidental Inhalation-Powder	NR	NR	NR	2.2[c]	NR	0.96
Dermal Contact	NR	0.9	NR	0.16-2.2	3	0.5-4.6
Deodorant (underarm)	NR	NR	NR	NR	NR	NR
Hair – Non-Coloring	NR	NR	NR	NR	NR	NR
Hair-Coloring	NR	NR	NR	NR	NR	NR
Nail	NR	NR	NR	NR	NR	NR
Mucous Membrane	NR	NR	NR	0.2	27	7
Baby Products	NR	NR	NR	NR	NR	NR
	Polyglyceryl-2 Triisostearate		Polyglyceryl-3 Beeswax		Polyglyceryl-3 Caprate	
Totals	165	0.12-40	111	0.5-5.8	12	NR
Duration of Use						
Leave-On	*162*	*0.12-40*	*85*	*0.5-5.8*	*11*	*NR*
Rinse Off	*3*	*1-4*	*25*	*2.5*	*1*	*NR*
Diluted for (Bath) Use	*NR*	*NR*	*1*	*NR*	*NR*	*NR*

(continued)

Table 8. (continued)

	# of Uses[9]	Max Conc of Use (%)[10-14]	# of Uses[9]	Max Conc of Use(%)[10-14]	# of Uses[9]	Max Conc of Use (%)[10-14]
Exposure Type						
Eye Area	22	0.12-20	11	0.8-3	NR	NR
Incidental Ingestion	89	4.1-40	9	3.8-5.8	NR	NR
Incidental Inhalation-Spray	6[a]; 3[b]	NR	1; 32[a]; 15[c]	NR	NR	NR
Incidental Inhalation-Powder	2; 3[b]	0.49-2; 1-5[c]	15[c]	3.4; 4[c]	NR	NR
Dermal Contact	75	0.12-20	99	0.5-3.4	12	NR
Deodorant (underarm)	NR	NR	NR	NR	11[a]	NR
Hair – Non-Coloring	NR	NR	NR	NR	NR	NR
Hair-Coloring	NR	3	NR	NR	NR	NR
Nail	NR	NR	NR	NR	NR	NR
Mucous Membrane	90	4.1-40	18	3.8-5.8	1	NR
Baby Products	NR	NR	NR	NR	NR	NR
	Polyglyceryl-3 Caprylate		Polyglyceryl-3 Dicitrate/Stearate		Polyglyceryl-3 Diisostearate	
Totals*	8	0.05-1	13	2-4	371	0.00000015-39
Duration of Use						
Leave-On	*5*	*0.05-1*	*13*	*2-4*	*363*	*0.0000015-39*
Rinse-Off	*3*	*0.6*	*NR*	*NR*	*7*	*0.000025-29.7*
Diluted for (Bath) Use	*NR*	*NR*	*NR*	*NR*	*1*	*NR*
Exposure Type						
Eye Area	NR	NR	NR	NR	37	0.006-12.2
Incidental Ingestion	NR	NR	NR	NR	216	7.8-39
Incidental Inhalation-Spray	1[b]	0.05	6[a]; 7[b]	NR	35[a]; 25[b]	0.00000015-0.5
Incidental Inhalation-Powder	NR	0.05[c]	7[b]	2-4[c]	25[b]	0.25; 0.03-1[c]
Dermal Contact	8	0.05-1	10	2-4	150	0.003-12.2
Deodorant (underarm)	3[a]	not spray: 0.5-1; aerosol: 0.6	NR	NR	NR	0.003-0.3 (not spray)
Hair – Non-Coloring	NR	NR	3	2.2	NR	0.00000015-0.003
Hair-Coloring	NR	NR	NR	NR	NR	NR
Nail	NR	NR	NR	NR	NR	NR
Mucous Membrane	2	0.6	NR	NR	221	0.003-39
Baby Products	NR	NR	NR	NR	NR	2
	Polyglyceryl-3 Distearate		Polyglyceryl-3 Isostearate		Polyglyceryl-3 Laurate	
Totals*	10	0.02-3	11	NR	192	0.6-6
Duration of Use						
Leave-On	*7*	*0.02-3*	*9*	*NR*	*1*	*6*
Rinse-Off	*3*	*NR*	*2*	*NR*	*191*	*0.6-2*
Diluted for (Bath) Use	*NR*	*NR*	*NR*	*NR*	*NR*	*NR*
Exposure Type						
Eye Area	NR	0.02-0.066	1	NR	NR	6
Incidental Ingestion	NR	NR	NR	NR	NR	NR
Incidental Inhalation-Spray	1; 6[a]	3; 1[a]	3[a]; 4[b]	NR	1[b]	NR
Incidental Inhalation-Powder	NR	0.29[c]	4[b]	NR	1[b]	NR
Dermal Contact	4	0.29-3	11	NR	189	2-6
Deodorant (underarm)	NR	NR	NR	NR	NR	NR
Hair – Non-Coloring	6	1	NR	NR	3	0.6-2
Hair-Coloring	NR	NR	NR	NR	NR	NR
Nail	NR	NR	NR	NR	NR	NR
Mucous Membrane	NR	NR	NR	NR	186	NR
Baby Products	NR	NR	NR	NR	NR	NR
	Polyglyceryl-3 Oleate		Polyglyceryl-3 Palmitate		Polyglyceryl-3 Pentaricinoleate	
Totals	14	1.2-1.5	1	NR	NR	0.15
Duration of Use						
Leave-On	*11*	*1.2-1.5*	*NR*	*NR*	*NR*	*0.15*
Rinse Off	*3*	*NR*	*1*	*NR*	*NR*	*NR*
Diluted for (Bath) Use	*NR*	*NR*	*NR*	*NR*	*NR*	*NR*
Exposure Type						

(continued)

Table 8. (continued)

	# of Uses[9]	Max Conc of Use (%)[10-14]	# of Uses[9]	Max Conc of Use(%)[10-14]	# of Uses[9]	Max Conc of Use (%)[10-14]
Eye Area	2	1.5	NR	NR	NR	0.15
Incidental Ingestion	NR	NR	NR	NR	NR	NR
Incidental Inhalation-Spray	6[a]; 2[b]	NR	NR	NR	NR	NR
Incidental Inhalation-Powder	2[b]	NR	NR	NR	NR	NR
Dermal Contact	14	1.5	1	NR	NR	0.15
Deodorant (underarm)	NR	NR	NR	NR	NR	NR
Hair – Non-Coloring	NR	1.2	NR	NR	NR	NR
Hair-Coloring	NR	NR	NR	NR	NR	NR
Nail	NR	NR	NR	NR	NR	NR
Mucous Membrane	NR	NR	1	NR	NR	NR
Baby Products	NR	NR	NR	NR	NR	NR
	Polyglyceryl-3 Ricinoleate		Polyglyceryl-3 Stearate		Polyglyceryl-4 Caprate	
Totals*	48	0.25-2	17	0.5-0.61	19	0.5-1.5
Duration of Use						
Leave-On	*48*	*0.25-2*	*14*	*0.5-0.54*	*6*	*0.5-1.5*
Rinse-Off	*NR*	*NR*	*3*	*0.61*	*12*	*0.9-1.5*
Diluted for (Bath) Use	*NR*	*NR*	*NR*	*NR*	*1*	*NR*
Exposure Type						
Eye Area	5	NR	NR	*NR*	2	NR
Incidental Ingestion	NR	NR	1	*0.5*	NR	NR
Incidental Inhalation-Spray	36[a]; 3[b]	NR	4[a]; 8[b]	NR	1[a]; 2[b]	0.5[a]
Incidental Inhalation-Powder	3[b]	0.25[b]	8[b]	NR	2[b]	0.72[c]
Dermal Contact	46	0.25-2	16	0.54-0.61	18	0.72-1.5
Deodorant (underarm)	NR	NR	NR	NR	1[a]	1.5 (not spray)
Hair – Non-Coloring	NR	NR	NR	NR	1	0.5-1.1
Hair-Coloring	NR	NR	NR	NR	NR	NR
Nail	NR	NR	NR	NR	NR	NR
Mucous Membrane	NR	NR	1	0.5	5	1-1.5
Baby Products	NR	NR	NR	NR	NR	NR
	Polyglyceryl-4 Cocoate		Polyglyceryl-4 Isostearate		Polyglyceryl-4 Laurate	
Totals*	1	NR	280	0.067-24.1	12	0.47
Duration of Use						
Leave-On	*NR*	*NR*	*279*	*0.067-24.1*	*8*	*NR*
Rinse-Off	*1*	*NR*	*1*	*0.16-1.7*	*4*	*0.47*
Diluted for (Bath) Use	*NR*	*NR*	*NR*	*NR*	*NR*	*NR*
Exposure Type						
Eye Area	NR	NR	51	0.51-24.1	1	NR
Incidental Ingestion	NR	NR	44	0.067-10.9	NR	NR
Incidental Inhalation-Spray	NR	NR	20[a]; 7[b]	0.26; 2.1[a]	4[a]	NR
Incidental Inhalation-Powder	NR	NR	47[b]	0.17; 0.5-2.5[c]	NR	NR
Dermal Contact	1	NR	229	0.067-24.1	12	0.47
Deodorant (underarm)	NR	NR	NR	NR	NR	NR
Hair – Non-Coloring	NR	NR	2	2.1	NR	NR
Hair-Coloring	NR	NR	NR	NR	NR	NR
Nail	NR	NR	1	NR	NR	NR
Mucous Membrane	1	NR	44	0.067-10.9	NR	NR
Baby Products	NR	NR	1	1	NR	NR
	Polyglyceryl-4 Oleate		Polyglyceryl-5 Dioleate		Polyglyceryl-5 Isostearate	
Totals	7	1.8	1	NR	2	NR
Duration of Use						
Leave-On	*7*	*1.8*	*NR*	*NR*	*2*	*NR*
Rinse Off	*NR*	*NR*	*1*	*NR*	*NR*	*NR*
Diluted for (Bath) Use	*NR*	*NR*	*NR*	*NR*	*NR*	*NR*
Exposure Type						
Eye Area	2	NR	NR	NR	1	NR
Incidental Ingestion	NR	NR	NR	NR	NR	NR

(continued)

Table 8. (continued)

	# of Uses[9]	Max Conc of Use (%)[10-14]	# of Uses[9]	Max Conc of Use(%)[10-14]	# of Uses[9]	Max Conc of Use (%)[10-14]
Incidental Inhalation-Spray	3[a]	1.8	NR	NR	1[b]	NR
Incidental Inhalation-Powder	NR	NR	NR	NR	1[b]	NR
Dermal Contact	7	1.8	1	NR	2	NR
Deodorant (underarm)	NR	NR	NR	NR	NR	NR
Hair – Non-Coloring	NR	NR	NR	NR	NR	NR
Hair-Coloring	NR	NR	NR	NR	NR	NR
Nail	NR	NR	NR	NR	NR	NR
Mucous Membrane	NR	NR	1	NR	NR	NR
Baby Products	NR	NR	NR	NR	NR	NR
	Polyglyceryl-5 Laurate		Polyglyceryl-5 Oleate		Polyglyceryl-5 Stearate	
Totals*	2	0.6	11	0.35	1	1
Duration of Use						
Leave-On	*NR*	*0.6*	*9*	*0.35*	*1*	*1*
Rinse-Off	*1*	*0.6*	*2*	*NR*	*NR*	*NR*
Diluted for (Bath) Use	*1*	*NR*	*NR*	*NR*	*NR*	*NR*
Exposure Type						
Eye Area	NR	NR	NR	NR	NR	NR
Incidental Ingestion	NR	NR	NR	NR	NR	NR
Incidental Inhalation-Spray	NR	NR	7[a]	0.35[c]	1[b]	NR
Incidental Inhalation-Powder	NR	0.6[c]	NR	NR	1[b]	1[c]
Dermal Contact	2	0.6	11	0.35	1	1
Deodorant (underarm)	NR	NR	NR	NR	NR	NR
Hair – Non-Coloring	NR	NR	NR	NR	NR	NR
Hair-Coloring	NR	NR	NR	NR	NR	NR
Nail	NR	NR	NR	NR	NR	NR
Mucous Membrane	2	NR	1	NR	NR	NR
Baby Products	NR	NR	NR	NR	NR	NR
	Polyglyceryl-5 Triisostearate		Polyglyceryl-5 Trioleate		Polyglyceryl-6 Caprylate/Caprate	
Totals*	NR	1-5	7	2.8	NR	0.75
Duration of Use						
Leave-On	*NR*	*1-5*	*6*	*NR*	*NR*	*NR*
Rinse-Off	*NR*	*NR*	*NR*	*2.8*	*NR*	*0.75*
Diluted for (Bath) Use	*NR*	*NR*	*NR*	*NR*	*NR*	*NR*
Exposure Type						
Eye Area	NR	NR	NR	NR	NR	NR
Incidental Ingestion	NR	5	NR	NR	NR	NR
Incidental Inhalation-Spray	NR	NR	2[a]; 5[b]	NR	NR	NR
Incidental Inhalation-Powder	NR	NR	5[b]	NR	NR	NR
Dermal Contact	NR	1	7	NR	NR	NR
Deodorant (underarm)	NR	NR	NR	NR	NR	NR
Hair – Non-Coloring	NR	NR	NR	2.8	NR	0.75
Hair-Coloring	NR	NR	NR	NR	NR	NR
Nail	NR	NR	NR	NR	NR	NR
Mucous Membrane	NR	5	NR	NR	NR	NR
Baby Products	NR	NR	NR	NR	NR	NR
	Polyglyceryl-6 Dioleate		Polyglyceryl-6 Distearate		Polyglyceryl-6 Isostearate	
Totals	30	1.8-2.4	71	4-22.4	14	NR
Duration of Use						
Leave-On	*23*	*2.4*	*52*	*4-22.4*	*14*	*NR*
Rinse Off	*7*	*1.8*	*18*	*NR*	*NR*	*NR*
Diluted for (Bath) Use	*NR*	*NR*	*1*	*NR*	*NR*	*NR*
Exposure Type						
Eye Area	NR	NR	7	4	NR	NR
Incidental Ingestion	2	NR	1	22.4	1	NR
Incidental Inhalation-Spray	12[b]	NR	26[a]; 16[b]	NR	4[a]; 8[b]	NR
Incidental Inhalation-Powder	12[b]	2.4[c]	1; 16[b]	NR	8[b]	NR
Dermal Contact	22	2.4	67	4-10.5	13	NR
Deodorant (underarm)	NR	NR	NR	NR	NR	NR
Hair – Non-Coloring	6	1.8	NR	NR	NR	NR

(continued)

Table 8. (continued)

	# of Uses[9]	Max Conc of Use (%)[10-14]	# of Uses[9]	Max Conc of Use(%)[10-14]	# of Uses[9]	Max Conc of Use (%)[10-14]
Hair-Coloring	NR	NR	NR	NR	NR	NR
Nail	NR	NR	NR	5	NR	NR
Mucous Membrane	2	NR	11	22.4	1	NR
Baby Products	NR	NR	1	NR	NR	NR
	Polyglyceryl-6 Octastearate		Polyglyceryl-6 Oleate		Polyglyceryl-6 Pentastearate	
Totals*	1	NR	1	NR	NR	5
Duration of Use						
Leave-On	*1*	*NR*	*1*	*NR*	*NR*	*5*
Rinse-Off	*NR*	*NR*	*NR*	*NR*	*NR*	*NR*
Diluted for (Bath) Use	*NR*	*NR*	*NR*	*NR*	*NR*	*NR*
Exposure Type						
Eye Area	NR	NR	NR	NR	NR	5
Incidental Ingestion	NR	NR	NR	NR	NR	NR
Incidental Inhalation-Spray	1[a]	NR	1[b]	NR	NR	NR
Incidental Inhalation-Powder	NR	NR	1[b]	NR	NR	NR
Dermal Contact	1	NR	1	NR	NR	5
Deodorant (underarm)	NR	NR	NR	NR	NR	NR
Hair – Non-Coloring	NR	NR	NR	NR	NR	NR
Hair-Coloring	NR	NR	NR	NR	NR	NR
Nail	NR	NR	NR	NR	NR	NR
Mucous Membrane	NR	NR	NR	NR	NR	NR
Baby Products	NR	NR	NR	NR	NR	NR
	Polyglyceryl-6 Ricinoleate		Polyglyceryl-6 Tricaprylate		Polyglyceryl-8 Decabehenate/Caprate	
Totals*	2	NR	NR	3.6	NR	9
Duration of Use						
Leave-On	*1*	*NR*	*NR*	*3.6*	*NR*	*9*
Rinse-Off	*1*	*NR*	*NR*	*NR*	*NR*	*NR*
Diluted for (Bath) Use	*NR*	*NR*	*NR*	*NR*	*NR*	*NR*
Exposure Type						
Eye Area	NR	NR	NR	NR	NR	NR
Incidental Ingestion	1	NR	NR	NR	NR	9
Incidental Inhalation-Spray	NR	NR	NR	NR	NR	NR
Incidental Inhalation-Powder	NR	NR	NR	NR	NR	NR
Dermal Contact	1	NR	NR	3.6	NR	NR
Deodorant (underarm)	NR	NR	NR	NR	NR	NR
Hair – Non-Coloring	NR	NR	NR	NR	NR	NR
Hair-Coloring	NR	NR	NR	NR	NR	NR
Nail	NR	NR	NR	NR	NR	NR
Mucous Membrane	2	NR	NR	NR	NR	9
Baby Products	NR	NR	NR	NR	]NR	NR
	Polyglyceryl-8 Decaerucate/ Decaisostearate/Decaricinoleate		Polyglyceryl-10 Behenate/Eicosadioate		Polyglyceryl-10 Caprylate/Caprate	
Totals	1	NR	2	2-5	1	NR
Duration of Use						
Leave-On	*1*	*NR*	*1*	*2*	*NR*	*NR*
Rinse Off	*NR*	*NR*	*1*	*5*	*1*	*NR*
Diluted for (Bath) Use	*NR*	*NR*	*NR*	*NR*	*NR*	*NR*
Exposure Type						
Eye Area	NR	NR	NR	NR	NR	NR
Incidental Ingestion	NR	NR	NR	2	NR	NR
Incidental Inhalation-Spray	1[b]	NR	NR	NR	NR	NR
Incidental Inhalation-Powder	1[b]	NR	NR	NR	NR	NR
Dermal Contact	1	NR	2	5	1	NR
Deodorant (underarm)	NR	NR	NR	NR	NR	NR
Hair – Non-Coloring	NR	NR	NR	NR	NR	NR

(continued)

Table 8. (continued)

