

Methacrylate Ester Monomers

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Abstract

The Expert Panel for Cosmetic Ingredient Safety reviewed newly available studies since their original assessment in 2005, along with updated information regarding product types and concentrations of use, and confirmed that these 22 methacrylate ester monomers are safe as used in nail enhancement products in the practices of use and concentration as described in this report, when skin contact is avoided.

Keywords

Cosmetics, Safety, Bis(Glyceryl Dimethacrylate), Pyromellitate (formerly Pyromellitic Glycidyl Dimethacrylate), Butylcarbamoyl Methacrylate (Formerly Urethane Methacrylate), Butyl Methacrylate, t-Butyl Methacrylate, Cyclohexylmethacrylate (Formerly Cyclohexyl Methacrylate), Ethoxyethyl Methacrylate, 2-Ethoxy Ethoxy Ethyl Methacrylate, Glycol Dimethacrylate (Formerly Ethylene Glycol Dimethacrylate), Hexyl Methacrylate, HEMA (2-Hydroxyethyl Methacrylate), HEMA Acetoacetate (Formerly Hydroxyethylmethacrylate Acetoacetate), Di-HEMA Trimethylhexyl Dicarbamate, Hydroxypropyl Meth Acrylate, Isobutyl Methacrylate, Isopropylidenediphenyl Bisoxhydroxypropyl Methacrylate (Formerly Isopropylidenediphenyl Bisglycidyl Methacrylate), Lauryl Methacrylate, Methoxydiglycol Methacrylate, PEG-4 Dimethacrylate, Tetrahydrofurfuryl Methacrylate, Triethylene Glycol Dimethacrylate, Trimethylolpropane Trimethacrylate

Introduction

The Expert Panel for Cosmetic Ingredient Safety first published the Final Report on the Safety Assessment of methacrylate ester monomers in 2005.¹ The Expert Panel concluded that the 22 methacrylate ester monomers listed below are safe as used in nail enhancement products when skin contact is avoided. The conclusion also states that products containing these ingredients should be accompanied with directions to avoid skin contact, because of the sensitizing potential of methacrylates.

Bis(Glyceryl Dimethacrylate) Pyromellitate) (formerly Pyromellitic Glycidyl Dimethacrylate), Butylcarbamoyl Methacrylate (formerly Urethane Methacrylate), Butyl Methacrylate, t-Butyl Methacrylate, Cyclohexylmethacrylate (formerly Cyclohexyl Methacrylate), Ethoxyethyl Methacrylate, 2-Ethoxy Ethoxy Ethyl Methacrylate, Glycol Dimethacrylate (formerly Ethylene Glycol Dimethacrylate), Hexyl Methacrylate, HEMA (2-Hydroxyethyl Methacrylate), HEMA Acetoacetate (formerly Hydroxyethylmethacrylate Acetoacetate), Di-HEMA Trimethylhexyl Dicarbamate, Hydroxypropyl Methacrylate, Isobornyl Methacrylate, Isobutyl Methacrylate,

Isopropylidenediphenyl Bisoxhydroxypropyl Methacrylate (formerly Isopropylidenediphenyl Bisglycidyl Methacrylate), Lauryl Methacrylate, Methoxydiglycol Methacrylate, PEG-4 Dimethacrylate, Tetrahydrofurfuryl Methacrylate, Triethylene Glycol Dimethacrylate, Trimethylolpropane Trimethacrylate.

It should be noted that two of the ingredients reviewed in the published final report, 2-Ethoxy Ethoxy Ethyl Methacrylate and Hexyl Methacrylate, are no longer listed in the International Cosmetic Ingredient Dictionary and Handbook.² Because it has been at least 15 years since the final report was published, in accordance with Cosmetic Ingredient Review

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Table I. Current and Historical Frequency and Concentration of Use According to Duration and Exposure.

