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# Safety Assessment of *Rosa centifolia*-Derived Ingredients as Used in Cosmetics

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## ABBREVIATIONS

CFR	Code of Federal Regulations
CFU	colony forming units
CIR	Cosmetic Ingredient Review
Council	Personal Care Products Council
CPA	cyclophosphamide
CPSC	Consumer Product Safety Commission
EC	European Commission
EU	European Union
FCA	Freund's complete adjuvant
FDA	Food and Drug Administration
GRAS	generally recognized as safe
HRIPT	human repeated insult patch test
LA	Luria agar
LD <sub>50</sub>	median lethal dose
OECD	Organisation for Economic Cooperation and Development
Panel	Expert Panel for Cosmetic Ingredient Safety
Rif <sup>R</sup>	rifampicin-resistant
Rif <sup>S</sup>	rifampicin-sensitive
<i>rpoB</i>	RNA polymerase B
RIFM	Research Institute for Fragrance Materials
s.c.	subcutaneous
SLS	sodium lauryl sulfate
TG	test guideline
US	United States
VCRP	Voluntary Cosmetic Registration Program
wINCI; <i>Dictionary</i>	web-based <i>International Cosmetic Ingredient Dictionary and Handbook</i>

## ABSTRACT

The Expert Panel for Cosmetic Ingredient Safety (Panel) assessed the safety of 12 *Rosa centifolia*-derived ingredients as used in cosmetic formulations. The majority of these ingredients are reported to function in cosmetics as skin-conditioning agents. *Rosa centifolia*-derived ingredients comprise constituents that may cause adverse effects. Because final product formulations may contain multiple botanicals, each possibly containing similar constituents of concern, formulators are advised to be aware of these constituents and to avoid reaching levels that may be hazardous to consumers. With *Rosa centifolia*-derived ingredients, the Panel was concerned about the presence of potential sensitizers (e.g., citronellol and geraniol) in cosmetics. Additionally, industry should use good manufacturing practices to minimize impurities, such as heavy metals and pesticide residues. The Panel considered the available data and concluded that 9 *Rosa centifolia*-derived ingredients (i.e., the flower-, bud-, and stem-derived ingredients) are safe in cosmetics in the present practices of use and concentration described in this safety assessment when formulated to be non-sensitizing. Additionally, the Panel also concluded that the available data are insufficient to make a determination that the remaining 3 *Rosa centifolia*-derived ingredients are safe under the intended conditions of use in cosmetic formulations.

## INTRODUCTION

The safety of the following 12 *Rosa centifolia*-derived ingredients as used in cosmetics is reviewed in this safety assessment.

Rosa Centifolia Bud Extract	Rosa Centifolia Flower Extract	Rosa Centifolia Flower Water
Rosa Centifolia Callus Culture Extract	Rosa Centifolia Flower Juice	Rosa Centifolia Flower Wax
Rosa Centifolia Extract	Rosa Centifolia Flower Oil	Rosa Centifolia Leaf Cell Extract
Rosa Centifolia Flower	Rosa Centifolia Flower Powder	Rosa Centifolia Stem Extract

According to the web-based *International Cosmetic Ingredient Dictionary and Handbook* (wINCI; *Dictionary*), most *Rosa centifolia*-derived ingredients are reported to function as skin-conditioning agents in cosmetic products (Table 1).<sup>1</sup> Other functions associated with ingredients in this group include abrasives, antioxidants, fragrance ingredients, and skin protectants. Additionally, Rosa Centifolia Flower Oil is reported to function as a fragrance ingredient (only) in cosmetics. The Expert Panel for Cosmetic Ingredient Safety (Panel) does not review ingredients that function only as fragrance ingredients because, as fragrances, the safety of these ingredients is evaluated by the Research Institute for Fragrance Materials (RIFM). However, this ingredient is not currently scheduled for review by RIFM; thus, the Panel is reviewing the safety of this ingredient.