	# of Uses[9]	Max Conc of Use (%)[10-14]	# of Uses[9]	Max Conc of Use(%)[10-14]	# of Uses[9]	Max Conc of Use (%)[10-14]
Hair-Coloring	NR	NR	NR	NR	NR	NR
Nail	NR	NR	NR	NR	NR	NR
Mucous Membrane	NR	NR	NR	2	NR	NR
Baby Products	NR	NR	NR	NR	NR	NR
	Polglyceryl-10 Decaisostearate		Polyglyceryl-10 Decaoleate		Polyglyceryl-10 Diisostearate	
Totals*	3	2.7	11	0.01-5	10	0.8-17
Duration of Use						
Leave-On	*3*	*2.7*	*11*	*1-5*	*9*	*0.8-2*
Rinse-Off	*NR*	*NR*	*NR*	*0.01*	*1*	*1.6-17*
Diluted for (Bath) Use	*NR*	*NR*	*NR*	*NR*	*NR*	*NR*
Exposure Type						
Eye Area	3	2.7	NR	NR	NR	NR
Incidental Ingestion	NR	NR	3	0.01-5	NR	NR
Incidental Inhalation-Spray	NR	NR	5[a]	NR	4[a]; 4[b]	2[a]
Incidental Inhalation-Powder	NR	NR	NR	NR	4[b]	0.8[c]
Dermal Contact	3	2.7	8	1-5	10	0.8-17
Deodorant (underarm)	NR	NR	NR	NR	NR	NR
Hair – Non-Coloring	NR	NR	NR	NR	NR	2
Hair-Coloring	NR	NR	NR	NR	NR	NR
Nail	NR	NR	NR	NR	NR	NR
Mucous Membrane	NR	NR	3	0.01-5	NR	NR
Baby Products	NR	NR	NR	NR	NR	NR
	Polyglyceryl-10 Dioleate		Polyglyceryl-10 Dipalmitate		Polyglyceryl-10 Distearate	
Totals*	NR	3.9	17	2-10	10	NR
Duration of Use						
Leave-On	*NR*	*NR*	*3*	*10*	*9*	*NR*
Rinse-Off	*NR*	*NR*	*12*	*2*	*1*	*NR*
Diluted for (Bath) Use	*NR*	*NR*	*2*	*2*	*NR*	*NR*
Exposure Type						
Eye Area	NR	NR	NR	NR	NR	NR
Incidenta Ingestion	NR	NR	1	NR	NR	NR
Incidental Inhalation-Spray	NR	NR	1[b]	NR	9[a]	NR
Incidental Inhalation-Powder	NR	NR	1[b]	10[c]	NR	NR
Dermal Contact	NR	3.9	16	2-10	10	NR
Deodorant (underarm)	NR	NR	NR	NR	NR	NR
Hair – Non-Coloring	NR	NR	NR	NR	NR	NR
Hair-Coloring	NR	NR	NR	NR	NR	NR
Nail	NR	NR	NR	NR	NR	NR
Mucous Membrane	NR	NR	12	2	1	NR
Baby Products	NR	NR	NR	NR	NR	NR
	Polyglyceryl-10 Heptahydroxystearate		Polyglyceryl-10 Hydroxystearate/Stearate/ Eicosadioate		Polyglyceryl-10 Isostearate	
Totals	1	1-2	2	0.62-1.8	6	0.6
Duration of Use						
Leave-On	*1*	*1-2*	*1*	*0.62-1.2*	*6*	*0.6*
Rinse Off	*NR*	*NR*	*1*	*1.8*	*NR*	*NR*
Diluted for (Bath) Use	*NR*	*NR*	*NR*	*NR*	*NR*	*NR*
Exposure Type						
Eye Area	NR	NR	NR	NR	NR	NR
Incidental Ingestion	NR	2	NR	0.62-1.2	NR	NR
Incidental Inhalation-Spray	NR	NR	NR	NR	5[a]; 1[b]	0.6
Incidental Inhalation-Powder	NR	NR	NR	NR	1[b]	NR
Dermal Contact	1	1	2	1.8	6	0.6
Deodorant (underarm)	NR	NR	NR	NR	NR	NR
Hair – Non-Coloring	NR	NR	NR	NR	NR	NR
Hair-Coloring	NR	NR	NR	NR	NR	NR

(continued)

Table 8. (continued)

	# of Uses[9]	Max Conc of Use (%)[10-14]	# of Uses[9]	Max Conc of Use(%)[10-14]	# of Uses[9]	Max Conc of Use (%)[10-14]
Nail	NR	NR	NR	NR	NR	NR
Mucous Membrane	NR	2	NR	0.62-1.2	NR	NR
Baby Products	NR	NR	NR	NR	NR	NR
	Polyglyceryl-10 Laurate		Polyglyceryl-10 Myristate		Polyglyceryl-10 Nonaisostearate	
Totals*	52	0.0009-6.5	19	0.0003-1.2	45	0.5
Duration of Use						
Leave-On	*43*	*0.0009-6.5*	*12*	*0.0003-1.2*	*45*	*NR*
Rinse-Off	*9*	*0.2-5*	7	*0.0003-0.04*	*NR*	*0.5*
Diluted for (Bath) Use	*NR*	*0.69-2*	*NR*	*NR*	*NR*	*NR*
Exposure Type						
Eye Area	5	NR	2	NR	20	NR
Incidental Ingestion	NR	NR	NR	NR	16	NR
Incidental Inhalation-Spray	11[a]; 12[b]	0.5; 6.5[a]	5[a]; 4[b]	NR	NR	NR
Incidental Inhalation-Powder	12[b]	NR	4[b]	0.8[c]	NR	NR
Dermal Contact	46	0.0009-2	18	0.0003-1.2	29	0.5
Deodorant (underarm)	NR	NR	NR	not spray: 0.0003 aerosol: 0.1	NR	NR
Hair – Non-Coloring	6	0.4-6.5	1	NR	NR	NR
Hair-Coloring	NR	NR	NR	NR	NR	NR
Nail	NR	NR	NR	NR	NR	NR
Mucous Membrane	NR	0.69-2	NR	NR	16	NR
Baby Products	7	1	1	NR	NR	NR
	Polyglyceryl-10 Oleate		Polyglyceryl-10 Pentahydroxystearate		Polyglyceryl-10 Pentaisostearate	
Totals*	29	0.0000085-3	3	NR	NR	2-4.8
Duration of Use						
Leave-On	*21*	*0.21-3*	*2*	*NR*	*NR*	*2-4.8*
Rinse-Off	*8*	*0.0000085*	*1*	*NR*	*NR*	*NR*
Diluted for (Bath) Use	*NR*	*2*	*NR*	*NR*	*NR*	*NR*
Exposure Type						
Eye Area	NR	0.63	1	NR	NR	NR
Incidental Ingestion	NR	NR	NR	NR	NR	4.8
Incidental Inhalation-Spray	9[a]; 10[b]	1	1[a]	NR	NR	NR
Incidental Inhalation-Powder	10[b]	0.21-3[c]	NR	NR	NR	2[c]
Dermal Contact	23	0.0000085-3	NR	NR	NR	2
Deodorant (underarm)	NR	NR	2	NR	NR	NR
Hair – Non-Coloring	6	0.0000085	NR	NR	NR	NR
Hair-Coloring	NR	NR	NR	NR	NR	NR
Nail	NR	NR	NR	NR	NR	NR
Mucous Membrane	NR	2	NR	NR	NR	4.8
Baby Products	1	NR	NR	NR	NR	NR
	Polyglyceryl-10 Pentaoleate		Polyglyceryl-10 Pentastearate		Polyglyceryl-10 Stearate	
Totals*	6	1-2.6	15	0.0003-2.2	99	0.13-2
Duration of Use						
Leave-On	*6*	*1-2.6*	*13*	*0.0003-2.2*	*92*	*0.13-2*
Rinse-Off	*NR*	*NR*	*2*	*0.0003-0.1*	*7*	*1*
Diluted for (Bath) Use	*NR*	*NR*	*NR*	*NR*	*NR*	*NR*
Exposure Type						
Eye Area	NR	NR	2	NR	13	0.41-1.8
Incidental Ingestion	1	2.6	NR	0.0003-2	NR	NR
Incidental Inhalation-Spray	3; 2[a]	1[a]	5[a]; 5[b]	NR	33[a]; 34[b]	0.25[a]
Incidental Inhalation-Powder	NR	NR	5[b]	1-2.2[c]	34[b]	0.13-2[c]
Dermal Contact	1	NR	14	0.0003-2.2	98	0.13-2
Deodorant (underarm)	NR	NR	NR	NR	NR	NR
Hair – Non-Coloring	4	1	1	NR	1	0.25
Hair-Coloring	NR	NR	NR	NR	NR	NR
Nail	NR	NR	NR	NR	NR	NR
Mucous Membrane	1	2.6	NR	0.0003-2	NR	NR

(continued)

Table 8. (continued)

	# of Uses[9]	Max Conc of Use (%)[10-14]	# of Uses[9]	Max Conc of Use(%)[10-14]	# of Uses[9]	Max Conc of Use (%)[10-14]
Baby Products	NR	NR	NR	NR	NR	NR
	Polyglyceryl-10 Tristearate		Triisostearoyl Polyglyceryl-3 Dimer Dilinoleate			
Totals*	1	NR	20	1-11.2		
Duration of Use						
Leave-On	*1*	*NR*	*20*	*1-11.2*		
Rinse-Off	*NR*	*NR*	*NR*	*NR*		
Diluted for (Bath) Use	*NR*	*NR*	*NR*	*NR*		
Exposure Type						
Eye Area	1	NR	2	1-1.2		
Incidental Ingestion	NR	NR	17	9-11.2		
Incidental Inhalation-Spray	NR	NR	NR	NR		
Incidental Inhalation-Powder	NR	NR	NR	NR		
Dermal Contact	1	NR	3	1-1.2		
Deodorant (underarm)	NR	NR	NR	NR		
Hair – Non-Coloring	NR	NR	NR	NR		
Hair-Coloring	NR	NR	NR	NR		
Nail	NR	NR	NR	NR		
Mucous Membrane	NR	NR	17	9-11.2		
Baby Products	NR	NR	NR	NR		

*Because each ingredient may be used in cosmetics with multiple exposure types, the sum of all exposure types may not equal the sum of total uses.
[a]Includes products that can be sprays, but it is not known whether the reported uses are sprays.
[b]Not specified whether this product is a spray or a powder or neither, but it is possible it may be a spray or a powder, so this information is captured for both categories of incidental inhalation.
[c]Includes products that can be powders, but it is not known whether the reported uses are powders.
NR – not reported.

The ability to enhance skin penetration was determined *in vitro* by measuring skin permeability coefficients for human abdominal skin samples.

Polyglyceryl-3 Dioleate. Polyglyceryl-3 Dioleate is reported to be a water-in-oil surfactant/solubilizer associated with enhanced drug penetration.[28]

Polyglyceryl-4 Laurate and Polyglyceryl-4 Oleate. The effect of 2 microemulsions on the rate and extent of release and penetration of ceramide AP (Figure 5) was evaluated using an *in vitro*, multi-layer, membrane model with 4 layers of circular 40-mm membrane films arranged one over the other.[29]

One test microemulsion, an o/w emulsion, contained 15% Polyglyceryl-4 Laurate, 15% Polyglyceryl-4 Oleate, and 60% water-1,2 pentanediol (1:9); the other, a w/o emulsion, contained 30% Polyglyceryl-4 Laurate, 15% isopropyl palmitate/linoleic acid (5:2), and 55% water-1,2 pentanediol (1.5-8.5). Both test formulations contained 0.4% ceramide AP. A non-ionic hydrophilic cream containing 0.5% ceramide AP was used as a reference formulation. Each test substance, in an amount that contained 50 µg ceramide AP, was spread evenly over a 4 cm^2 area. The formulation was left in place for 15-180 min; the unabsorbed test material was then removed and the ceramide was extracted from the membranes. When compared to the reference cream, the microemulsions increased the rate and extent of penetration of ceramide AP. Within 15 min, a higher percentage of ceramide AP was released from the microemulsions and penetrated into the deeper membrane layers; ceramide AP was not detected in the 3rd and 4th layers when the reference cream was used. Also, the amount that penetrated into each layer at each time point was greater with the microemulsions than with the cream. The total percent ceramide AP released and penetrated was 93.4% with the microemulsion containing 15% Polyglyceryl-4 Laurate and 15% Polyglyceryl-4 Oleate, 84.2% for the second test formulation, and 73.3% with the reference formulation.

The effect of similar microemulsions and microemulsion gels on the permeation of ceramide NP was evaluated in human thigh skin samples using Franz diffusion cells.[30] Several microemulsions were evaluated;

Table 9. Supplier Recommended Use Levels.

Ingredient	Supplier-Recommended Concentration	Reference
Diisostearoyl Polyglyceryl-3 Dimer Dilinoleate	3.0%	159
Polyglyceyrl-4 Caprate	2-10%	164
Polyglyceryl-3 Caprylate	0.2-2%	163
Polyglyceryl-10 Caprylate/Caprate	1-7%	166
Polyglyceryl-4 Cocoate	1-5%	226
Polyglyceryl-6 Distearate	1-3%	184
	4-6	224
Polyglyceryl-10 Eicosanedioate/Tetradecanedioate	1-10%	227
Polyglyceyrl-4 Isostearate	2.5-4%	180
Polyglyceryl-4 Laurate (in o/w lotion wipes)	5.0-10.0 % in concentrates 0.5-1.0 % in impregnating liquids	187
Polyglyceryl-10 Laurate (~60% pure, with ~40% polyglycerin-10 and ~2% sodium laurate)	≤3%	20
Polyglyceryl-3 Oleate	2.5-4%	190
Polyglyceryl-10 Oleate	1-7%	193
Polyglyceryl-3 Ricinoleate	3.5-4% (w/o emulsions); 5-25% (anhydrous products)	206
Polyglyceryl-2 Sesquioleate	2-3%	207

the formulations were composed of 30 or 35% Polyglyceryl-4 Laurate/Polyglyceryl-4 Oleate (1:1), 10-15% isopropyl palmitate/linoleic acid (9:12), 50-60% water/1,2 pentanediol (1.5:8.5), 0.2% ceramide AP, and 0.1% deuterated ceramide NP. The gels were prepared by dispersing 2.5% Carbopol® 940 into the microemulsion. Some of the formulations were o/w, and some were bi-continuous. A hydrophilic cream containing 0.2% deuterated ceramide NP was used as a reference formulation. Twenty mg of each formulation was applied to the skin surface (3.1416 cm^2) and allowed to permeate for 300 min. After 300 min, the skin surface was wiped and the stratum corneum layer was removed with 10 tape strips over a 2.016 cm^2 area. Subsequently, 3 skin punches were taken and the epidermal layer was removed. Permeation was deeper from the microemulsions, as compared to the cream and the microemulsion gels; additionally, penetration was deeper with the o/w formulations compared to the bi-continuous formulations. Deuterated ceramide NP in the cream did not permeate into the deeper layers of the stratum corneum and other skin layers. Permeation from the gel was shallow due to its high viscosity.

Polyglyceryl-10 Trioleate. The effect of Polyglyceryl-10 Trioleate on the permeation of tenoxicam (a non-steroidal anti-inflammatory drug; Figure 6) in a propylene glycol solution was examined *in vitro* using dorsal skin from male Hartley strain guinea pigs.[31]

The test solution was prepared by suspending 0.3 g tenoxicam in a mixed solution of 3.0 g propylene glycol and 1.5 g Polyglyceryl-10 Trioleate, and the suspension was adjusted to a pH of 6.0. Using a Franz-type diffusion chamber, 1 g of the resulting suspension, which contained 1% tenoxicam, 10% propylene glycol, and 5% Polyglyceryl-10 Trioleate, was applied to the donor skin, and 1.0 ml of the receptor solution was sampled every 3 h for 48 h. The flux of tenoxicam was statistically significantly enhanced by the inclusion of Polyglyceryl-10 Trioleate, from 8.11 x 10^{-5} μg/s·cm^2 to 28.48 μg/s·cm^2.

Absorption, Distribution, Metabolism, and Excretion (ADME)

Oral. Metabolic studies of polyglyceryl esters indicated that these esters are hydrolyzed in the gastrointestinal (GI) tract, and utilization and digestibility studies supported the assumption that the fatty acid moiety is metabolized in the normal manner.[32] Analytical studies have produced no evidence of accumulation of the polyglycerol moiety in body tissues.

Albino Wistar rats were fed a diet containing 5% or 10% polyglyceryl ester; the exact composition of the ester was not provided, but it was stated that the ester was mostly prepared with stearic and oleic acids.[33] Control animals were given untreated feed. The number of animals per group and duration of dosing also was not specified, however some animals were fed the test diet for up to 14 mos, and some were maintained through 3 generations. Feed consumption was determined for 2 males and 2 females per group, and feces were collected for these animals for 24 days. Fecal lipids were increased in the test groups when compared to the controls; however, the researchers stated

Table 10. Ingredients Not Reported to be Used.[9-14]