	# of Uses		Max Conc of Use (%)		# of Uses		Max Conc of Use (%)	
	Bis(Glyceryl Dimethacrylate) Pyromellitate (previously, Pyromellitic Glycidyl Dimethacrylate)				Butylcarbamoethyl Methacrylate (previously, Urethane Methacrylate)			
	2021 ³	2001 ¹	2020 ⁴	2001 ¹	2021 ³	2001 ¹	2020 ⁴	2001 ¹
Totals ^a	19	NR	NR	5	NR	NR	NR	3
Duration of use								
Leave-on	19	NR	NR	5	NR	NR	NR	3
Rinse-off	NR	NR	NR	NR	NR	NR	NR	NR
Diluted for (bath) use	NR	NR	NR	NR	NR	NR	NR	NR
Exposure type								
Eye area	NR	NR	NR	NR	NR	NR	NR	NR
Incidental ingestion	NR	NR	NR	NR	NR	NR	NR	NR
Incidental inhalation – spray	NR	NR	NR	NR	NR	NR	NR	NR
Incidental inhalation – powder	NR	NR	NR	NR	NR	NR	NR	NR
Dermal contact	NR	NR	NR	NR	NR	NR	NR	NR
Deodorant (underarm)	NR	NR	NR	NR	NR	NR	NR	NR
Hair – non-coloring	NR	NR	NR	NR	NR	NR	NR	NR
Hair – coloring	NR	NR	NR	NR	NR	NR	NR	NR
Nail	19	NR	NR	5	NR	NR	NR	3
Mucous membrane	NR	NR	NR	NR	NR	NR	NR	NR
Baby products	NR	NR	NR	NR	NR	NR	NR	NR
	Butyl Methacrylate				t-Butyl Methacrylate			
	2021 ³	2001 ¹	2020 ⁴	2001 ¹	2021 ³	2001 ¹	2020 ⁴	2001 ¹
Totals ^a	NR	NR	NR	7	NR	NR	NR	7
Duration of use								
Leave-on	NR	NR	NR	7	NR	NR	NR	7
Rinse-off	NR	NR	NR	NR	NR	NR	NR	NR
Diluted for (bath) use	NR	NR	NR	NR	NR	NR	NR	NR
Exposure type								
Eye area	NR	NR	NR	NR	NR	NR	NR	NR
Incidental ingestion	NR	NR	NR	NR	NR	NR	NR	NR
Incidental inhalation – spray	NR	NR	NR	NR	NR	NR	NR	NR
Incidental inhalation – powder	NR	NR	NR	NR	NR	NR	NR	NR
Dermal contact	NR	NR	NR	NR	NR	NR	NR	NR
Deodorant (underarm)	NR	NR	NR	NR	NR	NR	NR	NR
Hair – non-coloring	NR	NR	NR	NR	NR	NR	NR	NR
Hair – coloring	NR	NR	NR	NR	NR	NR	NR	NR
Nail	NR	NR	NR	7	NR	NR	NR	7
Mucous membrane	NR	NR	NR	NR	NR	NR	NR	NR
Baby products	NR	NR	NR	NR	NR	NR	NR	NR
	Cyclohexylmethacrylate (previously, Cyclohexyl Methacrylate)				Di-HEMA Trimethylhexyl Dicarbamate			
	2021 ³	2001 ¹	2020 ⁴	2001 ¹	2021 ³	2001 ¹	2020 ⁴	2001 ¹
Totals ^a	NR	NR	NR	2	76	NR	35.8-91.8	3
Duration of use								
Leave-on	NR	NR	NR	2	76	NR	35.8-91.8	3

(continued)

Table I. (continued)