The Panel has previously reviewed the safety of one of the main volatile components of *Rosa centifolia*. In 1990, the Panel published a safety assessment of phenethyl alcohol, with the conclusion that phenethyl alcohol is safe in cosmetic products in the present practices of use at concentrations of up to 1%;<sup>2</sup> the Panel reaffirmed this conclusion, as published in 2008.<sup>3</sup> The full report and re-review summary on this ingredient can be accessed on the Cosmetic Ingredient Review (CIR) website (<https://www.cir-safety.org/ingredients>).

This safety assessment includes relevant published and unpublished data that are available for each endpoint that is evaluated. Published data are identified by conducting an exhaustive search of the world's literature. A list of the search engines and websites that are used and the sources that are typically explored, as well as the endpoints that the Panel typically evaluates, is provided on the CIR website (<https://www.cir-safety.org/supplementaldoc/preliminary-search-engines-and-websites>; <https://www.cir-safety.org/supplementaldoc/cir-report-format-outline>). Unpublished data may be provided by the cosmetics industry, as well as by other interested parties. A published RIFM monograph was available for "Rose Oil Moroccan,"<sup>4</sup> and unpublished studies were provided by RIFM to the CIR on Rosa Centifolia Flower Oil.<sup>5-13</sup> The unpublished studies were ascribed, typically, to an "absolute" or a "concrete;" these names are provided with the data.

Botanicals, such as *Rosa centifolia*-derived ingredients, may contain numerous constituents, some of which may have the potential to cause toxic effects; for example, citronellol and geraniol are potential sensitizers. In this assessment, the Panel is evaluating the potential toxicity of each of the *Rosa centifolia*-derived ingredients as a whole, complex mixture; toxicity from single components may not predict the potential toxicity of botanical ingredients.

The names of the ingredients in this report are written in accordance with the INCI naming conventions, i.e., capitalized without italics or abbreviations. When referring to the genus and species from which the ingredients are derived, the standard taxonomic practice of using italics is followed (e.g., *Rosa centifolia*). It is often not known how the substance being tested in a study compares to the cosmetic ingredient. In the report text, if it is known that the material being tested is a cosmetic ingredient, the INCI naming convention will be used (e.g., Rosa Centifolia Extract). However, if it is not known that the test substance is the same as the cosmetic ingredient, the taxonomic naming conventions (e.g., a *Rosa centifolia* extract) will be used.

## CHEMISTRY

### **Definition and Plant Identification**

Botanicals are cosmetic ingredients directly derived from plants.<sup>1</sup> Generally, these ingredients have not undergone chemical modification and some are classified as follows: extracts, juices, waters, powders, oils, and waxes. Definitions of the *Rosa centifolia*-derived ingredients reviewed in this safety assessment are presented in Table 1.

Cabbage rose is a common name for *Rosa centifolia*.<sup>14</sup> *Rosa centifolia* L. (Rosaceae), a perennial plant that is also commonly known as hundred-leaved rose or shatapatri or taruni, is available throughout India.<sup>15</sup> It is a complex hybrid that is bred from *Rosa gallica* L., *Rosa moschata* Herm., *Rosa canina* L., and *Rosa damascene* Mill.

According to another source, *Rosa centifolia* grows as a plant, shrub, bush, or thicket.<sup>16</sup> This plant is of Asiatic origin, and the countries where it is extensively cultivated for extractive purposes include: Bulgaria, Turkey, Morocco, France, and Italy. The parts used are the flowers, buds, leaves, and fruit (hips).

### **Chemical Properties**

*Rosa Centifolia* Extract is a light-brown, viscous liquid, and *Rosa Centifolia* Flower Wax is a solid that is insoluble in water.<sup>16,17</sup> According to another source, *Rosa Centifolia* Bud Extract, *Rosa Centifolia* Callus Culture Extract, or *Rosa Centifolia* Flower Extract may be a solid or liquid, depending upon the components of the extract.<sup>18-20</sup> Also, the water solubility of the extract is related to components of the extract and the solvent that is used for extraction. *Rosa Centifolia* Flower Oil is miscible with chloroform.<sup>21</sup> UV absorption data indicate an absorption peak at 320 nm (shoulder) for *Rosa Centifolia* Flower Extract (rose absolute).<sup>5</sup> A flash point of  $\geq 100^{\circ}\text{C}$  has been reported for a *Rosa Centifolia* Flower Extract trade name mixture.<sup>22</sup> Chemical properties data on *Rosa centifolia*-derived ingredients are presented in Table 2.