Adansonia Digitata Seed Oil Polyglyceryl-6 Esters	Polyglyceryl-3 Soyate/Shea Butterate	Polyglyceryl-6 Sclerocarya Birrea Seedate	Polyglyceryl-10 Tricocoate
Almond Oil/Polyglyceryl-10 Esters	Polyglyceryl-3 Stearate SE	Polyglyceryl-6 Sesquicaprylate	Polyglyceryl-10 Tridecanoate
Apricot Kernel Oil Polyglyceryl-3 Esters	Polyglyceryl-3 Triisostearate	Polyglyceryl-6 Sesquiisostearate	Polyglyceryl-10 Trierucate
Apricot Kernel Oil Polyglyceryl-4 Esters	Polyglyceryl-3 Triolivate	Polyglyceryl-6 Sesquistearate	Polyglyceryl-10 Triisostearate
Apricot Kernel Oil Polyglyceryl-5 Esters	Polyglyceryl-4 Almondate/Shea Butterate	Polyglyceryl-6 Stearate	Polyglyceryl-10 Trilaurate
Apricot Kernel Oil Polyglyceryl-6 Esters	Polyglyceryl-4 Caprylate	Polyglyceryl-6 Tetrabehenate	Polyglyceryl-10 Trioleate
Apricot Kernel Oil Polyglyceryl-10 Esters	Polyglyceryl-4 Caprylate/Caprate	Polyglyceryl-6 Tetracaprylate	Polyglyceryl-10 Undecylenate
Argan Oil Polyglyceryl-6 Esters	Polyglyceryl-4 Dilaurate	Polyglyceryl-6 Tetraoleate	Polyglyceryl-15 Diisostearate
Astrocaryum Vulgare Oil Polyglyceryl-6 Esters	Polyglyceryl-4 Distearate	Polyglyceryl-6 Trichilia Emetica Seedate	Polyglyceryl-20 Docosabehenate/Isostearate
Avocado Oil Polyglyceryl-6 Esters	Polyglyceryl-4 Hazelnutseedate	Polyglyceryl-6 Tristearate	Polyglyceryl-20 Docosabehenate/Laurate
Babassu Oil Polyglyceryl-6 Esters	Polyglyceryl-4 Isostearate/Laurate	Polyglyceryl-6 Undecylenate	Polyglyceryl-20 Docosabehenate/Oleate
Bertholletia Excelsa Seed Oil Polyglyceryl-6 Esters	Polyglyceryl-4 Laurate/Sebacate	Polyglyceryl-6 Ximenia Americana Seedate	Polyglyceryl-20 Heptacaprylate
Borage Seed Oil Polyglyceryl-4 Esters	Polyglyceryl-4 Laurate/Succinate	Polyglyceryl-8 C12-20 Acid Ester	Polyglyceryl-20 Heptadecabehenate/Laurate
Borage Seed Oil Polyglyceryl-6 Esters	Polyglyceryl-4 Pentaoleate	Polyglyceryl-8 Oleate	Polyglyceryl-20 Hexacaprylate
Carapa Guaianensis Oil Polyglyceryl-6 Esters	Polyglyceryl-4 Pentapalmitate/Stearate	Polyglyceryl-8 Stearate	Polyglyceryl-20 Octadecabehenate/Laurate
Castor Oil Polyglyceryl-6 Esters	Polyglyceryl-4 Pentastearate	Polyglyceryl-10 Apricot Kernelate	Polyglyceryl-20 Octaisononanoate
Cocoa Butter Polyglyceryl-6 Esters	Polyglyceryl-4 Punicate	Polyglyceryl-10 Caprate	Pumpkin Seed Oil Polyglyceryl-4 Esters
Coffee Seed Oil Polyglyceryl-6 Esters	Polyglyceryl-4 Stearate	Polyglyceryl-10 Caprylate	Pumpkin Seed Oil Polyglyceryl-4 Esters Succinate
Hazelnut Seed Oil Polyglyceryl-6 Esters	Polyglyceryl-4 Sweet Almondate	Polyglyceryl-10 Cocoate	Rice Bran Oil Polyglyceryl-3 Esters
Linseed Oil Polyglyceryl-4 Esters	Polyglyceryl-4 Tristearate	Polyglyceryl-10 Decaethylhexanoate	Rosa Rubiginosa Seed Oil Polyglyceryl-6 Esters
Macadamia Seed Oil Polyglyceryl-6 Esters	Polyglyceryl-5 Caprate	Polyglyceryl-10 Decahydroxystearate	Safflower Seed Oil Polyglyceryl-6 Esters
Mauritia Flexuosa Seed Oil Polyglyceryl-6 Esters	Polyglyceryl-5 Dicaprylate	Polyglyceryl-10 Decalinoleate	Schinziophyton Rautanenii Kernel Oil Polyglyceryl-6 Esters
Olive Oil Polyglyceryl-3 Esters	Polyglyceryl-5 Dilaurate	Polyglyceryl-10 Decamacadamiate	
Olive Oil Polyglyceryl-4 Esters	Polyglyceryl-5 Hexastearate	Polyglyceryl-10 Decastearate	Sclerocarya Birrea Seed Oil Polyglyceryl-6 Esters
Olive Oil Polyglyceryl-6 Esters	Polyglyceryl-5 Myristate	Polyglyceryl-10 Dicocoate	Sclerocarya Birrea Seed Oil Polyglyceryl-10 Esters
Palm Kernel Oil Polyglyceryl-4 Esters	Polyglyceryl-5 Pentamyristate	Polyglyceryl-10 Didecanoate	Sesame Oil Polyglyceryl-6 Esters
Palm Oil Polyglyceryl-3 Esters	Polyglyceryl-5 Ricinoleate	Polyglyceryl-10 Dilaurate	Shea Butter Polyglyceryl-3 Esters
Palm Oil Polyglyceryl-5 Esters	Polyglyceryl-5 Tribehenate	Polyglyceryl-10 Dimyristate	Shea Butter Polyglyceryl-4 Esters
Palm Oil Polyglyceryl-6 Esters	Polyglyceryl-5 Trimyristate	Polyglyceryl-10 Dodecabehenate	Shea Butter Polyglyceryl-6 Esters
Parinari Curatellifolia Oil Polyglyceryl-6 Esters	Polyglyceryl-5 Tristearate	Polyglyceryl-10 Dodecacaprate	Soybean Oil Polyglyceryl-6 Esters
Pinus Sibirica Seed Oil Polyglyceryl-6 Esters	Polyglyceryl-6 Adansonia Digitata Seedate	Polyglyceryl-10 Dodecacaprylate	Sunflower Seed Oil Polyglyceryl-3 Esters
Polyglyceryl-2 Caprylate	Polyglyceryl-6 Apricot Kernelate	Polyglyceryl-10 Dodeca-Caprylate/Caprate	Sunflower Seed Oil Polyglyceryl-4 Esters
Polyglyceryl-2 Dioleate	Polyglyceryl-6 Argan Kernelate	Polyglyceryl-10 Eicosanedioate/Tetradecanedioate	Sunflower Seed Oil Polyglyceryl-5 Esters
Polyglyceryl-2 Distearate	Polyglyceryl-6 Behenate	Polyglyceryl-10 Hepta(Behenate/Stearate)	Sunflower Seed Oil Polyglyceryl-6 Esters
Polyglyceryl-2 Isopalmitate/Sebacate	Polyglyceryl-6 Caprate	Polyglyceryl-10 Heptaoleate	Sunflower Seed Oil Polyglyceryl-10 Esters
Polyglyceryl-2 Myristate	Polyglyceryl-6 Caprylate	Polyglyceryl-10 Heptastearate	Sweet Almond Oil Polyglyceryl-4 Esters
Polyglyceryl-2 Palmitate	Polyglyceryl-6 Citrullus Lanatus Seedate	Polyglyceryl-10 Hexaerucate	Sweet Almond Oil Polyglyceryl-6 Esters
Polyglyceryl-2 Sesquicaprylate	Polyglyceryl-6 Dicaprate	Polyglyceryl-10 Hexaisostearate	Theobroma Grandiflorum Seed Butter Polyglyceryl-6 Esters
Polyglyceryl-2 Sesquioleate	Polyglyceryl-6 Diisostearate	Polyglyceryl-10 Hexaoleate	
Polyglyceryl-2 Tetrabehenate/ Macadamiate/Sebacate	Polyglyceryl-6 Dipalmitate	Polyglyceryl-10 Linoleate	Trichilia Emetica Seed Oil Polyglyceryl-6 Esters
Polyglyceryl-2 Tetraoleate	Polyglyceryl-6 Heptacaprylate	Polyglyceryl-10 Mono/Dioleate	Watermelon Seed Oil Polyglyceryl-6 Esters
Polyglyceryl-2 Tetrastearate	Polyglyceryl-6 Hexaoleate	Polyglyceryl-10 Nonaerucate	Watermelon Seed Oil Polyglyceryl-10 Esters
Polyglyceryl-3 Behenate	Polyglyceryl-6 Hexastearate	Polyglyceryl-10 Palmate	Ximenia Americana Seed Oil Polyglyceryl-6 Esters
Polyglyceryl-3 Cocoate	Polyglyceryl-6 Laurate	Polyglyceryl-10 Palmitate	
Polyglyceryl-3 Dicaprate	Polyglyceryl-6 Myristate	Polyglyceryl-10 Pentacaprylate	
Polyglyceryl-3 Dicocoate	Polyglyceryl-6 Octacaprylate	Polyglyceryl-10 Pentalaurate	
Polyglyceryl-3 Di-Hydroxystearate	Polyglyceryl-6 Palmitate	Polyglyceryl-10 Pentalinoleate	
Polyglyceryl-3 Dioleate	Polyglyceryl-6 Palmitate/Succinate	Polyglyceryl-10 Pentaricinoleate	
Polyglyceryl-3 Myristate	Polyglyceryl-6 Pentacaprylate	Polyglyceryl-10 Sesquistearate	
Polyglyceryl-3 Pentacaprylate/Caprate	Polyglyceryl-6 Pentaoleate	Polyglyceryl-10 Tetradecanedioate	
Polyglyceryl-3 Pentaolivate	Polyglyceryl-6 Pentaricinoleate	Polyglyceryl-10 Tetralaurate	
Polyglyceryl-3 Rice Branate	Polyglyceryl-6 Schinziophyton Rautanenii Kernelate	Polyglyceryl-10 Tetraoleate	

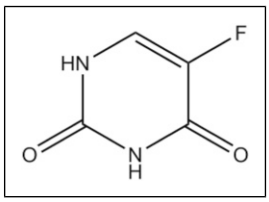


Figure 4. 5-Fluorouracil.

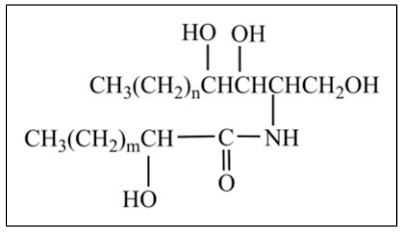


Figure 5. Ceramide AP (wherein m has a value ranging from 13 to 27 and n has a value ranging from 12 to 20).

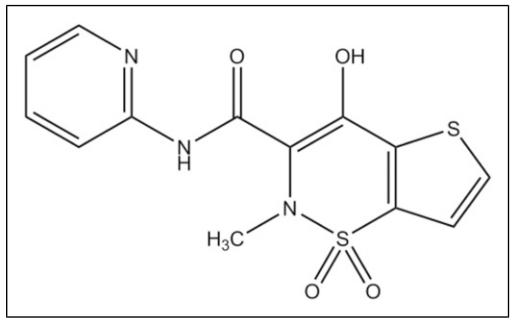


Figure 6. Tenoxicam.

that at least 95-98% of the polyglyceryl esters were digested.

Similarly, groups of Wistar rats were fed a diet containing 5% polyglyceryl ester prepared with oleic acid or with linseed oil, and feed consumption was measured and feces collected for 2 males and 2 females per group for 24 days.[33] The polyglyceryl esters were almost completely utilized.

Groups of 8 male Sherman rats were fed a restricted diet consisting of 1 g of a polyglyceryl ester in 5 g basic diet/day for 3 wks, followed by 8 wks feeding, *ad libitum*, of a diet containing 8% of the test material.[34] The esters used in the study ranged in size from 2 to 30 glyceryl radicals, with hydrogenated cottonseed oil or peanut oil. Fecal fat excretion, calculated as total lipid extract, absorption, and digestibility values, were determined during the restricted and *ad libitum* feeding periods. The fecal lipids from rats fed the polyglyceryl hydrogenated cottonseed oil esters were higher in palmitic, stearic, and oleic acids, and lower in linoleic acid, than those the fed the polyglyceryl peanut oil esters. Gas-liquid chromatography (GLC) analysis of the fatty acids of the extracted

lipids from the epididymal fat pads determined that only triglycerides were present and no appreciable amounts of polyglycerols were deposited.

A study was conducted in which rats were fed a polyglyceryl ester with a high melting point for 8 mos.[35] No residues were detected in depot fat, or in fat of muscle, liver, kidney or spleen. (Details were not provided.)

Polyglyceryl Oleates and Decaoleate. The metabolism of Polyglyceryl-3 Oleate, Polyglyceryl-10 Oleate, and Polyglyceryl-10 Decaoleate was investigated in male Sprague-Dawley rats.[36] Groups of 4 rats were dosed with 1% Polyglyceryl-3 [^{14}C]Oleate, Polyglyceryl-10 [^{14}C]Oleate, [^{14}C]Polyglyceryl-10 Oleate, Polyglyceryl-10 [^{14}C]Decaoleate, and [^{14}C]Polyglyceryl-10 Decaoleate by stomach tube in a liquid diet; the diet contained 7-14 μCi of ^{14}C. The study also included 2 polyglyceryl esters that are not cosmetic ingredients, but are similar to ingredients reviewed in this report: triglycerol [^{14}C]tetraoleate and polyglycerin-10 [^{14}C]monoeicosanoate. Catabolism studies were conducted by administering the test diet, collecting expired CO_2, feces, and urine with the use of metabolism chambers, and collecting GI tract contents and examining the carcass of each animal after 51 h. In additional groups of 4 animals, simultaneous catabolism-absorption studies were conducted by inserting a thoracic duct cannula in each animal, dosing the animals, and then using a metabolism chamber for the collection of lymph, respiratory CO_2, feces, and urine (each as a single fraction) for 51 h. Lipids were extracted from the lymph of animals dosed with fatty-acid labelled esters, and the distribution of radioactivity among the various lipid constituents of lymph was obtained to determine whether any intact polyglyceryl esters were present in the lymph lipids. The metabolism of the esters was also compared to glycerol-1,3-[^{14}C], [^{14}C]polyglycerin-3, and [^{14}C]polyglycerin-10.

The disposition of radioactivity following administration of each compound is presented in Table 11. In the catabolism studies, total recovery of the radioactivity ranged from 88-98% of the dose. The distribution of the absorbed [^{14}C]Polyglyceryl-10 Oleate and [^{14}C]Polyglyceryl-10 Decaoleate was considerably different from that of glycerol. The absorbed polyglyceryls were excreted primarily in the urine (33.5-37%) with less than 4% of the ^{14}C appearing in the respiratory CO_2 and less than 5.5% in the carcass; ~44.5-46.5% was found in the GI contents. Only small amounts of radioactivity from the [^{14}C]oleic acid moiety were recovered in feces (~0.1-0.9%) and GI content (~2.8-4.0%), and the fatty acid appeared to be equally well-absorbed as the polyceryl-3 and the polyglyceryl-10 ester. Radioactivity from labeled oleic acid moieties of the esters appeared in expired CO_2 at close to the same rates as that from glycerol; however, recovery of labeled polyglycerin-3 and polyglycerin-10 in expired CO_2 was less than 4% of the dose, with unpolymerized glycerol accounting for most of what was recovered. Radioactivity from the eicosanoic acid-labeled ester was excreted in CO_2 at a lower rate (55.5%) than that for the oleic acid-labeled compounds.

In the catabolism-absorption studies, 83-102% of the radioactivity was recovered. No more than 5% of the radioactivity from glycerol-labeled esters was absorbed via the lymphatic system; however, ~67.5-78.5% of the radioactivity from the oleic acid-labeled polyglyceryl esters was recovered in the lymph, and ~54% was recovered in the lymph of animals given the eicosanoate-labeled polyglyceryl ester. Lipids from the oleate- (and eicosanoate-) labeled compounds contained 97-99% of the total lymph radioactivity.

In vitro hydrolysis studies confirmed that the oleic acid ester bond in the polyglyceryl-3 and polyglyceryl-10 esters was readily cleaved. Additionally, it was shown that the eicosanoate bond was cleaved more slowly than the oleate bond. The researchers concluded that the polyglycerols were not catabolized, the ether linkages are inert to normal enzymatic hydrolysis, and the polyglycerols were absorbed and rapidly excreted in the urine without being catabolized.

Groups of 10 male and 10 female Sprague-Dawley rats were fed a diet containing 2.5, 5.0, or 10.0% Polyglyceryl-10 Decaoleate for 90 days, and the control group was fed a diet containing soybean oil as the dietary fat.[37] The percentage of dietary fatty acids absorbed decreased as the levels of Polyglyceryl-10 Decaoleate in the diet increased. Fat absorption by males and females of the 5 and 10% test groups was statistically significantly less than controls at wk 4 and 10, and was statistically significantly decreased in females of the 2.5% group at wk 4 and males of the 2.5% group at wk 10. GLC analysis of fecal fatty acids revealed excretion of oleic acid increased in a dose-related manner; the increased excretion of fatty acids in general, and oleic acid in particular, indicated that the absorption of dietary Polyglyceryl-10 Decaoleate was not complete. The researchers stated that fecal oleic acid may have resulted from excretion of intact Polyglyceryl-10 Decaoleate or from hydrolyzed or partially hydrolyzed but unabsorbed material.

In Vitro

Polyglyceryl-2 Diisostearate. The metabolism of Polyglyceryl-2 Diisostearate was evaluated using a lipase assay; olive oil was used as a reference substance.[38] Both Polyglyceryl-Diisostearate and olive oil increased the fatty acid concentration in all reaction vials in a time dependent manner, and the speed of fatty acid formation was comparable for both substrates. The *in vitro* experimental results support the hypothesis that accumulation of Polyglyceryl-2 Diisostearate in the gut is unlikely.

Toxicological Studies

Acute Toxicity. Acute toxicity studies are summarized in Table 12.[32,38-54]

In an acute dermal toxicity study in rats, the LD_{50} of 1,2,3-propanetriol, homopolymer, diisooctadecanoate was > 5 g/kg.

Table 11. Disposition of Radioactivity in Rats After a Single Oral Dose (51 h After Feeding).

Catabolism Study[36]						
	% radioactivity recovered					
	CO2	urine	Feces	GI contents	carcass	
Test Compound – Ingredients						
[^{14}C]Polyglyceryl-10 Oleate	2.1	36.8	9.5	46.5	5.3	
[^{14}C]Polyglyceryl-10 Decaoleate	3.5	33.5	15.5	44.6	3.0	
polyglyceryl-3 [^{14}C]oleate	68.2	1.3	0.1	2.8	27.7	
polyglyceryl-10 [^{14}C]oleate	68.5	2.2	0.6	4.0	24.7	
polyglyceryl-10 [^{14}C]decaoleate	66.0	1.7	0.9	2.8	28.7	
For Comparison						
glycerol-1,3-^{14}C	73.3	5.2	0.7	1.3	19.5	
[^{14}C]polyglycerin-3	2.1	88.3	5.5	2.9	1.2	
[^{14}C]polyglycerin-10	4.2	34.1	23.9	35.2	2.5	
triglycerol [^{14}C]tetraoleate	70.4	1.4	1.5	3.0	23.6	
polyglycerin-10 [^{14}C]monoeicosanoate	55.5	1.6	9.9	12.2	20.8	
Catabolism – Absorption Study[36]						
	% radioactivity recovered					
	CO2	urine	feces	GI contents	carcass	lymph
Test Compound – Ingredients						
[^{14}C]Polyglyceryl-10 Oleate	1.5	42.4	45.6	3.5	5.1	1.9
[^{14}C]Polyglyceryl-10 Decaoleate	1.7	25.6	60.8	3.1	3.8	5.0
polyglyceryl-3 [^{14}C]oleate	13.7	0.9	3.4	0.4	3.1	78.5
polyglyceryl-10 [^{14}C]oleate	14.4	1.0	6.1	1.6	1.9	75.0
polyglyceryl-10 [^{14}C]decaoleate	13.3	1.4	8.4	2.3	7.1	67.5
For Comparison						
glycerol-1,3-^{14}C	73.6	4.8	1.7	0.4	12.7	6.8
[^{14}C]polyglycerin-3	1.7	69.5	20.2	0.6	4.7	3.3
[^{14}C]polyglycerin-10	3.9	45.4	34.0	4.3	11.6	0.8
triglycerol [^{14}C]tetraoleate	12.7	0.9	6.2	1.7	2.6	76.0
polyglycerin-10 [^{14}C]monoeicosanoate	8.9					

Low toxicity was reported in acute oral studies. In rats, the LD_{50} > 2 g/kg for Polyglyceryl-3 Caprate, Polyglyceryl-3 Caprylate, Polyglyceryl-4 Caprate, Diisostearoyl Polyglyceryl-3 Dimer Dilinoleate, and Polyglyceryl-8 Decabehenate/Caprate, the LD_{50} was estimated to be > 2.5 g/kg for Glyceryl/Polyglyceryl-6 Isostearate/Behenate Esters, Macadamia Seed Oil Polyglyceryl-6 Esters Behenate, Polyglyceryl-8 Decaerucate/Decaisostearate/Decaricinoleate, and Polyglyceryl-10 Nonaisostearate, and the LD_{50} was > 5 g/kg for Polyglyceryl-3 Isostearate, Polyglyceryl-3 Oleate, Polyglyceryl-2 Diisostearate and Polyglyceryl-3 Diisostearate.