Rinse-off	NR	NR	NR	NR	NR	NR	50.2	NR
Diluted for (bath) use	NR	NR	NR	NR	NR	NR	NR	NR
Exposure type								
Eye area	NR	NR	NR	NR	NR	NR	NR	NR
Incidental ingestion	NR	NR	NR	NR	NR	NR	NR	NR
Incidental inhalation – spray	NR	NR	NR	NR	NR	NR	NR	NR
Incidental inhalation – powder	NR	NR	NR	NR	NR	NR	NR	NR
Dermal contact	NR	NR	NR	NR	NR	NR	NR	NR
Deodorant (underarm)	NR	NR	NR	NR	NR	NR	NR	NR
Hair – non-coloring	NR	NR	NR	NR	NR	NR	NR	NR
Hair – coloring	NR	NR	NR	NR	NR	NR	NR	NR
Nail	NR	NR	NR	2	76	NR	35.8-91.8	3
Mucous membrane	NR	NR	NR	NR	NR	NR	NR	NR
Baby products	NR	NR	NR	NR	NR	NR	NR	NR
<hr/>								
<div style="display: flex; justify-content: space-around;"> <div style="text-align: center;"> 2-Ethoxy Ethoxy Ethyl Methacrylate </div> <div style="text-align: center;"> Ethoxyethyl Methacrylate </div> </div>								
<hr/>								
	2021 ³	2001 ¹	2020 ⁴	2001 ¹	2021 ³	2001 ¹	2020 ⁴	2001 ¹
<hr/>								
Totals ^a	NA	NR	NA	75	NR	NR	NR	85
Leave-on	NA	NR	NA	85	NR	NR	NR	85
Rinse-off	NA	NR	NA	NR	NR	NR	NR	NR
Diluted for (bath) use	NA	NR	NA	NR	NR	NR	NR	NR
<hr/>								
Eye area	NA	NR	NA	NR	NR	NR	NR	NR
Incidental ingestion	NA	NR	NA	NR	NR	NR	NR	NR
Incidental inhalation – spray	NA	NR	NA	NR	NR	NR	NR	NR
Incidental inhalation – powder	NA	NR	NA	NR	NR	NR	NR	NR
Dermal contact	NA	NR	NA	NR	NR	NR	NR	NR
Deodorant (underarm)	NA	NR	NA	NR	NR	NR	NR	NR
Hair – non-coloring	NA	NR	NA	NR	NR	NR	NR	NR
Hair – coloring	NA	NR	NA	NR	NR	NR	NR	NR
Nail	NA	NR	NA	85	NR	NR	NR	85
Mucous membrane	NA	NR	NA	NR	NR	NR	NR	NR
Baby products	NA	NR	NA	NR	NR	NR	NR	NR
<hr/>								
<div style="display: flex; justify-content: space-around;"> <div style="text-align: center;"> Glycol Dimethacrylate (previously, Ethylene Glycol Dimethacrylate) </div> <div style="text-align: center;"> HEMA </div> </div>								
<hr/>								
	2021 ³	2001 ¹	2020 ⁴	2001 ¹	2021 ³	2001 ¹	2020 ⁴	2001 ¹
<hr/>								
Totals ^a	17	NR	1.2	5	149	NR	.11-79	30
Duration of use								
Leave-on	17	NR	1.2	5	149	NR	.11-79	30
Rinse-off	NR	NR	NR	NR	NR	NR	NR	NR
Diluted for (bath) use	NR	NR	NR	NR	NR	NR	NR	NR
Exposure type								
Eye area	NR	NR	NR	NR	1	NR	NR	NR
Incidental ingestion	NR	NR	NR	NR	NR	NR	NR	NR
Incidental inhalation – spray	NR	NR	NR	NR	NR	NR	NR	NR
Incidental inhalation – powder	NR	NR	NR	NR	NR	NR	NR	NR
Dermal contact	NR	NR	NR	NR	1	NR	NR	NR
Deodorant (underarm)	NR	NR	NR	NR	NR	NR	NR	NR
Hair – non-coloring	NR	NR	NR	NR	NR	NR	NR	NR
Hair – coloring	NR	NR	NR	NR	NR	NR	NR	NR
Nail	17	NR	1.2	5	148	NR	.11-79	30

(continued)

Table I. (continued)