### **Method of Manufacture**

Some of the following methods of manufacturing described below are general to the production of some of the *Rosa centifolia*-derived ingredients, and it is unknown whether these methods are used in the manufacture of these ingredients for use in cosmetics. Additionally, in some cases, the definition of the ingredients, as given in the *Dictionary*, provides insight as to the method of manufacture.<sup>1</sup>

#### Rosa Centifolia Extract

A whole plant extract of *Rosa centifolia* is prepared by extraction with volatile solvents, which are subsequently removed (usually under vacuum).<sup>16</sup> The removal of solvents is followed by redissolution in alcohol, chilling, filtration, and removal of the alcohol.

#### Rosa Centifolia Flower Extract

According to a supplier of *Rosa Centifolia* Flower Extract, a fraction of the petals of rose of Morocco (*Rosa centifolia*) is extracted by a mixture of propylene glycol + water.<sup>23</sup> This process is followed by filtration, yielding a *Rosa Centifolia* Flower Extract trade name mixture.

The production method for another *Rosa Centifolia* Flower Extract trade name mixture has also been described.<sup>24</sup> Dried raw material is extracted with hot water, and this step is followed by filtration and then concentration. The concentrated filtrate is dissolved in 1,3-butylene glycol (50 vol%) solution. The resulting solution is subjected to sedimentation and filtration, and the production sequence ends with adjustment, and packaging.

#### Rosa Centifolia Flower Juice

According to a supplier of *Rosa Centifolia* Flower Juice, petals of *Rosa centifolia* are rehydrated and then pressed.<sup>25</sup> This process is followed by stabilization with vegetal glycerin and then filtration, yielding a *Rosa Centifolia* Flower Juice trade name mixture. The supplier also stated that, in the method of manufacture of this trade name mixture, the *Rosa centifolia* petals are cold pressed without using any solvents.<sup>26</sup>

#### Rosa Centifolia Flower Oil

*Rosa centifolia* flower oil is produced by the steam distillation of the flowers of *Rosa centifolia*.<sup>4,21</sup>

#### Rosa Centifolia Flower Powder

*Rosa Centifolia* Flower Powder is obtained from the dried, ground flowers of *Rosa centifolia*.<sup>1</sup>

#### Rosa Centifolia Flower Water

*Rosa Centifolia* Flower Water is an aqueous extract obtained by steam distillation of rose petals from *Rosa centifolia*.<sup>27</sup> Another source states *Rosa Centifolia* Flower Water is manufactured by subjecting dried raw material to steam distillation, yielding a water-soluble fraction.<sup>24</sup> Ethanol (15 vol%) is then added to this fraction, and the production sequence ends with filtration and packaging.

According to another source, the distillation of *Rosa centifolia* (rose) yields the following 3 products: rose water, rose oil, and rose waste biomass.<sup>28,29</sup> The method of manufacture of a Rosa Centifolia Flower Water trade name material involves the steam distillation of *Rosa centifolia* petals, and this process is followed by filtration.<sup>30</sup>

#### Rosa Centifolia Flower Wax

The extraction process that is used to produce rose absolutes (aromatic oils) from *Rosa centifolia* also yields an intermediary product that contains resins, waxes, and other lipids.<sup>31</sup> After the volatile oils have been removed, the waxy components can be used to produce floral wax, also referred to as a concrete.

#### Rosa Centifolia Stem Extract

A production method for a Rosa Centifolia Stem Extract was provided by a supplier.<sup>32</sup> An extract was harvested using the epicormic, new, and old shoots of *Rosa Centifolia* through direct thermomechanical extraction in a water/ethanol solution. Following a series of 3 solid-liquid separations first to remove coarser solid fraction, second via centrifugation to remove fine particles, and third via filtration to remove the finest particles), the extract is then concentrated by vacuum distillation and spray-dried (both steps remove the solvent) to form a powder.