Short-Term Toxicity

Animal

Oral

Polyglyceryl Esters – general. In rats, repeated oral dosing with 10 g/kg bw polyglyceryl ester daily over 5 days caused no deaths.[32] No further details were provided.

The feeding of a restricted diet consisting of 1 g of a polyglyceryl ester in 5 g basic diet/day for 3 wk to Sherman rats, followed by 8 wk feeding, *ad libitum*, of a diet containing 8% of the test material (8 males/group; study described in the ADME section) did not result in any microscopic abnormalities in the liver, kidneys, or ileum.[34]

Polyglyceryl Stearate. Two groups of 4 male albino rats were administered a suspension of 1 g/kg bw/day of polyglyceryl stearate (glyceryl chain length not stated) in an aqueous solution of 0.5% carboxymethylcellulose (CMC) and 0.1% Tween 80 for 10 wk; one group was fed a basic diet, and the other a diet supplemented with 5% hydrogenated fat.[55] Two untreated control groups, one fed a basal diet and one the fat-supplemented diet, were used. Polyglyceryl stearate was not toxic, and it did not have an effect on red blood cell count, white blood cell count, or hemoglobin values.

Polyglyceryl-2 Diisostearate. In a dietary study, 5 male and 5 female rats per group were given feed containing 0, 0.012, 0.12, or 1.2% Polyglyceryl-2 Diisostearate (for a targeted dose of 0, 10, 100, or 1000 mg/kg/day, respectively) for 28 days, and a control group was given untreated feed.[38] There were no mortalities, clinical signs of toxicity, effects on body weight, clinical pathology, or gross or histopathology alterations that were considered related to the dietary administration of the test substance and/or considered to be of toxicological significance. The no observed adverse effect level (NOAEL) was 845 mg/kg/day in males and 922 mg/kg/day in females, corresponding to the highest dietary concentration tested.

Human

Oral

Polyglyceryl Esters – general. For 3 wk, 37 subjects were fed 2-20 g/day polyglyceryl ester in their diet.[32] No abnormalities were detected in the hematology or clinical chemistry values or urinary or fecal parameters that were examined.

Subchronic Toxicity Studies

Animal

Oral

Polyglyceryl-10 Decaoleate. Groups of 10 male and 10 female Sprague-Dawley rats were fed a diet containing 2.5, 5.0, or 10.0% Polyglyceryl-10 Decaoleate for 90 days, and the control group was fed a diet containing soybean oil as the dietary fat.[37] Urine was collected from each group during wk 3 and 9, total fatty acid absorption was determined in feces collected during wk 4 and 10, and hematological studies were conducted during wk 5 and 11, and at study termination. No test article-related signs of toxicity were observed. Gross and microscopic examination of the testes and ovaries and other organs did not reveal any evidence of toxicity, and relative and absolute organ weights were unremarkable.

Chronic Toxicity Studies

Animal

Oral

Polyglyceryl Esters – general. Groups of 25 male and 25 female mice were fed a diet with 5% polyglyceryl ester for 80 wk.[32] No adverse effects on body weight, feed consumption, hematology values, or survival rate were noted. Carcass fat of the test group showed no polyglycerol residues. The levels of free fatty acids, unsaponifiable material, and the fatty acid composition of carcass fat were the same for the test group compared to a control group fed 5% ground nut oil in the diet. The only differences noted in organ weights were for the liver and kidneys of female mice, which were significantly higher. Microscopic examination of all major organs showed nothing remarkable.

In a 2-yr study, 28 male and 28 female rats were fed 5% polyglyceryl ester in the diet.[32] No adverse effects on body weight, feed consumption, hematology values, or survival rate were noted. Organ weights were similar in control and test groups. Liver function tests and renal function tests performed at 59 and 104 wk of the study were comparable between the test group and a control group fed 5% ground nut oil. The carcass fat contained no polyglycerol, and the levels of free fatty acid, unsaponifiable residue and fatty acid composition of carcass fat were not different from the controls. A complete histological examination of major organs showed nothing remarkable.

Table 12. Acute Toxicity Studies.

Ingredient	Animals	No./Group	Vehicle	Concentration/Dose/ Protocol	LD_{50}/Results	Reference
			DERMAL			
Polyglyceryl Multi-Esters						
1,2,3-propanetriol, homopolymer, diisooctadecanoate (n not defined; most likely Polyglyceryl-3 Diisostearate)	Wistar rats	5/sex	undiluted	5 g/kg (5.2 mL/kg bw) was applied with a semi-occlusive patch for 24 h	>5 g/kg no local effects were observed	39
			ORAL			
polyglyceryl ester (unspecified)	rats	not provided	not specified	7, 14 and 29 g/kg bw by gavage	no signs of any toxic effect	32
polyglyceryl ester (unspecified)	rabbits	not provided	not specified	10-29 g/kg bw	no signs of any toxic effect	32
			Polyglyceryl Monoesters			
Polyglyceryl-3 Caprate	rat	not provided	not specified	OECD 401 (acute oral toxicity by gavage)	LD_{50} > 2 g/kg	40
Polyglyceryl-3 Caprylate	rat	not provided	not specified	OECD 423 (acute oral toxicity by gavage)	LD_{50} > 2 g/kg	41
Polyglyceryl-3 Isostearate	rat	not provided	not specified	FHSA, 16 CFR 1500.3	LD_{50} > 5 g/kg	42
Polyglyceryl-3 Oleate	rat	not provided	not specified	FHSA, 16 CFR 1500.3	LD_{50} > 5 g/kg	43
Polyglyceryl-4 Caprate	rat	not provided	not specified	OECD 401 (acute oral toxicity by gavage)	LD_{50} > 2 g/kg	44
Glyceryl/Polyglyceryl-6 Isostearate/ Behenate Esters	Sprague Dawley rats	3 females	arachis oil BP	2 g/kg bw by gavage (2 groups)	LD_{50} > 2.5 g/kg bw (estimated)	45
			Polyglyceryl Multi-Esters			
Polyglyceryl-2 Diisostearate	female Wistar rats	10	water	not provided	>5 g/kg	38
Polyglyceryl-2 Diisostearate	rats	5/sex	not specified	not provided	>5 g/kg	38
Polyglyceryl-3 Diisostearate	NMRI mice	5 females	not specified	2 g/kg	>2 g/kg	46,47
1,2,3-propanetriol, homopolymer, diisooctadecanoate (n not defined; most likely Polyglyceryl-3 Diisostearate)	Wistar rats	5/sex	peanut oil	single oral dose of 50% (w/v) by gavage	>5 g/kg	39
Diisostearoyl Polyglyceryl-3 Dimer Dilinoleate	rat	not provided	not specified	OECD 423 (acute oral toxicity by gavage)	LD_{50} > 2 g/kg bw	48
tetraisostearoyl polyglyceryl-3 dimer dilinoleate (as read-across for Diisostearoyl Polyglyceryl-3 Dimer Dilinoleate and Triisostearoyl Polyglyceryl-3 Dimer Dilinoleate)	rats	not provided	not provided	not provided	>5 g/kg	49,50
Macadamia Seed Oil Polyglyceryl-6 Esters Behenate	Sprague-Dawley rats	3 females	arachis oil	dosed with 2 g/kg by gavage (2 groups)	>2.5 g/kg bw (estimated) no mortality	51
Polyglyceryl-8 Decabehenate/Caprate	Sprague-Dawley rats	1 female; 4females	arachis oil BP	dosed with 2 g/kg by gavage (2 groups)	>2.0 g/kg bw (estimated) no mortality	52
Polyglyceryl-8 Decaerucate/ Decaisostearate/Decaricinoleate	Sprague-Dawley rats	3 females	none	dosed with 2 g/kg, neat, by gavage (2 groups)	>2.5 g/kg bw (estimated) no mortality	53
Polyglyceryl-10 Nonaisostearate	Sprague-Dawley rats	3 females	arachis oil	0.3 g/kg (30 mg/ml) in arachis oil or 2 g/kg neat by gavage	>2.5 g/kg bw (estimated) no mortality	54

Abbreviations: CFR – Code of Federal Regulations; FHSA – Federal Hazardous Substances Act; OECD – Organisation for Economic Co-operation and Development.

In the ADME study described previously, in which Wistar rats (number of animals per group not specified) were fed a diet containing 5 or 10% polyglyceryl ester (prepared mostly with stearic and oleic acid; duration of dosing not specified, however some animals were fed the test diet for up to 14 mo, and some were maintained through 3 generations), no abnormalities were observed upon microscopic examination of tissues (details not provided).[33]

Developmental and Reproductive Toxicity Studies

Oral

Polyglyceryl Esters – general. A test group of 22 rats was fed a diet containing 1.5% polyglyceryl ester for 3 generations.[32] A group of 28 rats was used as a control. The animals were kept for over 1 year without significant variation in fertility or reproductive performance. Gross and microscopic examination of the third generation revealed no consistent abnormality attributable to the test substance. No details were provided.

Polyglyceryl-3 Diisostearate. A combined repeated dose oral toxicity study with a reproduction/developmental toxicity screening test (OECD Guideline 422) was conducted in Wistar rats.[39] The animals were dosed once daily by gavage with 0, 100, 300, or 1000 mg/kg bw/day 1,2,3-propanetriol, homopolymer, diisooctadecanoate (n not defined; this substance is most likely Polyglyceryl-3 Diisostearate) in corn oil. Initially, the groups consisted of 12 males and 12 females. However, because a disturbance of the light/dark cycle was believed to cause a reduction in mating rate of the females of the first delivery, additional male and female rats were added in a second delivery for breeding to meet guideline requirements for the number of gravid females per group. All (1st and 2nd delivery) animals were subjected to the same conditions of the study, with the exception that the males of the second delivery were necropsied on day 24 after mating, not on day 16 of mating. Therefore, Polyglyceryl-3 Diisostearate was administered to male rats for up to 28 days (first delivery) and up to 41 days (second delivery) and to female rats for 14 days prior to mating, through the mating and gestation periods, and until the F_1 generation reached day 4 post-partum.

Because an impact caused by the light/dark cycle disturbance could not be excluded (i.e., a prolonged duration of gestation and an increased post-implantation loss at the high dose), the study was repeated with a third delivery with control and high-dose groups under proper light conditions. The test article was administered to12 male rats/group for 33 days and to12 female rats/group for 14 days prior to mating, through mating and gestation, and until day 4 post-partum.

Five males and 5 females/group killed at the end of the study were selected for hematology and clinical chemistry examinations, and some additional organs were weighed. The NOEL and NOAEL for systemic effects were ≥300 mg/kg bw/day and ≥1000 mg/kg bw/day 1,2,3-propanetriol, homopolymer, diisooctadecanoate, respectively, in both males and females. No adverse effects on body weights and body weight gains, feed consumption, hematology, clinical chemistry, neurobehavior, or gross or microscopic lesions were observed. Statistically significant increases in absolute and relative liver and kidney weights in males and females of the 1000 mg/kg bw/day were not considered to be adverse effects because there was no evidence for an impairment of organ function by clinical pathology and histopathology. Additionally, increases in the absolute and relative heart weights in high-dose females were without histopathological correlation and considered to be incidental.

Genotoxicity Studies

Genotoxicity studies are summarized in Table 13.[20,38-44,46,48,56-65]

Generally, negative results were obtained in genotoxicity tests. Polyglyceryl-2 Oleate, Polyglyceryl-2 Diisostearate, and 1,2,3-propanetriol, homopolymer, diisooctadecanoate were not genotoxic in the Ames test, mammalian cell gene mutation assay, or chromosomal aberration assay, with or without metabolic activation. Polyglyceryl-3 Caprate, Polyglyceryl-3 Caprylate, Polyglyceryl-3 Laurate, Polyglyceryl-3 Isostearate, Polyglyceryl-4 Caprate, Polyglyceryl-4 Isostearate, Polyglyceryl-4 Laurate/Succinate, Glyceryl/Polyglyceryl-6 Isostearate/Behenate Esters, Diisostearoyl Polyglyceryl-3 Dimer Dilinoleate, Macadamia Seed Oil Polyglyceryl-6 Esters Behenate, Polyglyceryl-8 Decabehenate/Caprate, Polyglyceryl-8 Decaerucate/Decaisostearate/Decaricinoleate, Polyglyceryl-6 Decaethylhexanoate, Polyglyceryl-10 Pentaisostearate, and Polyglyceryl-10 Nonaisostearate were negative in the Ames test. Polyglyceryl-6 Caprylate/CapratePolyglyceryl-10 Laurate (~60% pure) gave equivocal results in the absence and positive results in the presence of metabolic activation when tested at concentrations up to 125 and 2250 µg/ml, respectively, in a chromosomal aberration assay using Chinese hamster V79 cells, but was not clastogenic in a chromosomal aberration assay in human peripheral lymphocytes, with or without activation.

According to the European Food Safety Authority (EFSA) Panel, the impurities of polyglyceryl fatty acid esters, i.e. free fatty acids and their esters, have no structural alerts for genotoxicity.[23]

Carcinogenicity Studies

Oral

In a 2-yr study (summarized previously in "Chronic Toxicity"), 28 male and 28 female rats were fed 5% polyglyceryl ester in the diet.[32] Tumor incidence and tumor distribution were similar in control and test groups.

Table 13. Genotoxicity Studies.

Test Article	Concentration/Vehicle	Test System	Procedure	Results	Reference
IN VITRO					
Polyglyceryl Monoesters					
Polyglyceryl-2 Oleate	333-5000 μg/plate in DMSO	*S. typhimurium* TA1535, TA1537, TA98 and TA100; *E. coli* WP2uvrA	Ames test, with and without metabolic activation (OECD Guideline 471)	not mutagenic cytotoxic at 5000 μg/plate in strain TA1537 without activation and TA1535 with activation positive and vehicle controls gave expected results	46
Polyglyceryl-2 Oleate	10-150 μg/ml, 4-h exposure with and without activation 5-75 μg/ml, 24-h exposure without activation in DMSO	mouse lymphoma L5178Y cells	mammalian cell gene mutation assay, with and without metabolic activation (OECD test guideline 476)	not genotoxic cytotoxic without activation at ≥30 μg/ml and with activation at ≥50 μg/m positive and vehicle controls gave expected results	46
Polyglyceryl-2 Oleate	25-150 and 50-200 μg/ml, 4-h exposure without and with activation, respectively; 25-100 μg/ml, 22-h exposure without activation in DMSO	human peripheral blood lymphocytes	chromosomal aberration assay, with and without metabolic activation (OECD Guideline 473)	not genotoxic positive and vehicle controls gave expected results	46
Polyglyceryl-3 Caprate	not provided	not provided	Ames test; OECD 471	no evidence of mutagenic activity	40
Polyglyceryl-3 Caprylate	not provided	not provided	Ames test; OECD 471	no evidence of mutagenic activity	41
Polyglyceryl-3 Laurate	50-5000 μg/plate (vehicle not specified)	not provided	Ames test; details not provided	negative	56
Polyglyceryl-3 Isostearate	not provided	not provided	Ames test; details not provided	no evidence of mutagenic activity	42
Polyglyceryl-4 Caprate	not provided	not provided	Ames test; OECD 471	no evidence of mutagenic activity	44
Polyglyceryl-4 Isostearate	not provided	not provided	Ames test; details not provided	negative	43
Polyglyceryl-4 Laurate/ Succinate	1.5-5000 μg/plate in distilled water	*S. typhimurium* TA1535, TA1537, TA98, TA100; *E. coli* WP2uvrA	Ames test, with and without metabolic activation	not mutagenic cytotoxicity was observed in *S. typhimurium* with several concentrations positive and vehicle controls gave expected results	57
Glyceryl/Polyglyceryl-6 Isostearate/Behenate Esters	50-5000 μg/plate in acetone	*S. typhimurium* TA1535, TA1537, TA98, TA100; *E. coli* WP2uvrA	Ames test, assayed in triplicate, with and without metabolic activation; (2 experiments performed)	not mutagenic positive and vehicle controls gave expected results	58

(continued)

Table 13. (continued)

Test Article	Concentration/Vehicle	Test System	Procedure	Results	Reference
Polyglceryl-6 Caprylate/ Caprate	0.15-5000 μg/plate in distilled water	*S. typhimurium* TA1535, TA1537, TA98, TA100; *E. coli* WP2uvrA	Ames test, with and without metabolic activation	not mutagenic cytotoxicity was observed with several concentrations positive and vehicle controls gave expected results	[59]
Polyglyceryl-10 Laurate (~60% pure, with ~40% polyglycerin-10 and ~2% sodium laurate)	0-125 μg/ml without activation 0-2250 μg/ml with activation	Chinese hamster V79 cells	chromosomal aberration assay; 20 h harvest time	equivocal without and positive with activation without activation, a slight increase of aberrant cells was seen with 50 and 70, but not 65 μg/ml with activation, the aberration rates with 1250 and 1500 μg/mL were significantly increased, and a dose relationship was observed	[20]
Polyglyceryl-10 Laurate (~60% pure, with ~40% polyglycerin-10 and ~2% sodium laurate)	10-1000 μg/ml, 4-h exposure without and with activation 10-500 μg/ml, 20-h exposure without activation	human peripheral lymphocytes	chromosomal aberration assay; 20 h harvest time metaphase analysis was performed with cultures exposed to 50-250 μg/ml for 4 h and 50-300 μg/ml for 20 h without metabolic activation, and to 125 -500 μg/ml with metabolic activation	not clastogenic; no significant increases in chromosomal aberrations were observed in any treatment group at any dose level	[20]
Polyglyceryl Multi-esters					
Polyglyceryl-2 Diisostearate	4-5000 μg/plate in acetone	*S. typhimurium* TA1535, TA1537, TA98, TA100	Ames test, with and without metabolic activation	not mutagenic	[38]
Polyglyceryl-2 Diisostearate	3.16-5000 μg/ml, 4-h exposure without and with activation 10-5000 μg/ml, 20-h exposure without activation cell culture medium (MEM) served as the vehicle	Chinese hamster lung fibroblasts V79 cells	mammalian cell gene mutation assay, with and without metabolic activation; 20 h harvest time chromosomal aberrations were evaluated in cultures exposed to 1000-5000 μg/ml for 4 h and 50-5000 μg/ml for 20 h without metabolic activation, and to 100 -5000 μg/ml with metabolic activation	no evidence of a concentration-related positive response	[38]

(continued)

Table 13. (continued)