Mucous membrane	NR	NR	NR	NR	NR	NR	NR	NR
Baby products	NR	NR	NR	NR	NR	NR	NR	NR
	HEMA Acetoacetate (previously, Hydroxyethylmethacrylate Acetoacetate)				Hexyl Methacrylate			
	2021 ³	2001 ¹	2020 ⁴	2001 ¹	2021 ³	2001 ¹	2020 ⁴	2001 ¹
Totals ^a	NR	NR	NR	10	NR	NR	NR	5
Duration of use								
Leave-on	NR	NR	NR	10	NR	NR	NR	NR
Rinse-off	NR	NR	NR	NR	NR	NR	NR	NR
Diluted for (bath) use	NR	NR	NR	NR	NR	NR	NR	NR
Exposure type								
Eye area	NR	NR	NR	NR	NR	NR	NR	NR
Incidental ingestion	NR	NR	NR	NR	NR	NR	NR	NR
Incidental inhalation – spray	NR	NR	NR	NR	NR	NR	NR	NR
Incidental inhalation – powder	NR	NR	NR	NR	NR	NR	NR	NR
Dermal contact	NR	NR	NR	NR	NR	NR	NR	5
Deodorant (underarm)	NR	NR	NR	NR	NR	NR	NR	NR
Hair – non-coloring	NR	NR	NR	NR	NR	NR	NR	NR
Hair – coloring	NR	NR	NR	NR	NR	NR	NR	NR
Nail	NR	NR	NR	10	NR	NR	NR	NR
Mucous membrane	NR	NR	NR	NR	NR	NR	NR	NR
Baby products	NR	NR	NR	NR	NR	NR	NR	NR
	Hydroxypropyl Methacrylate				Isobornyl Methacrylate			
	2021 ³	2001 ¹	2020 ⁴	2001 ¹	2021 ³	2001 ¹	2020 ⁴	2001 ¹
Totals ^a	40	NR	.8-23	25	NR	NR	8.3-20.2	5
Duration of use								
Leave-on	40	NR	.8-23	25	NR	NR	8.3-20.2	5
Rinse-off	NR	NR	NR	NR	NR	NR	NR	NR
Diluted for (bath) use	NR	NR	NR	NR	NR	NR	NR	NR
Exposure type								
Eye area	NR	NR	NR	NR	NR	NR	NR	NR
Incidental ingestion	NR	NR	NR	NR	NR	NR	NR	NR
Incidental inhalation – spray	NR	NR	NR	NR	NR	NR	NR	NR
Incidental inhalation – powder	NR	NR	NR	NR	NR	NR	NR	NR
Dermal contact	NR	NR	NR	NR	NR	NR	NR	NR
Deodorant (underarm)	NR	NR	NR	NR	NR	NR	NR	NR
Hair – non-coloring	NR	NR	NR	NR	NR	NR	NR	NR
Hair – coloring	NR	NR	NR	NR	NR	NR	NR	NR
Nail	40	NR	.8-23	25	30	NR	8.3-20.2	5
Mucous membrane	NR	NR	NR	NR	NR	NR	NR	NR
Baby products	NR	NR	NR	NR	NR	NR	NR	NR
	# of Uses		Max Conc of Use (%)		# of Uses		Max Conc of Use (%)	
	Isobutyl Methacrylate				Isopropylidenediphenyl Bisoxhydroxypropyl Methacrylate (previously, Isopropylidenediphenyl Bisglycidyl Methacrylate)			
	2021 ³	2001 ¹	2020 ⁴	2001 ¹	2021 ³	2001 ¹	2020 ⁴	2001 ¹
Totals ^a	NR	NR	.0005	10	1	NR	4.3-9.5	5

(continued)

Table I. (continued)