#### **Composition/Impurities**

The main volatile constituents of *Rosa centifolia* have been identified as citronellol, geraniol, and phenethyl alcohol.<sup>16</sup> Composition data relating to the essential oil, flower and leaf parts, stem, and whole plant of *Rosa centifolia* are presented in Table 3.<sup>14,16,26,27,33-35</sup>

Composition data on *Rosa centifolia* hydrosol were also found in the published literature.<sup>36</sup> Hydrosols are products of the hydro-distillation of aromatic herbs and plants and are basically saturated solutions of essential oils (volatile fraction) in water. Rose hydrosols (e.g., *Rosa centifolia*) contain  $103 \pm 4.1$  mg/l of total volatile compounds. The major volatile compounds in *Rosa centifolia* hydrosol have been identified as: phenethyl alcohol ( $42 \pm 2$  mg/l), citronellol ( $22 \pm 1$  mg/l), geraniol ( $14 \pm 1$  mg/l).

#### Rosa Centifolia Flower Extract

A Rosa Centifolia Flower Extract trade mixture of propylene glycol, water, and Rosa Centifolia Flower Extract contains 2.8% to 3.8% dry extract.<sup>37</sup> The total aerobic microbial count is  $\leq 100$  colony forming units (CFU)/g. Additional data on composition indicate that another Rosa Centifolia Flower Extract trade name mixture contains flavonoid and tannin.<sup>24</sup>

#### Rosa Centifolia Flower Juice

A Rosa Centifolia Flower Juice trade name mixture consisting of glycerin and Rosa Centifolia Flower Juice is preserved with 0.2% potassium sorbate.<sup>38</sup> Additional data on this Rosa Centifolia Flower Juice trade name mixture indicate that the total aerobic microbial count is  $\leq 100$  CFU/g.<sup>26</sup>

#### Rosa Centifolia Flower Water

Rosa Centifolia Flower Water (aqueous extract of *Rosa centifolia* petals) is preserved with 1.5% phenoxyethanol.<sup>27</sup> The total aerobic mesophilic microorganisms count is  $\leq 100$  CFU/g. A bibliographical study on realized *Rosa centifolia* revealed the potential presence of citral ( $< 8$  ppm), citronellol ( $< 100$  ppm), eugenol ( $< 6$  ppm), geraniol ( $< 150$  ppm) and farnesol ( $< 4$  ppm) in the plant. Composition data on another Rosa Centifolia Flower Water trade name material indicate that it contains  $\beta$ -phenylethyl alcohol and geraniol.<sup>24</sup>

#### Rosa Centifolia Stem Extract

According to a supplier, a Rosa Centifolia Stem Extract contains 2 - 6 % water,  $< 20\%$  ash (determined by sulfuric ashes),  $\leq 1$  % lipids, and  $\geq 20$  % polyphenols (typical concentration  $\leq 40$  %).<sup>35</sup> Of the allergens listed in Annex III of European Union (EU) Regulation 1223/2009,  $\leq 1$  ppm limonene and  $\leq 4$ ppm benzyl alcohol were present; the remaining 24 allergens, including geraniol and citronellol, were not detected.

### **USE**

#### **Cosmetic**

The safety of the cosmetic ingredients addressed in this 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 and does not cover their use in airbrush delivery systems. Data are submitted by the cosmetic industry via the FDA's Voluntary Cosmetic Registration Program (VCRP) database (frequency of use) and in response to a survey conducted by the Personal Care Products Council (Council) (maximum use concentrations). The data are provided by cosmetic product categories, based on 21CFR Part 720. For most cosmetic product categories, 21CFR Part 720 does not indicate type of application and, therefore, airbrush application is not considered. Airbrush delivery systems are within the purview of the US Consumer Product Safety Commission (CPSC), while ingredients, as used in airbrush delivery systems, are within the jurisdiction of the FDA. Airbrush delivery system use for cosmetic application has not been evaluated by the CPSC, nor has the use of cosmetic ingredients in

airbrush technology been evaluated by the FDA. Moreover, no consumer habits and practices data or particle size data are publicly available to evaluate the exposure associated with this use type, thereby preempting the ability to evaluate risk or safety.