Test Article	Concentration/Vehicle	Test System	Procedure	Results	Reference
Polyglyceryl-2 Diisostearate	3.16-5000μg/ml in cell culture medium (MEM)	Chinese hamster lung fibroblasts V79 cells	chromosomal aberration assay, with and without metabolic activation	not clastogenic	38
1,2,3-propanetriol, homopolymer, diisooctadecanoate (n not defined; most likely Polyglyceryl-3 Diisostearate)	8-5000 μg/plate in Tween 80/bidistilled water	*S. typhimurium* TA1535, TA1537, TA1538, TA98 and TA100	Ames test, with and without metabolic activation	not mutagenic positive and vehicle controls gave expected results	39
1,2,3-propanetriol, homopolymer, diisooctadecanoate (n not defined; most likely Polyglyceryl-3 Diisostearate)	3.13-200 μg/ml, 4-h exposure without activation 3.13-150 μg/ml, 4-h exposure with activation in DMSO	CHO cells	mammalian cell gene mutation assay, with and without metabolic activation; 4-h exposure	not genotoxic positive and negative controls gave expected results	39
1,2,3-propanetriol, homopolymer, diisooctadecanoate (n not defined; most likely Polyglyceryl-3 Diisostearate)	12.5-800μg/ml without and 3.13-800μg/ml with activation, in DMSO	Chinese hamster lung fibroblasts V79 cells	chromosomal aberration assay, with and without metabolic activation; 4 and 18-h exposure	not clastogenic	39
Diisostearoyl Polyglyceryl-3 Dimer Dilinoleate	not provided	not provided	Ames test; OECD 471	negative	48
Macadamia See Oil Polyglyceryl-6 Esters Behenate	50-5000 μg/plate in acetone	*S. typhimurium* TA1535, TA1537, TA98, TA100; *E. coli* WP2uvrA	Ames test, assayed in triplicate, with and without metabolic activation; (2 experiments performed)	not mutagenic positive and vehicle controls gave expected results	60
Polyglyceryl-8 Decabehenate/Caprate	50-5000 μg/plate in tetrahydrofuran	*S. typhimurium* TA1535, TA1537, TA98, TA100; *E. coli* WP2uvrA	Ames test, assayed in triplicate, with and without metabolic activation; (2 experiments performed)	not mutagenic positive and vehicle controls gave expected results	61
Polyglyceryl-8 Decaerucate/ Decaisostearate/ Decaricinoleate	50-5000 μg/plate in tetrahydrofuran	*S. typhimurium* TA1535, TA1537, TA98, TA100; *E. coli* WP2uvrA	Ames test, assayed in triplicate, with and without metabolic activation; (2 experiments performed)	not mutagenic positive and vehicle controls gave expected results	62
Polyglyceryl-10 Decaethylhexanoate	range-finding test: 10-5000 μg/plate; main experiments: 5-5000 μg/plate; in DMF	*S. typhimurium* TA1535, TA1537, TA98, TA100; *E. coli* WP2uvrA	Ames test, with and without metabolic activation	not mutagenic positive and vehicle controls gave expected results	63
Polyglyceryl-10 Pentaisostearate	range-finding test: 10-5000 μg/plate; main experiments: 5-5000 μg/plate; in acetone	*S. typhimurium* TA1535, TA1537, TA98, TA100; *E. coli* WP2uvrA	Ames test, with and without metabolic activation	not mutagenic positive and vehicle controls gave expected results	64

(continued)

Table 13. (continued)

Test Article	Concentration/Vehicle	Test System	Procedure	Results	Reference
Polyglyceryl-10 Nonaisostearate	50-5000 μg/plate in tetrahydrofuran	*S. typhimurium* TA1535, TA1537, TA98, TA100; *E. coli* WP2uvrA	Ames test, assayed in triplicate, with and without metabolic activation; (2 experiments performed)	not mutagenic positive and vehicle controls gave expected results	[65]

Abbreviations: CHO – Chinese hamster ovary; DMF – N,N-dimethylformamide; DMSO – dimethyl sulfoxide; MEM – minimum essential medium; OECD – Organisation for Economic Co-operation and Development.

Dermal Irritation and Sensitization Studies

Dermal irritation and sensitization studies are summarized in Table 14.[38,40-44,46-48,56,66-71,71-74,74-97]

Apricot Kernel Oil Polyglyceryl-4 Esters and Palm Oil Polyglyceryl-4 Esters were classified as non-irritant in the SkinEthic™ irritation test, Polyglyceryl-4 Laurate/Sebacate, Polyglyceryl-4 Laurate/Succinate, and Polyglyceryl-6 Caprylate/Caprate were considered to be non-irritant in the EpiSkin™ model for skin irritation, and Polyglyceryl-10 Decaethylhexanoate. Polyglyceryl-10 Pentaisostearate were considered non-irritating using the EpiDerm™ model for skin irritation.

In rabbits, Polyglyceryl-3 Caprate, a polyglyceryl mono/diester of capric acid (read-across for Polyglyceryl-3 Caprylate), Polyglyceryl-4 Caprate, Polyglyceryl-3 Diisostearate, 1,2,3-propanetriol, homopolymer, diisooctadecanoate, Macadamia Seed Oil Polyglyceryl-6 Esters Behenate, Polyglyceryl-8 Decabehenate/Caprate, and Polyglyceryl-8 Decaerucate/Decaisostearate/Decaricinoleate were not irritating to the skin. Polyglyceryl-2 Isostearate, Glyceryl/Polyglyceryl-6 Isostearate, and Polyglyceryl-10 Nonaisostearate were mildly irritating, Polyglyceryl-2 Diisostearate was slightly irritating, and Polyglyceryl-3 Isostearate and Polyglyceryl-3 Oleate were moderate irritants in rabbit skin. Polyglyceryl-3 Caprate, Polyglyceryl-3 Caprylate, Polyglyceryl-3 Isostearate, Polyglyceryl-4 Caprate, Polyglyceryl-4 Isostearate, Glyceryl/Polyglyceryl-6 Isostearate/Behenate Esters, Polyglyceryl-2 Diisostearate, Polyglyceryl-4 Diisostearate/Polyhydroxystearate/Sebacate (read-across for Diisostearoyl Polyglyceryl-3 Dimer Dilinoleate), Macadamia Seed Oil Polyglyceryl-6 Esters Behenate, Polyglyceryl-8 Decabehenate/Caprate, and Polyglyceryl-8 Decaerucate/Decaisostearate/Decaricinoleate were not sensitizers in guinea pig studies; Polyglyceryl-10 Nonaisostearate was not a sensitizer in a local lymph node assay. Polyglyceryl-3 Diisostearate was not a sensitizer in guinea pigs in one sensitization study (50% at induction and challenge; 25% at rechallenge), but results were inconclusive in a guinea pig maximization test (0.1% or 0.2% at intradermal induction; 40% at epicutaneous induction; 10 and 15% at challenge; 8 and 4% at rechallenge).

In clinical studies, 7% Polyglyceryl-2 Isostearate elicited slight irritation, and erythema was observed in 24-h occlusive patches tests of undiluted Polyglyceryl-10 Decaethylhexanoate (3/43 subjects and 3 controls) and Polyglyceryl-10 Pentaisostearate (1/43 subjects). Undiluted Glyceryl/Polyglyceryl-6 Isostearate/Behenate Esters, 5% Polyglyceryl-10 Laurate, 10% Polyglyceryl-10 Myristate, 5% Polyglyceryl-10 Isostearate, 5% Polyglyceryl-10 Oleate, 10% Polyglyceryl-10 Stearate, a mixture containing 60% Polyglyceryl-10 Eicosanedioate/Tetradecanedioate/40% glycerin, undiluted Polyglyceryl-2 Sesquiisostearate, 20% active 1,2,3-propanetriol, homopolymer, diisooctadecanoate, undiluted Macadamia See Oil Polyglyceryl-6 Esters Behenate, undiluted Polyglyceryl-8 Decabehenate/Caprate, 5% Polyglyceryl-10 Diisostearate, 50% Polyglyceryl-10 Pentaisostearate, and Polyglyceryl-10 Decaoleate (concentration not given) were not skin irritants. Undiluted Polyglyceryl-3 Laurate, Triisostearoyl Polyglyceryl-3 Dimer Dilinoleate, Polyglyceryl-10 Decaethylhexanoate, and Polyglyceryl-10 Pentaisostearate were not irritants or sensitizers (Table 15).

Photosensitization/Phototoxicity

Animal

Polyglyceryl-10 Nonaisostearate. The phototoxicity and photosensitization potential of Polyglyceryl-10 Nonaisostearate were evaluated in female albino Dunkin-Hartley guinea pigs. In the phototoxicity study, 0.5 ml undiluted Polyglyceryl-10 Nonaisostearate was[39,47] applied to the right flank of 10 guinea pigs.[82] The animals were exposed to the maximal non-erythematous dose of ultraviolet (UV) radiation, and exposure was first to 150 mJ/cm^2 UVB and then to 7000 mJ/cm^2 UVA (source: Biotronic, Vilbert Lourmat). A non-irradiated test site served as a negative control, and 8-methoxypsoralen was used as the positive control. Reactions were scored 24 and 48 h after irradiation. No cutaneous reactions were observed; Polyglyceryl-10 Nonaisostearate was not phototoxic in guinea pigs.

In the photosensitization study, 3 induction applications were made, with 2 day intervals between applications, of 0.5 ml undiluted Polyglyceryl-10 Nonaisostearate (determined to be the maximal non-irritant concentration in a preliminary test) to a 25 cm^2 area of interscapular skin of 11

Table 14. Dermal Irritation and Sensitization.

Test Article	Concentration/Dose	test system/# per Group	Procedure	Results	Reference
Alternative studies					
Polyglyceryl Monoesters					
Apricot Kernel Oil Polyglyceryl-4 Esters	16 ± 0.5 µl	reconstituted human epidermis	SkinEthic™ irritation test; test material was applied for 42 min; cell viability assessment by MTT method after 42 h	classified as non-irritant	47
Palm Oil Polyglyceryl-4 Esters	16 ± 0.5 µl	reconstituted human epidermis	SkinEthic™ irritation test; protocol as described previously	classified as non-irritant	47
Polyglyceryl-4 Laurate/ Sebacate	neat	reconstituted human epidermis	EpiSkin™ model; 15 min treatment period with a 42 h post-exposure incubation period; cell viability was measured by MTT reduction	considered to be non-irritant relative mean viability was 105.4%	66
Polyglyceryl-4 Laurate/ Succinate	neat	reconstituted human epidermis	EpiSkin™ model; protocol as described previously	considered to be non-irritant relative mean viability was 104.1%	67
Polyglyceryl-6 Caprylate/ Caprate	neat	reconstituted human epidermis	EpiSkin™ model; protocol as described previously	considered to be non-irritant relative mean viability was 105.7%	68
Polyglyceryl-10 Decaethylhexanoate	neat; 30 µl	reconstituted human epidermis (surface: 0.63 cm^2); 3 tissues	EpiDerm™ model performed according to Method B.46; 60 min exposure time, followed by a 42-h incubation period; cell viability was measured in an MTT assay	considered to be non-irritating avg. viability was 101.4% of negative control avg. value	69
Polyglyceryl-10 Pentaisostearate	neat; 30 µl	reconstituted human epidermis (surface: 0.63 cm^2); 3 tissues	EpiDerm™ model; protocol as described previously	considered to be non-irritating avg. viability was 94.7% of negative control avg. value	70
ANIMAL					
Polyglyceryl Monoesters					
Polyglyceryl-2 Isostearate	undiluted; 0.5 ml	3 NZW rabbits	4-h, 2 x 3 cm semi-occlusive patch applied to clipped skin	PII of 0.8 (mildly irritating); very slight erythema was observed in all 3 animals and resolved in 2-7 days	83
Polyglyceryl-3 Caprate	not provided	rabbit	OECD TG 404 (acute dermal irritation/corrosion)	not irritating	40
Polyglyceryl-3 Caprate	not provided	guinea pig	OECD TG 406 (sensitization)	no skin sensitization effect	40
a polyglyceryl mono/diester of capric acid (C10) (provided as read-across for Polyglyceryl-3 Caprylate)	not provided	rabbit	OECD TG 404 (acute dermal irritation/corrosion)	not irritating	41
Polyglyceryl-3 Caprylate	not provided	mouse	OECD TG 429; LLNA	not sensitizing	41
Polyglyceryl-3 Isostearate	not provided	rabbit	FHSA, 16 CFR 1500.41	moderately irritating	42
Polyglyceryl-3 Isostearate	not provided	guinea pig	OECD TG 406 (sensitization)	no skin sensitization effect	42
Polyglyceryl-3 Oleate	not provided	rabbit	FHSA, 16 CFR 1500.41	moderately irritating	43
Polyglyceryl-4 Caprate	not provided	rabbit	OECD TG 404 (acute dermal irritation/corrosion)	not irritating	44
Polyglyceryl-4 Caprate	not provided	guinea pig	OECD TG 406 (sensitization)	no skin sensitization effect	44
Polyglyceryl-4 Isostearate	not provided	guinea pig	OECD TG 406 (sensitization)	no sensitizing effect	43
Glyceryl/Polyglyceryl-6 Isostearate/Behenate Esters	applied neat; 0.5 ml	1 NZW rabbit	single 3 min, 1 h, and 4 h semi-occlusive application using a 2.5 cm^2 patch	no irritation observed after 3 min or 1 h (4 results included below)	72
		2 NZW rabbits	single 4-h semi-occluded patch to clipped skin on the dorsal/flank are	PII of 0.3 (mild irritant); very slight erythema in 2 animals at 24 h was resolved by 48-h	
Glyceryl/Polyglyceryl-6 Isostearate/Behenate Esters	12.5, 25, 50% in liquid paraffin; undiluted	2 or 3 female albino guinea pigs	preliminary sighting tests for sensitization study; 24 h occlusive patch; determination of concentration for topical induction (2 animals) and topical challenge (3 animals)	no skin reactions were observed in either group	73

(continued)

Table 14. (continued)

Test Article	Concentration/Dose	test system/# per Group	Procedure	Results	Reference
Glyceryl/Polyglyceryl-6 Isostearate/Behenate Esters	intradermal induction: 25% in olive oil topical induction: 100% topical challenge: 100%; 50% in liquid paraffin	female albino guinea pigs; 10 test and 5 control animals	GPMT intradermal induction: 3 pairs of injections on day 1: 1) FCA + isotonic sodium chloride (1:1) 2) test article 3) test article + FCA/isotonic sodium chloride topical induction: 48-h occlusive patch on day 7 challenge: 24-h occlusive patches (study day not specified)	not sensitizing; no reactions were observed	[73]
			Polyglyceryl Multi-Esters		
Polyglyceryl-2 Diisostearate	undiluted; 0.5 ml	3 NZW rabbits	4-h, 2.5 cm^2 semi-occlusive patch	non-irritating; 1 animal had well-defined erythema 24 h after patch removal	[38]
Polyglyceryl-2 Diisostearate	1 and 10% in saline, and undiluted; 0.5 ml	2 Albino-Himalayan-Kaninchen rabbits/gp	24-h, 2.5 cm^2 occlusive patch on intact and abraded skin	slightly irritating; with undiluted test substance, distinct erythema and slight to distinct edema was observed in both animals; with 10%, marked erythema was observed in 1 animal for a short time; with 1%, slight erythema in 1 animal	[38]
Polyglyceryl-2 Diisostearate	induction: 100% challenge: 20% in acetone	20 female Pirbright-White guinea pigs/gp	Buehler test using occlusive patches; 10 control animals were exposed to an ethanol-water (80:20) mixture	non-sensitizing	[38]
Polyglyceryl-3 Diisostearate	not specified	3 NZW rabbits	method was described as OECD Guideline 404, but study details were not provided; test sites were scored according to Draize	not irritating; slight erythema was seen on skin of all 3 animals tested starting 1 hour following application, and this effect was fully reversible within by 72 h	[46,47]
Polyglyceryl-3 Diisostearate	5-50% in paraffin perliquid DAB 8	3 Pirbright-White guinea pigs	in a range-finding study for a sensitization test, the test material was applied to the shaved flank for 6 h	not irritating after 24 h	[46]
1,2,3-propanetriol, homopolymer, diisooctadecanoate (n not defined; most likely Polyglyceryl-3 Diisostearate)	undiluted; 0.5 ml	4 male rabbits	4-h occlusive patch to a shaved 6.25 cm^2 area	not irritating; very slight to slight erythema in 3/4 animals at 24 and 48 h; slight and moderate erythema in 2/4 animals at 72 h; the effects were reversible in all animals within 7 d	[39]
Polyglyceryl-3 Diisostearate	induction: 50% in paraffin perliquid DAB 8 (induction 1) or in petrolatum (inductions 2 and 3) challenge: 50% paraffin perliquid DAB 8 rechallenge: 25%	20 (test) or 19 (control) female Pirbright-White guinea pigs	test sites were pre-treated with 10% SDS in petrolatum, 24 h prior to each induction application epicutaneous induction: 6-h occlusive patches (0.2 ml) applied 1x/wk for 3 wk; half of the controls were pretreated with SDS 24 h prior to application of patches containing vehicle challenge: 6-h occlusive patch (0.1 ml) applied on day 28 rechallenge: 6-h occlusive patch (0.1 ml) applied on day 35	non-sensitizing very slight skin reactions (erythema and edema) were seen at 24-h following the challenge and rechallenge patches in test and control animals; these reactions were reversible in all animals within 48 h and were attributed to irritation	[46]

(continued)

Table 14. (continued)

Test Article	Concentration/Dose	test system/# per Group	Procedure	Results	Reference
Polyglyceryl-3 Diisostearate	intradermal induction: 0.1% or 0.2% topical induction: 40% challenge: 10 and 15% rechallenge: 8 and 4% vehicle was paraffinum perliquidum DAB 8 for all phases	20 (test) or 19 (control) female Pirbright-White guinea pigs	GPMT, no positive control intradermal induction: 3 pairs of injections on day 1: 1) FCA + physiological saline in water (1:1) 2) 0.1% test article 3) 0.2% test article + FCA/ physiological saline in water (1:1) topical induction: 48-h occlusive patch on day 8 (0.1 ml) challenge: 24-h occlusive patches on day 22 (0.1 ml) rechallenge: 24 h occlusive patches on day 29 (0.1 ml)	results were inconclusive intradermal induction: 0.1 ml FCA (50% (v/v)), the test substance (0.1% (v/v)) and a 1:1 mixture of the test substance with FCA caused moderate to severe skin reactions; in the control group, 0.1 ml of the vehicle resulted in moderate skin reactions epicutaneous induction: after treatment with 40% of the test substance, the injection sites of the intradermal induction were bloody and purulent and at a later stage, this sites showed necrotic and scabby skin lesions challenge with 15%: at 24 h, erythema (1) was observed in 9 test and 2 control animals; edema (2) in 1 test animal, and edema (1) in 2 test and 2 control animals; at 48 h, erythema (2) in 1 test animal (that was 0 at 24 h), erythema (1) in 7 test animals, same edema scores as at 24 h for test animals, no edema in controls challenge with 10%: at 24 h, erythema (3) in 1 and erythema (1) in 5 test animals, edema (3) in 1 and edema (2) in 1 test animal; at 48 h, erythema (3) and edema (3) in 1 animal and erythema (1) and edema (1) in 1 test animal; no erythema or edema in controls at 24 or 48 h rechallenge with 8%: at 24 h, erythema (1) in 6 test and 4 control animals, no edema in test or controls; at 48-h, erythema (1) in 3 test and 1 control animals, no edema in test or controls rechallenge with 4%: no erythema or edema	[46]
Polyglyceryl-4 Diisostearate/ Polyhydroxystearate/ Sebacate (provided as read-across for Diisostearoyl Polyglyceryl-3 Dimer Dilinoleate due to similar MW and chemical characterization)	not provided	guinea pig	OECD 406 (sensitization)	not sensitizing	[48]
Macadamia Seed Oil Polyglyceryl-6 Esters Behenate	applied neat; 0.5 ml	1 NZW rabbit	single 3 min, 1 h, and 4 h semi-occlusive application using a 2.5 cm^2 patch	no irritation observed after 3 min or 1 h (4 results included below)	[74]
		2 NZW rabbits	single 4-h semi-occluded patch to clipped skin on the dorsal/flank area	PII of 0.0 (non-irritant; very slight erythema was observed at two sites 1 h after patch removal	