Duration of use								
Leave-on	NR	NR	.0005	10	1	NR	4.3-9.5	5
Rinse-off	NR	NR	NR	NR	NR	NR	NR	NR
Diluted for (bath) use	NR	NR	NR	NR	NR	NR	NR	NR
Exposure type								
Eye area	NR	NR	NR	NR	NR	NR	NR	NR
Incidental ingestion	NR	NR	NR	NR	NR	NR	NR	NR
Incidental inhalation – spray	NR	NR	NR	NR	NR	NR	NR	NR
Incidental inhalation – powder	NR	NR	NR	NR	NR	NR	NR	NR
Dermal contact	NR	NR	NR	NR	NR	NR	NR	NR
Deodorant (underarm)	NR	NR	NR	NR	NR	NR	NR	NR
Hair – non-coloring	NR	NR	NR	NR	NR	NR	NR	NR
Hair – coloring	NR	NR	NR	NR	NR	NR	NR	NR
Nail	19	NR	.0005	10	1	NR	4.3-9.5	5
Mucous membrane	NR	NR	NR	NR	NR	NR	NR	NR
Baby products	NR	NR	NR	NR	NR	NR	NR	NR
Lauryl Methacrylate								
	2021 ³	2001 ¹	2020 ⁴	2001 ¹				
Methoxydiglycol Methacrylate								
	2021 ³	2001 ¹	2020 ⁴	2001 ¹				
Totals ^a	1	NR	NR	5	NR	NR	24.8-65	85
Duration of use								
Leave-on	1	NR	NR	5	NR	NR	24.8-65	85
Rinse-off	NR	NR	NR	NR	NR	NR	NR	NR
Diluted for (bath) use	NR	NR	NR	NR	NR	NR	NR	NR
Exposure type								
Eye area	NR	NR	NR	NR	NR	NR	NR	NR
Incidental ingestion	NR	NR	NR	NR	NR	NR	NR	NR
Incidental inhalation – spray	NR	NR	NR	NR	NR	NR	NR	NR
Incidental inhalation – powder	NR	NR	NR	NR	NR	NR	NR	NR
Dermal contact	NR	NR	NR	NR	NR	NR	NR	NR
Deodorant (underarm)	NR	NR	NR	NR	NR	NR	NR	NR
Hair – non-coloring	NR	NR	NR	NR	NR	NR	NR	NR
Hair – coloring	NR	NR	NR	NR	NR	NR	NR	NR
Nail	1	NR	NR	5	NR	NR	24.8-65	85
Mucous membrane	NR	NR	NR	NR	NR	NR	NR	NR
Baby products	NR	NR	NR	NR	NR	NR	NR	NR
PEG-4 Dimethacrylate								
	2021 ³	2001 ¹	2020 ⁴	2001 ¹				
Tetrahydrofurfuryl Methacrylate								
	2021 ³	2001 ¹	2020 ⁴	2001 ¹				
Totals ^a	NR	NR	6.6-10	15	NR	1	20.6-38.2	7
Duration of use								
Leave-on	NR	NR	6.6-10	15	NR	1	20.6-38.2	7
Rinse-off	NR	NR	NR	NR	NR	NR	NR	NR
Diluted for (bath) use	NR	NR	NR	NR	NR	NR	NR	NR
Exposure type								
Eye area	NR	NR	NR	NR	NR	NR	NR	NR
Incidental ingestion	NR	NR	NR	NR	NR	NR	NR	NR
Incidental inhalation – spray	NR	NR	NR	NR	NR	NR	NR	NR
Incidental inhalation – powder	NR	NR	NR	NR	NR	NR	NR	NR
Dermal contact	NR	NR	NR	NR	NR	NR	NR	NR
Deodorant (underarm)	NR	NR	NR	NR	NR	NR	NR	NR
Hair – non-coloring	NR	NR	NR	NR	NR	NR	NR	NR

(continued)

Table I. (continued)