(continued)

Table 14. (continued)

Test Article	Concentration/Dose	test system/# per Group	Procedure	Results	Reference
Macadamia Seed Oil Polyglyceryl-6 Esters Behenate	12.5, 25, 50% in liquid paraffin; undiluted	2 or 3 female albino guinea pigs	preliminary sighting tests for sensitization study; 24 h occlusive patch; determination of concentration for topical induction (2 animals) and topical challenge (3 animals)	no skin reactions were observed in either group	[75]
Macadamia Seed Oil Polyglyceryl-6 Esters Behenate	intradermal induction: 25% in olive oil topical induction: 100% topical challenge: 100%; 50% in liquid paraffin	female albino Dunkin Hartley guinea pigs; 10 test and 5 control animals	GPMT intradermal induction: 3 pairs of injections on day 1: 1) FCA + isotonic sodium chloride (1:1) 2) test article 3) test article + FCA/isotonic sodium chloride topical induction: 48-h occlusive patch on day 7 challenge: 24-h occlusive patches (study day not specified)	not sensitizing; no reactions were observed	[75]
Polyglyceryl-8 Decabehenate/Caprate	applied neat; 0.5 g moistened with 0.5 ml distilled water	1 NZW rabbit	single 3 min, 1 h, and 4 h semi-occlusive application using a 2.5 cm^2 patch	no irritation observed after 3 min or 1 h (4 results included below)	[76]
		2 NZW rabbits	single 4-h semi-occluded patch to clipped skin on the dorsal/flank area	PII of 0.0 (non-irritant; very slight erythema was observed at two sites 1 h after patch removal	
Polyglyceryl-8 Decabehenate/Caprate	7.5, 15, 30, and 60% in liquid paraffin	2 or 3 female albino guinea pigs	preliminary sighting tests for sensitization study; 24 h occlusive patch; determination of concentration for topical induction (2 animals) and topical challenge (3 animals)	no skin reactions were observed in either group	[77]
Polyglyceryl-8 Decabehenate/Caprate	intradermal induction: 5% in olive oil topical induction: 60% in liquid paraffin topical challenge: 30 and 60% in liquid paraffin	female albino Dunkin Hartley guinea pigs; 10 test and 5 control animals	GPMT intradermal induction: 3 pairs of injections on day 1: 1) FCA + isotonic sodium chloride (1:1) 2) test article 3) test article + FCA/isotonic sodium chloride topical induction: 10% SLS in vaseline was applied on day 6; 48-h occlusive patch on day 7 challenge: 24-h occlusive patches (study day not specified)	not sensitizing; no reactions were observed	[77]
Polyglyceryl-8 Decaerucate/ Decaisostearate/ Decaricinoleate	applied neat; 0.5 ml	3 NZW rabbits	single 4 h semi-occlusive application to clipped skin on the dorsal/flank area using a 2.5 cm^2 patch	PII of 0.0 (non-irritant)	[78]
Polyglyceryl-8 Decaerucate/ Decaisostearate/ Decaricinoleate	undiluted and 25, 50, and 75% in arachis oil BP	2 male albino guinea pigs	preliminary sighting tests for sensitization study; animals were injected with FCA, and after 145 days, a 48 h occlusive patch was applied	1 h after patch removal, both animals had erythema scores of 2 (moderate and confluent erythema) at concentrations 50-100%, one animal had an erythema score of 2 and one had a score of 1 discrete or patchy erythema) with 25%; all reactions resolved by 24 h	[79]
Polyglyceryl-8 Decaerucate/ Decaisostearate/ Decaricinoleate	undiluted and 25, 50, and 75% in arachis oil BP	2 male albino guinea pigs	preliminary sighting tests for dermal induction in the sensitization study; 24 h occlusive patch; animals were not part of the main study, but were treated identically to controls up to day 14	1 h after patch removal, 1 animal had a score of 2 for erythema with 100% test article; all other erythema scores were 1 at 1 ; all reactions resolved by 24 h	[79]

(continued)

Table 14. (continued)

Test Article	Concentration/Dose	test system/# per Group	Procedure	Results	Reference
Polyglyceryl-8 Decaerucate/ Decaisostearate/ Decaricinoleate	intradermal induction: 5% in arachis oil BP topical induction: 100% topical challenge: 100%; 75% arachis oil BP	male albino Dunkin Hartley guinea pigs; 10 test and 5 control animals	GPMT; intradermal induction: 3 pairs of injections on day 1: 1) FCA + distilled water (1:1) 2) test article 3) test article + FCA/distilled water topical induction: 48-h occlusive patch (40 mm x 20 mm patch) on day 7 challenge: 24-h occlusive patch (20 mm x 20 mm) on day 21	not sensitizing at 24 h after intradermal induction, all test and control animals had an erythema score of 1 or 2, which was resolved in almost all control animals, but not test animals at 48 h; 1 h after topical induction, there was bleeding from the intradermal injection sites of 8/10 test animals, and at 24 h, 2 animals had an erythema score of 2	79
Polyglyceryl-10 Nonaisostearate	undiluted; 0.5 ml	3 rabbits	24-h closed patch to intact and abraded skin	very slightly irritation; PII = 1.08 PII of untreated patch was 0.42) intact skin: very slight erythema was observed in all 3 animals at 24 h and in 2 animals at 72 h abraded skin: very slight to slight erythema was observed in all 3 animals at 24 h, and slight erythema was still observed at 72 h	81
Polyglyceryl-10 Nonaisostearate	100%; 50 µl	Dunkin Hartley albino guinea pigs, 4/sex	the test material was applied daily for 14 days to a 2 cm x 2 cm area of the right flank; paraffin oil was applied to the left flank and served as the control	practically non-irritant; the wk 1 and maximum WII was 0.06; the week 2 WII was 0 slight erythema was observed in 3 test animals on day 2	228
Polyglyceryl-10 Nonaisostearate	undiluted and 0, 25, and 50% v/v in acetone/ olive oil (4:1); 25 µl/ear	4 CBA/Ca mice	LLNA; the test material was applied to the dorsal surface of each ear for 3 consecutive days; all mice were injected with ^{3}HTdR on day 6	non-sensitizer; stimulation index of 0.68, 0.70, and 0.87 with 25, 50, and 100%	80
			HUMAN		
			Polyglyceryl Monoesters		
Polyglyceryl-2 Isostearate	7% in ESTOL 1512 (i.e., isopropyl myristate); 0.4 ml	30 subjects	three 24-h occlusive patches, with 24 to 48-h between applications	elicited slight irritation; significantly less irritating than the positive control (0.3% sodium lauryl sulfate) and significantly more irritating than the negative control (deionized water) (p=0.05)	83
Polyglyceryl-3 Laurate	100%; 150 µl/patch	114 subjects	HRIPT	not an irritant or a sensitizer	56
Glyceryl/Polyglyceryl-6 Isostearate/Behenate Esters	100%; 0.01 g	45 subjects	24-h occlusive patch test using Finn chambers applied to the upper arm; petrolatum and 0.5% "soap" were used as controls	no reactions 1 or 24 h after patch removal	84
Polyglyceryl-10 Laurate	5% in purified water; 0.03 g	35 subjects	24-h occlusive patch applied to the upper arm	not irritating; no responses were observed 1 or 24 h after patch removal	85
Polyglyceryl-10 Myristate	5% in purified water; 0.03 g	35 subjects	24-h occlusive patch applied to the upper arm	not irritating; no responses were observed 1 or 24 h after patch removal	85
Polyglyceryl-10 Myristate	10%	48 subjects	48-h occlusive patch test	negative	86
Polyglyceryl-10 Isostearate	5% in purified water; 0.03 g	35 subjects	24-h occlusive patch applied to the upper arm	not irritating; no responses were observed 1 or 24 h after patch removal	85
Polyglyceryl-10 Oleate	5% in purified water; 0.03 g	35 subjects	24-h occlusive patch applied to the upper arm	not irritating; no responses were observed 1 or 24 h after patch removal	85
Polyglyceryl-10 Stearate	10%	48 subjects	48-h occlusive patch test	non-irritating	87

(continued)

Table 14. (continued)

Test Article	Concentration/Dose	test system/# per Group	Procedure	Results	Reference
60% Polyglyceryl-10 Eicosanedioate/ Tetradecanedioate/40% glycerin mixture	undiluted	45 subjects	closed patch test; details not provided	negative	88
			Polyglyceryl Multi-Esters		
Polyglyceryl-2 Sesquiisostearate	undiluted	50 subjects	24-h semi-occlusive patches	not irritating	38
1,2,3-propanetriol, homopolymer, diisooctadecanoate (n not defined; likely Polyglyceryl-3 Diisostearate)	20% "active substance" in "cosmetic alcohol"; 70 µl	20 subjects	24-h occlusive patches	not irritating slight erythema in 3 and slight scaling in 2 subjects	39
Diisostearoyl Polyglyceryl-3 Dimer Dilinoleate	not provided	no provided	occlusive patch test; details not provided	"no concern"	48
Triisostearoyl Polyglyceryl-3 Dimer Dilinoleate	100%; 150 µl/patch	103 subjects	HRIPT	not an irritant or a sensitizer	56
Macadamia Seed Oil Polyglyceryl-6 Esters Behenate	100%; 0.01 g	45 subjects	24-h occlusive patch test using Finn chambers applied to the upper arm; petrolatum and 0.5% "soap" were used as controls	no reactions 1 or 24 h after patch removal	89
Polyglyceryl-8 Decabehenate/Caprate	100%; 0.01 g	43 subjects	24-h occlusive patch test using Finn chambers applied to the upper arm; petrolatum and 0.5% "soap" were used as controls	no reactions 1 or 24 h after patch removal	90
Polyglyceryl-10 Decaethylhexanoate	100%	43 subjects	24-h occlusive patch test using Finn chambers applied to the upper arm; purified water served as the control	at 1 h after patch removal, erythema with swelling or with papule was observed at the test and control site of 1 subject, and the test site had well-defined erythema at 24 h after patch removal; well-defined erythema was observed in 3 subjects; 3 controls also had well-defined erythema	91
Polyglyceryl-10 Decaethylhexanoate	100%; 25 µl	50 subjects	induction: 48-h occlusive patches applied using 8 mm Finn chambers 3x/wk for 3 wk challenge: 48-h occlusive patch was applied following a 2-wk non-treatment period	non-irritating and non-sensitizing	92
Polyglyceryl-10 Diisostearate	5% in purified water; 0.03 g	35 subjects	24-h occlusive patch applied to the upper arm	not irritating; no responses were observed 1 or 24 h after patch removal	85
Polyglyceryl-10 Pentaisostearate	50%	44 Japanese subjects	24-h occlusive patch	negative	96
Polyglyceryl-10 Pentaisostearate	100%	43 subjects	24-h occlusive patch test using Finn chambers applied to the upper arm; purified water served as the control	1 subject exhibited well-defined erythema at 1h after patch removal (this subject had erythema with swelling at the control site)	93
Polyglyceryl-10 Pentaisostearate	100%; 25 µl	51 subjects	induction: 48-h occlusive patches applied using 8 mm Finn chambers 3x/wk for 3 wk challenge: 48-h occlusive patch was applied following a 2-wk non-treatment period	non-irritating and non-sensitizing	94
Polyglyceryl-10 Nonaisostearate	0.01 g	35 subjects	24-h occlusive application to the upper arm using a Finn chamber	negative; no responses were observed 1 or 24 h after patch removal	95
Polyglyceryl-10 Decaoleate	neat	44 Japanese subjects	24-h occlusive patch	negative	97

Abbreviations: CFR – Code of Federal Regulations; CPSC – Consumer Product Safety Commission; FCA – Freund's Complete Adjuvant; FHSA Federal Hazardous Substances Act; GPMT – guinea pig maximization test; HET-CAM – hen's egg test chorioallantoic membrane; HRIPT – human repeated insult patch test; 3HTdR – 3H-methyl thymidine; LLNA – local lymph node assay; ME – microemulsion; MW – molecular weight; OECD – Organisation for Economic Co-operation and Development; SDS – sodium dodecyl sulfate; SLS – sodium lauryl sulfate; TG – test guideline; WII – weakly irritation indices.

Table 15. Ocular Irritation Studies.

Test Article	Concentration/ Dose	#/Animals/Grp	Method	Results	Reference
ALTERNATIVE STUDIES					
Polyglyceryl Monoesters					
Polyglyceryl-3 Laurate	10% in corn oil	—	EpiOcular™ tissue model	classified as non-irritating ET_{50} was >256 min	99
ME containing 30% Polyglyceryl-4 Laurate	100 µl	6 replicates	HET-CAM assay; the test article also contained 1 or 2% linoleic acid, 4 or 5% isopropyl palmitate, and 65% water-1,2-pentanediol (1:9) or 63 or 65% water-1,2-pentanediol (1.5:8.5)	non-irritant	30
ME containing 40% Polyglyceryl-4 Laurate	100 µl	6 replicates	HET-CAM; this test article also contained 2% linoleic acid, 5% isopropyl palmitate, 53% water-1,2-pentanediol (1:9)	non-irritant	30
Apricot Kernel Oil Polyglyceryl-4 Esters	0.3 g	# of replicates not stated	HET-CAM; CAM was rinsed with 5 ml physiological saline after 240 s of contact	practically non-irritating	47
Palm Oil Polyglyceryl-4 Esters	0.3 g	# of replicates not stated	HET-CAM; CAM was rinsed with 5 ml physiological saline after 240 s of contact	practically non-irritating	47
Polyglyceryl-4 Laurate/Sebacate	30 µl	human corneal epithelial cells	SkinEthic™ reconstituted HCE model; protocol as described previously	considered to be non-irritant relative mean viability was 85.9%	100
Polyglyceryl-4 Laurate/Succinate	30 µl	human corneal epithelial cells	SkinEthic™ reconstituted HCE model; protocol as described previously	considered to be non-irritant relative mean viability was 70.0%	101,102
Polyglyceryl-6 Caprylate/ Caprate	30 µl	human corneal epithelial cells	SkinEthic™ reconstituted HCE model; protocol as described previously	considered to be non-irritant relative mean viability was 88.4%	229
Polyglyceryl-10 Laurate	0.1 ml	3 rabbit enucleated eyes	REET; test material was applied onto the cornea 0.9% saline was applied to 2 controls	considered unlikely to cause severe ocular irritation *in vivo*	103
Polyglyceryl-10 Myristate	1000 mg/l (max)	rabbit corneal epithelial cells	SIRC-NR	non-irritant	86
Polyglceryl-10 Myristate	0.1 ml	3 rabbit enucleated eyes	REET; test material was applied onto the cornea 0.9% saline was applied to 2 controls	considered unlikely to cause severe ocular irritation *in vivo*	104
Polyglyceryl-10 Isostearate	0.1 ml	3 rabbit enucleated eyes	REET; test material was applied onto the cornea 0.9% saline was applied to 2 controls	considered unlikely to cause severe ocular irritation *in vivo*	114
Polyglyceryl-10 Stearate	1000 mg/l (max)	rabbit corneal epithelial cells	SIRC-NR	non-irritant	87
60% Polyglyceryl-10 Eicosanedioate/ Tetradecanedioate/40% glycerin mixture	undiluted	—	EpiOcular™ test	non-irritant	88

(continued)

Table 15. (continued)

Test Article	Concentration/ Dose	#/Animals/Grp	Method	Results	Reference
			Polyglyceryl Multi-Esters		
Polyglyceryl-2 Dioleate	undiluted; 300 µl	6 eggs	HET-CAM assay	classified as non-irritating Q-score <1.2 (up to 300 s)	46
Diisostearoyl Polyglyceryl-3 Dimer Dilinoleate	not stated	not stated	HET-CAM assay	minor irritation	48
Triisostearoyl Polyglyceryl-3 Dimer Dilinoleate	10% in corn oil	—	EpiOcular™ tissue model	classified as non-irritating ET_{50} was >256 min	49
Polyglyceryl-10 Decaethylhexanoate	undiluted; 100 µl	human-derived epidermal keratinocytes	EpiOcular™ tissue model distilled water served as a negative control	classified as non-irritating ET_{50} was >256 min	105
Polyglyceryl-10 Diisostearate	1000 mg/l (max)	rabbit corneal epithelial cells	SIRC-NR	non-irritant	106
Polyglyceryl-10 Pentaisostearate	undiluted; 100 µl	human-derived epidermal keratinocytes	EpiOcular™ tissue model distilled water served as a negative control	classified as non-irritating ET_{50} was >256 min	107
			ANIMAL		
			Polyglyceryl Monoesters		
Polyglyceryl-3 Caprate	not provided	rabbits; # not stated	OECD 405 (acute eye irritation/corrosion)	not irritating	40
a polyglyceryl mono/diester of capric acid (C10) (provided as read-across for Polyglyceryl-3 Caprylate)	not provided	rabbits; # not stated	OECD 405 (acute eye irritation/corrosion)	not irritating	41
Polyglyceryl-3 Isostearate	not provided	rabbits;# not stated	FHSA/CPSC 16 CFR 1500.42	mildly irritating	42
Polyglyceryl-3 Oleate	not provided	rabbits;# not stated	FHSA/CPSC 16 CFR 1500.42	mildly irritating	43
Polyglyceryl-4 Caprate	not provided	rabbits; # not stated	OECD 405 (acute eye irritation/corrosion)	not irritating	44
Glyceryl/Polyglyceryl-6 Isostearate/Behenate Esters	undiluted; 0.1 ml	3 NZW rabbits	single instillation into the conjunctival sac of the right eye, and the eyes were not rinsed; the contralateral eye served as a control	minimal irritant; maximum group mean score of 2.7 minimal conjunctival irritation was observed in all treated eyes 1 h after instillation; 2 eyes were normal after 24 h, and all 3 were normal at 48 h	108
Polyglyceryl-10 Laurate	undiluted; 0.1ml	3 NZW rabbits	in accordance with OECD 405 test guideline eyes were not rinsed	minimal irritant; maximum group mean score of 10.7/ 110 (at 1 h); moderate conjunctival irritation observed after 1 h and minimal conjunctival irritation at 24 h was completely reversible by 48 h	103

(continued)

Table 15. (continued)