Hair – coloring	NR	NR	NR	NR	NR	NR	NR	NR
Nail	NR	NR	6.6-10	15	NR	1	20.6-38.2	7
Mucous membrane	NR	NR	NR	NR	NR	NR	NR	NR
Baby products	NR	NR	NR	NR	NR	NR	NR	NR
	# of Uses		Max Conc of Use (%)		# of Uses		Max Conc of Use (%)	
	Triethylene Glycol Dimethacrylate		Trimethylolpropane Trimethacrylate					
	2021 ³	2001 ¹	2020 ⁴	2001 ¹	2021 ³	2001 ¹	2020 ⁴	2001 ¹
Totals ^a	NR	NR	8.7-20	7	1	NR	25.3	5
Duration of use								
Leave-on	NR	NR	8.7-20	7	1	NR	25.3	5
Rinse-off	NR	NR	NR	NR	NR	NR	NR	NR
Diluted for (bath) use	NR	NR	NR	NR	NR	NR	NR	NR
Exposure type								
Eye area	NR	NR	NR	NR	NR	NR	NR	NR
Incidental ingestion	NR	NR	NR	NR	NR	NR	NR	NR
Incidental inhalation – spray	NR	NR	NR	NR	NR	NR	NR	NR
Incidental inhalation – powder	NR	NR	NR	NR	NR	NR	NR	NR
Dermal contact	NR	NR	NR	NR	NR	NR	NR	NR
Deodorant (underarm)	NR	NR	NR	NR	NR	NR	NR	NR
Hair – non-coloring	NR	NR	NR	NR	NR	NR	NR	NR
Hair – coloring	NR	NR	NR	NR	NR	NR	NR	NR
Nail	NR	NR	8.7-20	7	1	NR	25.3	5
Mucous membrane	NR	NR	NR	NR	NR	NR	NR	NR
Baby products	NR	NR	NR	NR	NR	NR	NR	NR

NR – not reported, NA – this ingredient is no longer in use; therefore 2021 data are not applicable.

^aBecause 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.

^bAt the time of the 2003 safety assessment, concentration of use data were not reported by the FDA; however, industry provided a maximum concentration of use.

^cIt is possible these products are sprays, but it is not specified whether the reported uses are sprays.

^dIt is possible these products are powders, but it is not specified whether the reported uses are powders.

^eNot specified whether a spray or a powder, but it is possible the use can be as a spray or a powder, therefore the information is captured in both categories.

Procedures, the Expert Panel should determine whether the safety assessment should be reopened. At the December 2021 meeting, the Expert Panel considered updated information regarding product types and ingredient use frequencies as reported in the US Food and Drug Administration (FDA) Voluntary Cosmetic Registration Program (VCRP) database,³ and the maximum use concentrations provided by the Personal Care Products Council (Council).⁴ The cumulative frequency and concentration of use data are presented in Table 1 and described briefly below.

Data submitted to the FDA in 2001 did not include any uses for 21 of the methacrylate ester monomers that were reviewed; only Tetrahydrofurfuryl Methacrylate had a reported use in one nail extender product. However, concentration of use data received from the cosmetics industry in 2001 indicated that all ingredients had reported uses, with maximum use concentrations of methacrylate ester monomers up to 85% (reported for Methoxydiglycol Methacrylate and Ethoxyethyl Methacrylate) in nail enhancement products. The results of a

concentration of use survey conducted by the Council in 2020, and 2021 FDA VCRP data were provided. Collectively, these data indicate use of 14 methacrylate ester monomers in products that are applied to the nail. The most frequently used methacrylate ester monomer is HEMA, which has 149 uses and a reported maximum use concentration of 79% (in other manicuring products). Di-HEMA Trimethylhexyl Dicarbamate has a reported maximum use concentration of 91.8% (in nail extenders). Of the ingredients that are being reviewed, this is the highest reported maximum use concentration.

Importantly, the Expert Panel also reviewed safety data identified as published since 2001.³⁻¹⁹³ The Expert Panel agreed that an updated search of the published literature did not reveal toxicity data that warrant re-evaluation of the safety of these ingredients in cosmetic products. After reviewing data on ingredient use frequencies and concentrations and safety data, the Expert Panel determined to not reopen this safety assessment on methacrylate ester monomers and reaffirmed the original conclusion.

Author Contributions

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Author's Note

Unpublished sources cited in this report are available from the Director, Cosmetic Ingredient Review, 1620 L Street, NW, Suite 1200, Washington, DC 20036, USA.

Declaration of Conflicting Interest

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

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