Test Article	Concentration/ Dose	#/Animals/Grp	Method	Results	Reference
Polyglyceryl-10 Myristate	undiluted; 0.1ml	3 NZW rabbits	in accordance with OECD 405 test guideline eyes were not rinsed	minimal irritant; maximum group mean score of 10.0/ 110 (at 1 h); moderate conjunctival irritation observed after 1 h and minimal conjunctival irritation at 24 h was completely reversible by 48 h	104
Polyglyceryl-10 Isostearate	undiluted; 0.1ml	3 NZW rabbits	OECD 405 test guideline eyes were not rinsed	minimal irritant; maximum group mean score of 8.0/ 110 (at 1 h); moderate conjunctival irritation observed after 1 h was completely reversible by 48 h	114
			Polyglyceryl Multi-Esters		
Polyglyceryl-2 Diisostearate	undiluted, 0.1 ml	3 NZW rabbits	in accordance with OECD test guideline 405 eyes were rinsed after 24 h and at all exams	not irritating; some observations were made at 24 h, but were fully reversible at 48 h	38
Polyglyceryl-2 Diisostearate	undiluted, 0.1 ml	6 NZW rabbits	rinsing not specified	not a primary eye irritant; at 24 h, 4 animals had injected vessels and 1 had swelling; at 48 h, 2 animals had erythema and 2 had swelling; no effects were seen at 72 h	38
Polyglyceryl-2 Diisostearate	0.1 and 10% in saline and undiluted; 0.1 ml	2 Albino-Himalayan-Kaninchen rabbits/gp	eyes were rinsed after 24 h	some ocular effects, including reddening were observed at all concentrations tested, but the results were not quantified	38
Polyglyceryl-2 Dioleate	undiluted	3 rabbits	rinsing not specified	not irritating; no signs of irritation were observed	46
Polyglyceryl-3 Diisostearate	not stated; assumed to be undiluted	3 New Zealand albino rabbits	in accordance with OECD test guideline 405	non-irritating; at 1 h in animals, chemosis (score of 1) and redness (score of 2) were reported; at 72 h, chemosis was completely resolved and the redness score was 1	47
1,2,3-propanetriol, homopolymer, diisooctadecanoate (n not defined most likely Polyglyceryl-3 Diisostearate)	undiluted; 0.1 ml	4 male Kleinrusse rabbits	eyes were not rinsed	not irritating; at 24 h, very slight redness of the conjunctivae was observed in 1 animal, and the effect was reversible within 48 h	39
Macadamia Seed Oil Polyglyceryl-6 Esters Behenate	undiluted; 0.1 ml	3 NZW rabbits	single instillation into the conjunctival sac of the right eye, and the eyes were not rinsed; the contralateral eye served as a control	minimal irritant; maximum group mean score of 3.3 minimal conjunctival irritation was observed in all treated eyes 1 h after instillation; all eyes were normal after 24 h	109

(continued)

Table 15. (continued)

Test Article	Concentration/ Dose	#/Animals/Grp	Method	Results	Reference
Polyglyceryl-8 Decabehenate/ Caprate	undiluted; 0.1 ml	3 NZW rabbits	single instillation into the conjunctival sac of the right eye, and the eyes were not rinsed; the contralateral eye served as a control	minimal irritant; maximum group mean score of 13.0 moderate conjunctival irritation was observed in all treated eyes at 1 h and minimal conjunctival irritation in all treated eyes at 24 h after instillation; all eyes were normal after 48 h	110
Polyglyceryl-8 Decaerucate/ Decaisostearate/ Decaricinoleate	undiluted; 0.1 ml	3 NZW rabbits	single instillation into the conjunctival sac of the right eye, and the eyes were not rinsed; the contralateral eye served as a control	mild irritant; maximum group mean score of 10.0 moderate conjunctival irritation was observed in all treated eyes 1 h after instillation; minimal conjunctival irritation was observed in all treated eyes at 24 h and in 1 eye at 48 h after instillation	111
Polyglyceryl-10 Nonaisostearate	undiluted; 0.1 ml	3 NZW rabbits	in accordance with OECD 405 test guideline eyes were not rinsed	mild irritant; maximum group mean score of 6.7/110 (at 1 h); minimal to moderate conjunctival irritation was completely reversible by 48 h (2 animals) to 72 h	112
HUMAN					
Polyglyceryl Monoesters					
Polyglyceryl-10 Laurate (~60% pure, with ~40% polyglycerin-10 and ~2% sodium laurate)	not provided	not provided	not provided	possibly slightly irritating to the eyes	20

Abbreviations: HCE – human corneal epithelium; HET-CAM – Hen's Egg Test – Chorioallantoic Membrane; ME – microemulsion; NR – neutral red; NZW – New Zealand White; OECD – Organisation for Economic Co-operation and Development; REET – rabbit enucleated eye test; SIRC – Statens Seruminstitut rabbit cornea cells.

animals, and the test sites were exposed to 7000 mJ/cm^2 UVA irradiation 30 min after application.[98] Prior to application, 2 pair of intradermal injections were made with 50% Freund's Complete Adjuvant/physiological saline solution. Six control animals were treated in a similar manner using liquid paraffin. After a 16-day non-treatment period, the challenge was performed by applying 0.5 ml of undiluted Polyglyceryl-10 Nonaisostearate to a 50 cm^2 area on one flank of the test and control animals; 30 min after application, the treated site and an untreated site on the opposite flank were exposed to 7 J/cm^2 UVA irradiation. Cutaneous reactions were evaluated 24 and 48 h after challenge. No cutaneous reactions were observed during induction or challenge. Polyglyceryl-10 Nonaisostearate was not a photosensitizer.

Ocular Irritation Studies

Ocular irritation studies are summarized in Table 15.[20,30,38-44,47,86,99-112]

Polyglyceryl-3 Laurate, a mixture containing 60% Polyglyceryl-10 Eicosanedioate/Tetradecanedioate, Triisostearoyl Polyglyceryl-3 Dimer Dilinoleate (10% in corn oil), undiluted Polyglyceryl-10 Decaethylhexanoate, and undiluted Polyglyceryl-10 Pentaisostearate were classified as non-irritating using an EpiOcular™ tissue model. In the hen's egg test chorioallantoic membrane (HET-CAM) assay, microemulsions containing 30% or 40% Polyglyceryl-4 Laurate, Apricot Kernel Oil Polyglyceryl-4 Esters, Palm Oil Polyglyceryl-4 Esters, and Polyglyceryl-2 Dioleate were classified as non-irritant, and Diisostearoyl Polyglyceryl-3 Dimer Dilinoleate produced minor irritation. Polyglyceryl-4 Laurate/Sebacate, Polyglyceryl-4 Laurate/Succinate, and Polyglyceryl-6 Caprylate/Caprate were considered non-irritant in the SkinEthic™ reconstituted human corneal epithelium model, and Polyglyceryl-10 Laurate, Polyglyceryl-10 Myristate, and Polyglyceryl-10 Isostearate were considered unlikely to cause irritation when evaluated in the rabbit enucleated eye test (REET). Polyglyceryl-10 Myristate,

Polyglyceryl-10 Stearate, and Polyglyceryl-10 Diisostearate were non-irritating using the SIRC-neutral red (NR) method.

In rabbit eyes, Polyglyceryl-3 Caprate, a polyglyceryl mono/diester of capric acid (read-across for Polyglyceryl-3 Caprylate), Polyglyceryl-4 Caprate, Polyglyceryl-2 Diisostearate, Polyglyceryl-2 Dioleate, Polyglyceryl-3 Diisostearate, and 1,2,3-propanetriol, homopolymer, diisooctadecanoate were not irritating, and Polyglyceryl-3 Isostearate and Polyglyceryl-3 Oleate were slightly irritating. Glyceryl/Polyglyceryl-6 Isostearate/Behenate Esters, Polyglyceryl-10 Laurate, Polyglyceryl-10 Myristate, Polyglyceryl-10 Isostearate, Macadamia See Oil Polyglyceryl-6 Esters Behenate, and Polyglyceryl-8 Decabehenate Caprate caused minimal irritation in rabbit eyes, and Polyglyceryl-8 Decaerucate/Decaisostearate/Decaricinoleate and Polyglyceryl-10 Nonaisostearate were mild irritants. Polyglyceryl-10 Laurate (~60% pure) was possibly slightly irritating to the eyes of humans.

Clinical Reports

Case Reports

A case report described the incidence of recurring pruritic erythema over a 3-mo period in an 80-year-old female.[113] A 48-h closed patch test with the subject's cosmetics was positive (++). Subsequent testing with the individual ingredients was positive (+) with 0.5% aqueous (aq.) Polyglyceryl-10 Laurate, and the positive reaction caused by this substance was still present in this patient 7 days after exposure. Positive reactions (+) were reported at all concentrations with additional testing of 0.05-1% aq. Polyglyceryl-10 Laurate. After 6 mo, patch tests with 0.1-1% Polyglyceryl-10 Laurate (obtained from several suppliers), and 0.5-1% Polyglyceryl-4 Laurate and Polyglyceryl-6 Laurate, were positive. No reactions were reported with 0.1-1% aq. Polyglyceryl-10 Myristate, Polyglyceryl-10 Isostearate, Polyglyceryl-10 Stearate, and Polyglyceryl-10 Oleate, or with the control test materials.

Summary

This assessment reviews the safety of 274 polyglyceryl fatty acid esters as used in cosmetics. Each of the esters in this group is a polyether comprising 2 to 20 glyceryl residues, end-capped by esterification with simple carboxylic acids, such as fatty acids. Most of these ingredients are reported to function in cosmetics as skin-conditioning agents and/or surfactants.

Seventy-seven of the 274 ingredients included in this report are reported to be in use. Polyglyceryl-3 Diisostearate has the most reported uses (371, 216 of which are in lipsticks), and Polyglyceryl-4 Isostearate has the second highest number of reported uses (280). Polyglyceryl-2 Triisostearate and Polyglyceryl-3 Diisostearate have the highest concentration of use in a leave-on formulation; these ingredients are used at 40% and 39%, respectively. Many of these polyglyceryl fatty acid esters are used in products applied to the eye area, products that can result in incidental ingestion, or products that come into contact with mucous membranes, and a few of the polyglyceryl fatty acid esters are reported to be used in baby products. Additionally, some of the polyglyceryl fatty acid esters are used in cosmetic sprays and could possibly be inhaled.

Polyglyceryl esters of fatty acids, up to and including the decaglycerol esters, are permitted as multipurpose direct food additives. JECFA established an ADI of 0-25 mg/kg bw for polyglyceryl esters of fatty acids having an average chain length of up to 3 glycerol units, and an ADI of 0-7.5 mg/kg bw for polyglyceryl esters of interesterified ricinoleic acid. In the EU, the esters are listed as food additives at levels between 5000 and 10,000 mg/kg in certain foods, and up to 7% free glycerol/polyglycerol is allowed (i.e., 700 mg/kg).

Polyglyceryl esters are hydrolyzed in the GI tract, and the fatty acid moiety is metabolized in a normal manner. Analytical studies have produced no evidence of accumulation of the polyglycerol moiety in body tissues.

The ability to enhance skin penetration was examined for several of the polyglyceryl fatty acid esters. Polyglyceryl-3 Dioleate is reported to be a water-in-oil surfactant/solubilizer associated with enhanced drug penetration. Polyglyceryl-10 Trioleate enhanced the flux of tenoxicam in an *in vitro* study. Microemulsions containing Polyglyceryl-4 Laurate and Polyglyceryl-4 Oleate increased ceramide permeation into skin.

In an acute dermal toxicity study in rats, the LD_{50} of 1,2,3-propanetriol, homopolymer, diisooctadecanoate was>5 g/kg. Low toxicity was reported in acute oral studies. In rats, the LD_{50} >2 g/kg for Polyglyceryl-3 Caprate, Polyglyceryl-3 Caprylate, Polyglyceryl-4 Caprate, Diisostearoyl Polyglyceryl-3 Dimer Dilinoleate, and Polyglyceryl-8 Decabehenate/Caprate, the LD_{50} was estimated to be >2.5 g/kg for Glyceryl/Polyglyceryl-6 Isostearate/Behenate Esters, Macadamia Seed Oil Polyglyceryl-6 Esters Behenate, Polyglyceryl-8 Decaerucate/Decaisostearate/Decaricinoleate, and Polyglyceryl-10 Nonaisostearate, and the LD_{50} was >5 g/kg for Polyglyceryl-3 Isostearate, Polyglyceryl-3 Oleate, Polyglyceryl-2 Diisostearate and Polyglyceryl-3 Diisostearate.

Dietary studies with polyglyceryl ester, polyglyceryl stearate, Polyglyceryl-2 Diisostearate, and Polyglyceryl-10 Decaoleate did not produce any remarkable effects. No test-article related adverse effects were observed in multi-generational studies with polyglyceryl esters or 1,2,3-propanetriol, homopolymer, diisooctadecanoate.

Generally, negative results were obtained in genotoxicity tests. Polyglyceryl-2 Oleate, Polyglyceryl-2 Diisostearate, and 1,2,3-propanetriol, homopolymer, diisooctadecanoate were not genotoxic in the Ames test, mammalian cell gene mutation assay, or chromosomal aberration assay, with or without metabolic activation. Polyglyceryl-3 Caprate, Polyglyceryl-3 Caprylate, Polyglyceryl-3 Laurate, Polyglyceryl-3 Isostearate, Polyglyceryl-4 Caprate, Polyglyceryl-4 Isostearate, Polyglyceryl-4 Laurate/Succinate, Glyceryl/Polyglyceryl-6

Isostearate/Behenate Esters, Diisostearoyl Polyglyceryl-3 Dimer Dilinoleate, Macadamia Seed Oil Polyglyceryl-6 Esters Behenate, Polyglyceryl-8 Decabehenate/Caprate, Polyglyceryl-8 Decaerucate/Decaisostearate/Decaricinoleate, Polyglyceryl-6 Decaethylhexanoate, Polyglyceryl-10 Pentaisostearate, and Polyglyceryl-10 Nonaisostearate were negative in the Ames test. Polyglyceryl-6 Caprylate/Caprate and Polyglyceryl-10 Laurate (~60% pure) gave equivocal results in the absence and positive results in the presence of metabolic activation when tested at concentrations up to 125 and 2250 μg/ml, respectively, in a chromosomal aberration assay using Chinese hamster V79 cells, but were not clastogenic in a chromosomal aberration assay in human peripheral lymphocytes, with or without activation. The impurities of polyglyceryl fatty acid esters, i.e. free fatty acids and their esters, have no structural alerts for genotoxicity.

In a 2-yr dietary study in rats, 5% polyglyceryl ester was not carcinogenic and did not produce any adverse effects.

Apricot Kernel Oil Polyglyceryl-4 Esters and Palm Oil Polyglyceryl-4 Esters were classified as non-irritant in the SkinEthic™ irritation test, Polyglyceryl-4 Laurate/Sebacate, Polyglyceryl-4 Laurate/Succinate, and Polyglyceryl-6 Caprylate/Caprate were considered to be non-irritant in the EpiSkin™ model for skin irritation, and Polyglyceryl-10 Decaethylhexanoate. Polyglyceryl-10 Pentaisostearate was considered non-irritating using the EpiDerm™ model for skin irritation.

In rabbits, Polyglyceryl-3 Caprate, a polyglyceryl mono/diester of capric acid (read-across for Polyglyceryl-3 Caprylate), Polyglyceryl-4 Caprate, Polyglyceryl-3 Diisostearate, 1,2,3-propanetriol, homopolymer, diisooctadecanoate, Macadamia Seed Oil Polyglyceryl-6 Esters Behenate, Polyglyceryl-8 Decabehenate/Caprate, and Polyglyceryl-8 Decaerucate/Decaisostearate/Decaricinoleate were not irritating to the skin. Polyglyceryl-2 Isostearate, Glyceryl/Polyglyceryl-6 Isostearate, and Polyglyceryl-10 Nonaisostearate were mildly irritating, Polyglyceryl-2 Diisostearate was slightly irritating, and Polyglyceryl-3 Isostearate and Polyglyceryl-3 Oleate were moderate irritants in rabbit skin. Polyglyceryl-3 Caprate, Polyglyceryl-3 Caprylate, Polyglyceryl-3 Isostearate, Polyglyceryl-4 Caprate, Polyglyceryl-4 Isostearate, Glyceryl/Polyglyceryl-6 Isostearate/Behenate Esters, Polyglyceryl-2 Diisostearate, Polyglyceryl-4 Diisostearate/Polyhydroxystearate/Sebacate (read-across for Diisostearoyl Polyglyceryl-3 Dimer Dilinoleate), Macadamia Seed Oil Polyglyceryl-6 Esters Behenate, Polyglyceryl-8 Decabehenate/Caprate, and Polyglyceryl-8 Decaerucate/Decaisostearate/Decaricinoleate were not sensitizers in guinea pig studies; Polyglyceryl-10 Nonaisostearate was not a sensitizer in a local lymph node assay. Polyglyceryl-3 Diisostearate was not a sensitizer in guinea pigs in one sensitization study (50% at induction and challenge; 25% at rechallenge), but results were inconclusive in a guinea pig maximization test (0.1% or 0.2% at intradermal induction; 40% at epicutaneous induction; 10 and 15% at challenge; 8 and 4% at rechallenge).

In clinical studies, 7% Polyglyceryl-2 Isostearate elicited slight irritation, and erythema was observed in 24-h occlusive patches tests of undiluted Polyglyceryl-10 Decaethylhexanoate (3/43 subjects and 3 controls) and Polyglyceryl-10 Pentaisostearate (1/43 subjects). Undiluted Glyceryl/Polyglyceryl-6 Isostearate/Behenate Esters, 5% Polyglyceryl-10 Laurate, 10% Polyglyceryl-10 Myristate, 5% Polyglyceryl-10 Isostearate, 5% Polyglyceryl-10 Oleate, 10% Polyglyceryl-10 Stearate, a mixture containing 60% Polyglyceryl-10 Eicosanedioate/Tetradecanedioate/40% glycerin, undiluted Polyglyceryl-2 Sesquiisostearate, 20% active 1,2,3-propanetriol, homopolymer, diisooctadecanoate, undiluted Macadamia See Oil Polyglyceryl-6 Esters Behenate, undiluted Polyglyceryl-8 Decabehenate/Caprate, 5% Polyglyceryl-10 Diisostearate, 50% Polyglyceryl-10 Pentaisostearate, and Polyglyceryl-10 Decaoleate (concentration not given) were not skin irritants. Undiluted Polyglyceryl-3 Laurate, Triisostearoyl Polyglyceryl-3 Dimer Dilinoleate, Polyglyceryl-10 Decaethylhexanoate, and Polyglyceryl-10 Pentaisostearate were not irritants or sensitizers.

Undiluted Polyglyceryl-10 Nonaisostearate was not phototoxic or a photosensitizer in guinea pigs.

Polyglyceryl-3 Laurate, a mixture containing 60% Polyglyceryl-10 Eicosanedioate/Tetradecanedioate, Triisostearoyl Polyglyceryl-3 Dimer Dilinoleate (10% in corn oil), undiluted Polyglyceryl-10 Decaethylhexanoate, and undiluted Polyglyceryl-10 Pentaisostearate were classified as non-irritating using an EpiOcular™ tissue model. In the HET-CAM assay, microemulsions containing 30% or 40% Polyglyceryl-4 Laurate, Apricot Kernel Oil Polyglyceryl-4 Esters, Palm Oil Polyglyceryl-4 Esters, and Polyglyceryl-2 Dioleate were classified as non-irritant, and Diisostearoyl Polyglyceryl-3 Dimer Dilinoleate produced minor irritation. Polyglyceryl-4 Laurate/Sebacate, Polyglyceryl-4 Laurate/Succinate, and Polyglyceryl-6 Caprylate/Caprate were considered non-irritant in the SkinEthic™ reconstituted human corneal epithelium model, and Polyglyceryl-10 Laurate, Polyglyceryl-10 Myristate, and Polyglyceryl-10 Isostearate were considered unlikely to cause irritation when evaluated in the REET. Polyglyceryl-10 Myristate, Polyglyceryl-10 Stearate, and Polyglyceryl-10 Diisostearate were non-irritating using the SIRC-NR method.

In rabbit eyes, Polyglyceryl-3 Caprate, a polyglyceryl mono/diester of capric acid (read-across for Polyglyceryl-3 Caprylate), Polyglyceryl-4 Caprate, Polyglyceryl-2 Diisostearate, Polyglyceryl-2 Dioleate, Polyglyceryl-3 Diisostearate, and 1,2,3-propanetriol, homopolymer, diisooctadecanoate were not irritating, and Polyglyceryl-3 Isostearate and Polyglyceryl-3 Oleate were slightly irritating. Glyceryl/Polyglyceryl-6 Isostearate/Behenate Esters, Polyglyceryl-10 Laurate, Polyglyceryl-10 Myristate, Polyglyceryl-10 Isostearate, Macadamia See Oil Polyglyceryl-6 Esters Behenate, and Polyglyceryl-8 Decabehenate Caprate caused minimal irritation in rabbit eyes, and Polyglyceryl-8 Decaerucate/Decaisostearate/

Decaricinoleate and Polyglyceryl-10 Nonaisostearate were mild irritants.

Polyglyceryl-10 Laurate (~60% pure) was possibly slightly irritating to the eyes of humans.

Discussion

The ingredients in this report are esterification products of polyglycerin chains and fatty acids that vary in numbers of glycerin and fatty-acid equivalents and lengths of the fatty acids. The polymerization process used to produce polyglycerol yields a distribution of oligomers with primarily linear structures. In addition to linear configurations, branched polyglycerol configurations, originating from 1,2- and 2,2-*O*-ether linkages, are also possible.

The Panel acknowledged this is a very large group of ingredients; however, these ingredients are extensively metabolized to common nutrients and physiologic intermediates, therefore the Panel was satisfied that the data included in the report could be used to assess the safety of all the ingredients as used in cosmetics. Furthermore, the Panel has reviewed previously the safety of numerous ingredients that serve as starting materials for the synthesis of polyglyceryl fatty acid esters. These previously-reviewed ingredients, which can be residual impurities in the polyglyceryl esters products or potential metabolites (e.g., glycerin and free fatty acids released by the action of esterases in the skin), were found safe as used (or safe when formulated to be non-irritating) in cosmetic formulations.

Some of the polyglyceryl fatty acid esters can potentially enhance the penetration of other ingredients through the skin. The Panel cautioned that care should be taken in formulating cosmetic products that may contain these ingredients in combination with any ingredients whose safety was based on their lack of dermal absorption data, or when dermal absorption was a concern.

It was noted that some of these ingredients are derived from plants. The Panel expressed concern about pesticide residues and heavy metals that may be present in botanical ingredients, and stressed that the cosmetics industry should continue to use the necessary procedures to limit these impurities in the ingredient before blending into cosmetic formulations.

The Panel was concerned that the potential exists for dermal irritation with the use of products formulated using some of the polyglyceryl fatty acid esters. The Panel specified that products containing these ingredients must be formulated to be non-irritating.

Additionally, the Panel discussed the issue of incidental inhalation exposure, as some of the polyglyceryl fatty acid esters are used in cosmetic sprays and could possibly be inhaled. For example, Polyglyceryl-3 Distearate is reported to be used at 3% in spray body and hand creams. The Panel noted that droplets/particles from spray cosmetic products would not be respirable to any appreciable amount. Furthermore, droplets/particles deposited in the nasopharyngeal or bronchial regions of the respiratory tract present no toxicological concerns based on the chemical and biological properties of these ingredients. Coupled with the small actual exposure in the breathing zone and the concentrations at which the ingredients are used, the available information indicates that incidental inhalation would not be a significant route of exposure that might lead to local respiratory or systemic effects. A detailed discussion and summary of the Panel's approach to evaluating incidental inhalation exposures to ingredients in cosmetic products is available at http://www.cir-safety.org/cir-findings.

Conclusion

The Expert Panel for Cosmetic Ingredient Safety concluded that the 274 polyglyceryl fatty acid esters listed below are safe in cosmetics in the present practices of use and concentration described in this safety assessment when formulated to be non-irritating:

Adansonia Digitata Seed Oil Polyglyceryl-6 Esters*
Almond Oil/Polyglyceryl-10 Esters*
Apricot Kernel Oil Polyglyceryl-3 Esters*
Apricot Kernel Oil Polyglyceryl-4 Esters*
Apricot Kernel Oil Polyglyceryl-5 Esters*
Apricot Kernel Oil Polyglyceryl-6 Esters*
Apricot Kernel Oil Polyglyceryl-10 Esters*
Argan Oil Polyglyceryl-6 Esters*
Astrocaryum Vulgare Oil Polyglyceryl-6 Esters*
Avocado Oil Polyglyceryl-6 Esters*
Babassu Oil Polyglyceryl-4 Esters
Babassu Oil Polyglyceryl-6 Esters
Bertholletia Excelsa Seed Oil Polyglyceryl-6 Esters*
Borage Seed Oil Polyglyceryl-4 Esters*
Borage Seed Oil Polyglyceryl-6 Esters*
Candelilla/Jojoba/Rice Bran Polyglyceryl-3 Esters
Caprylic/Capric Glycerides Polyglyceryl-10 Esters
Carapa Guaianensis Oil Polyglyceryl-6 Esters*
Castor Oil Polyglyceryl-6 Esters*
Cocoa Butter Polyglyceryl-6 Esters*
Coconut Oil Polyglyceryl-6 Esters
Coffee Seed Oil Polyglyceryl-6 Esters*
Diisostearoyl Polyglyceryl-3 Dimer Dilinoleate
Glyceryl/Polyglyceryl-6 Isostearate/Behenate Esters
Hazelnut Seed Oil Polyglyceryl-6 Esters*
Linseed Oil Polyglyceryl-4 Esters*
Macadamia Seed Oil Polyglyceryl 6 Esters*
Macadamia Seed Oil Polyglyceryl 6 Esters Behenate
Mauritia Flexuosa Seed Oil Polyglyceryl-6 Esters*
Olive Oil Polyglyceryl-3 Esters*
Olive Oil Polyglyceryl-4 Esters*
Olive Oil Polyglyceryl-6 Esters*
Palm Kernel Oil Polyglyceryl-4 Esters*
Palm Oil Polyglyceryl-3 Esters*
Palm Oil Polyglyceryl-4 Esters

Palm Oil Polyglyceryl-5 Esters*
Palm Oil Polyglyceryl-6 Esters*
Parinari Curatellifolia Oil Polyglyceryl-6 Esters*
Pinus Sibirica Seed Oil Polyglyceryl-6 Esters*
Polyglyceryl-2 Caprate
Polyglyceryl-2 Caprylate*
Polyglyceryl-2 Diisostearate
Polyglyceryl-2 Dioleate*
Polyglyceryl-2 Distearate*
Polyglyceryl-2 Isopalmitate
Polyglyceryl-2 Isopalmitate/Sebacate*
Polyglyceryl-2 Isostearate
Polyglyceryl-2 Laurate
Polyglyceryl-2 Myristate*
Polyglyceryl-2 Oleate
Polyglyceryl-2 Palmitate*
Polyglyceryl-2 Sesquicaprylate*
Polyglyceryl-2 Sesquiisostearate
Polyglyceryl-2 Sesquioleate*
Polyglyceryl-2 Sesquistearate
Polyglyceryl-2 Stearate
Polyglyceryl-2 Tetrabehenate/Macadamiate/Sebacate*
Polyglyceryl-2 Tetraisostearate
Polyglyceryl-2 Tetraoleate*
Polyglyceryl-2 Tetrastearate*
Polyglyceryl-2 Triisostearate
Polyglyceryl-3 Beeswax
Polyglyceryl-3 Behenate*
Polyglyceryl-3 Caprate
Polyglyceryl-3 Caprylate
Polyglyceryl-3 Cocoate*
Polyglyceryl-3 Dicaprate*
Polyglyceryl-3 Dicitrate/Stearate
Polyglyceryl-3 Dicocoate*
Polyglyceryl-3 Di Hydroxystearate*
Polyglyceryl-3 Diisostearate
Polyglyceryl-3 Dioleate*
Polyglyceryl-3 Distearate
Polyglyceryl-3 Isostearate
Polyglyceryl-3 Laurate
Polyglyceryl-3 Myristate*
Polyglyceryl-3 Oleate
Polyglyceryl-3 Palmitate
Polyglyceryl-3 Pentacaprylate/Caprate*
Polyglyceryl-3 Pentaolivate*
Polyglyceryl-3 Pentaricinoleate
Polyglyceryl-3 Rice Branate*
Polyglyceryl-3 Ricinoleate
Polyglyceryl-3 Soyate/Shea Butterate*
Polyglyceryl-3 Stearate
Polyglyceryl-3 Stearate SE*
Polyglyceryl-3 Triisostearate*
Polyglyceryl-3 Triolivate*
Polyglyceryl-4 Almondate/Shea Butterate*
Polyglyceryl-4 Caprate
Polyglyceryl-4 Caprylate*
Polyglyceryl-4 Caprylate/Caprate*
Polyglyceryl-4 Cocoate
Polyglyceryl-4 Dilaurate*
Polyglyceryl-4 Distearate*
Polyglyceryl-4 Hazelnutseedate*
Polyglyceryl-4 Isostearate
Polyglyceryl-4 Isostearate/Laurate*
Polyglyceryl-4 Laurate
Polyglyceryl-4 Laurate/Sebacate*
Polyglyceryl-4 Laurate/Succinate*
Polyglyceryl-4 Oleate
Polyglyceryl-4 Pentaoleate*
Polyglyceryl-4 Pentapalmitate/Stearate*
Polyglyceryl-4 Pentastearate*
Polyglyceryl-4 Punicate*
Polyglyceryl-4 Stearate*
Polyglyceryl-4 Sweet Almondate*
Polyglyceryl-4 Tristearate*
Polyglyceryl-5 Caprate*
Polyglyceryl-5 Dicaprylate*
Polyglyceryl-5 Dilaurate*
Polyglyceryl-5 Dioleate
Polyglyceryl-5 Hexastearate*
Polyglyceryl-5 Isostearate
Polyglyceryl-5 Laurate
Polyglyceryl-5 Myristate*
Polyglyceryl-5 Oleate
Polyglyceryl-5 Pentamyristate*
Polyglyceryl-5 Ricinoleate*
Polyglyceryl-5 Stearate
Polyglyceryl-5 Tribehenate*
Polyglyceryl-5 Triisostearate
Polyglyceryl-5 Trimyristate*
Polyglyceryl-5 Trioleate
Polyglyceryl-5 Tristearate*
Polyglyceryl-6 Adansonia Digitata Seedate*
Polyglyceryl-6 Apricot Kernelate*
Polyglyceryl-6 Argan Kernelate*
Polyglyceryl-6 Behenate*
Polyglyceryl-6 Caprate*
Polyglyceryl-6 Caprylate*
Polyglyceryl-6 Caprylate/Caprate
Polyglyceryl-6 Citrullus Lanatus Seedate*
Polyglyceryl-6 Dicaprate*
Polyglyceryl-6 Diisostearate*
Polyglyceryl-6 Dioleate
Polyglyceryl-6 Dipalmitate*
Polyglyceryl-6 Distearate
Polyglyceryl-6 Heptacaprylate*
Polyglyceryl-6 Hexaoleate*
Polyglyceryl-6 Hexastearate*
Polyglyceryl-6 Isostearate
Polyglyceryl-6 Laurate*
Polyglyceryl-6 Myristate*

Polyglyceryl-6 Octacaprylate*
Polyglyceryl-6 Octastearate
Polyglyceryl-6 Oleate
Polyglyceryl-6 Palmitate*
Polyglyceryl-6 Palmitate/Succinate*
Polyglyceryl-6 Pentacaprylate*
Polyglyceryl-6 Pentaoleate*
Polyglyceryl-6 Pentaricinoleate*
Polyglyceryl-6 Pentastearate
Polyglyceryl-6 Ricinoleate
Polyglyceryl-6 Schinziophyton Rautanenii Kernelate*
Polyglyceryl-6 Sclerocarya Birrea Seedate*
Polyglyceryl-6 Sesquicaprylate*
Polyglyceryl-6 Sesquiisostearate*
Polyglyceryl-6 Sesquistearate*
Polyglyceryl-6 Stearate*
Polyglyceryl-6 Tetrabehenate*
Polyglyceryl-6 Tetracaprylate*
Polyglyceryl-6 Tetraoleate*
Polyglyceryl-6 Tricaprylate
Polyglyceryl-6 Trichilia Emetica Seedate*
Polyglyceryl-6 Tristearate*
Polyglyceryl-6 Undecylenate*
Polyglyceryl-6 Ximenia Americana Seedate*
Polyglyceryl-8 C12-20 Acid Ester*
Polyglyceryl-8 Decabehenate/Caprate
Polyglyceryl-8 Decaerucate/Decaisostearate/ Decaricinoleate
Polyglyceryl-8 Oleate*
Polyglyceryl-8 Stearate*
Polyglyceryl-10 Apricot Kernelate*
Polyglyceryl-10 Behenate/Eicosadioate
Polyglyceryl-10 Caprate*
Polyglyceryl-10 Caprylate*
Polyglyceryl-10 Caprylate/Caprate
Polyglyceryl-10 Cocoate*
Polyglyceryl-10 Decaethylhexanoate*
Polyglyceryl-10 Decahydroxystearate*
Polyglyceryl-10 Decaisostearate
Polyglyceryl-10 Decalinoleate*
Polyglyceryl-10 Decamacadamiate*
Polyglyceryl-10 Decaoleate
Polyglyceryl-10 Decastearate*
Polyglyceryl-10 Dicocoate*
Polyglyceryl-10 Didecanoate*
Polyglyceryl-10 Diisostearate
Polyglyceryl-10 Dilaurate*
Polyglyceryl-10 Dimyristate*
Polyglyceryl-10 Dioleate
Polyglyceryl-10 Dipalmitate
Polyglyceryl-10 Distearate
Polyglyceryl-10 Dodecabehenate*
Polyglyceryl-10 Dodecacaprate*
Polyglyceryl-10 Dodecacaprylate*
Polyglyceryl-10 Dodeca-Caprylate/Caprate*
Polyglyceryl-10 Eicosanedioate/Tetradecanedioate*
Polyglyceryl-10 Hepta(Behenate/Stearate)*
Polyglyceryl-10 Heptahydroxystearate
Polyglyceryl-10 Heptaoleate*
Polyglyceryl-10 Heptastearate*
Polyglyceryl-10 Hexaerucate*
Polyglyceryl-10 Hexaisostearate*
Polyglyceryl-10 Hexaoleate*
Polyglyceryl-10 Hydroxystearate/Stearate/Eicosadioate
Polyglyceryl-10 Isostearate
Polyglyceryl-10 Laurate
Polyglyceryl-10 Linoleate*
Polyglyceryl-10 Mono/Dioleate*
Polyglyceryl-10 Myristate
Polyglyceryl-10 Nonaerucate*
Polyglyceryl-10 Nonaisostearate
Polyglyceryl-10 Oleate
Polyglyceryl-10 Palmate*
Polyglyceryl-10 Palmitate*
Polyglyceryl-10 Pentacaprylate*
Polyglyceryl-10 Pentahydroxystearate
Polyglyceryl-10 Pentaisostearate
Polyglyceryl-10 Pentalaurate*
Polyglyceryl-10 Pentalinoleate*
Polyglyceryl-10 Pentaoleate
Polyglyceryl-10 Pentaricinoleate*
Polyglyceryl-10 Pentastearate
Polyglyceryl-10 Sesquistearate*
Polyglyceryl-10 Stearate
Polyglyceryl-10 Tetradecanedioate*
Polyglyceryl-10 Tetralaurate*
Polyglyceryl-10 Tetraoleate*
Polyglyceryl-10 Tricocoate*
Polyglyceryl-10 Tridecanoate*
Polyglyceryl-10 Trierucate*
Polyglyceryl-10 Triisostearate*
Polyglyceryl-10 Trilaurate*
Polyglyceryl-10 Trioleate*
Polyglyceryl-10 Tristearate
Polyglyceryl-10 Undecylenate*
Polyglyceryl-15 Diisostearate*
Polyglyceryl-20 Docosabehenate/Isostearate*
Polyglyceryl-20 Docosabehenate/Laurate*
Polyglyceryl-20 Docosabehenate/Oleate*
Polyglyceryl-20 Heptacaprylate*
Polyglyceryl-20 Heptadecabehenate/Laurate*
Polyglyceryl-20 Hexacaprylate*
Polyglyceryl-20 Octadecabehenate/Laurate*
Polyglyceryl-20 Octaisononanoate*
Pumpkin Seed Oil Polyglyceryl-4 Esters*
Pumpkin Seed Oil Polyglyceryl-4 Esters Succinate*
Rice Bran Oil Polyglyceryl-3 Esters*
Rosa Rubiginosa Seed Oil Polyglyceryl-6 Esters*
Safflower Seed Oil Polyglyceryl-6 Esters*
Schinziophyton Rautanenii Kernel Oil Polyglyceryl-6 Esters*

Sclerocarya Birrea Seed Oil Polyglyceryl-6 Esters*
Sclerocarya Birrea Seed Oil Polyglyceryl-10 Esters*
Sesame Oil Polyglyceryl-6 Esters*
Shea Butter Polyglyceryl-3 Esters*
Shea Butter Polyglyceryl-4 Esters*
Shea Butter Polyglyceryl-6 Esters*
Soybean Oil Polyglyceryl-6 Esters*
Sunflower Seed Oil Polyglyceryl 3 Esters*
Sunflower Seed Oil Polyglyceryl-4 Esters*
Sunflower Seed Oil Polyglyceryl-5 Esters*
Sunflower Seed Oil Polyglyceryl 6 Esters*
Sunflower Seed Oil Polyglyceryl 10 Esters*
Sweet Almond Oil Polyglyceryl-4 Esters*
Sweet Almond Oil Polyglyceryl-6 Esters*
Theobroma Grandiflorum Seed Butter Polyglyceryl-6 Esters*
Trichilia Emetica Seed Oil Polyglyceryl-6 Esters*
Triisostearoyl Polyglyceryl-3 Dimer Dilinoleate
Watermelon Seed Oil Polyglyceryl-6 Esters *
Watermelon Seed Oil Polyglyceryl-10 Esters*
Ximenia Americana Seed Oil Polyglyceryl-6 Esters*

*Not reported to be in current use. Were ingredients in this group not in current use to be used in the future, the expectation is that they would be used in product categories and at concentrations comparable to others in this group.

Author Contributions

Ghodsiyeh Joveini, Armin Zareiyan, and Laleh Lajevardi conceived the original idea. Afsoon Hasani Mehraban and Mitra Khalafbeigi helped to develop the theory. Afsoon Hasani Mehraban, Laleh Lajevardi, and Armin Zareiyan verified the analytical methods. Armin Zareiyan performed the analytic calculations. All authors discussed the results and contributed to the final manuscript. Laleh Lajevardi supervised the project.

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