According to 2023 VCRP data, *Rosa Centifolia* Flower Extract has the greatest frequency of use; it is reported to be used in 179 cosmetic products, 152 of which are leave-on formulations (Table 4).<sup>39</sup> The results of a concentration of use survey conducted by the Council in 2021 indicate that *Rosa Centifolia* Flower Water has the highest concentration of use; it is used at maximum use concentrations up to 0.096%, specifically in face and neck, body and hand, and moisturizing products.<sup>40</sup> According to both VCRP and Council survey data, 6 of the 12 *Rosa centifolia*-derived ingredients reviewed in this safety assessment are not currently in use in cosmetic products. These ingredients are listed in Table 5.<sup>39</sup>

Cosmetic products containing *Rosa centifolia*-derived ingredients may incidentally come in contact with the eyes (e.g., *Rosa Centifolia* Flower Extract is used in mascaras at up to 0.02%), and are used in cosmetic products that come in contact with mucous membranes and may be incidentally ingested (e.g., *Rosa Centifolia* Flower Extract is used at up to 0.002% in lipstick formulations).<sup>39</sup> Additionally, some of these ingredients are reported to be used in cosmetic products that could possibly be inhaled; for example, *Rosa Centifolia* Flower Extract is reported to be used at up to 0.025% in fragrance preparations and at up to 0.0001% in face powders.<sup>39,40</sup> In practice, as stated in the Panel's respiratory exposure resource document (<https://www.cir-safety.org/cir-findings>), most droplets/particles incidentally inhaled from cosmetic sprays would be deposited in the nasopharyngeal and tracheobronchial regions and would not be respirable (i.e., they would not enter the lungs) to any appreciable amount. Conservative estimates of inhalation exposures to respirable particles during the use of loose powder cosmetic products are 400-fold to 1000-fold less than protective regulatory and guidance limits for inert airborne respirable particles in the workplace.

Although products containing some of these ingredients may be marketed for use with airbrush delivery systems, this information is not available from the VCRP or the Council survey. Without information regarding the frequency and concentrations of use of these ingredients, and without consumer habits and practices data or particle size data related to this use technology, the data are insufficient to evaluate the exposure resulting from cosmetics applied via airbrush delivery systems.

The *Rosa centifolia*-derived ingredients are not restricted from use in any way under the rules governing cosmetic products in the EU.<sup>41</sup> However, it should be noted that 2 of the main volatile components of *Rosa centifolia*, citronellol and geraniol, are included in Annex III of the Cosmetics Regulation European Commission (EC) No. 1223/2009 (list of substances which cosmetic products must not contain except subject to the restrictions laid down) as fragrance allergens. These ingredients must be on the label if they exceed 0.001% in leave-on and 0.01% in rinse-off products.

### **Non-Cosmetic**

According to the US FDA, essential oils, oleoresins (solvent-free), and natural extractives (including distillates) of rose absolute (*Rosa alba* L., *Rosa centifolia* L., *Rosa damascena* Mill., *Rosa gallica* L., and vars. of these spp.), rose buds, and rose flowers are generally recognized as safe (GRAS) for use in foods for human consumption (21 CFR 182.20). The FDA has also determined that these are GRAS for use in foods, drugs, and related products for animal consumption (21 CFR 582.20).

*Rosa centifolia* is famous among oil-producing species of roses.<sup>42</sup> Additionally, it is used in the traditional systems of medicine for the management of inflammatory conditions, including arthritis, cough, asthma, bronchitis, wounds, and ulcers.<sup>15,43</sup> Specifically, therapeutic uses (as astringent) of the dried petals of rose flower (e.g., from *Rosa centifolia*) include treatment of mild inflammations of the oral and pharyngeal mucosa (dosage = 1 to 2 g of drug per cup (200 ml) of water, for tea).<sup>44</sup>

## **TOXICOKINETIC STUDIES**

Toxicokinetics studies of the *Rosa centifolia*-derived ingredients reviewed in this safety assessment were neither found in the published literature, nor were these data submitted. In general, toxicokinetic data are not expected to be found on botanical ingredients because each botanical ingredient is a complex mixture of constituents.

## **TOXICOLOGICAL STUDIES**

### **Acute Toxicity Studies**

#### **Dermal**

##### **Rosa Centifolia Flower Extract**

*Rosa Centifolia* Flower Extract (rose absolute; a product of extraction of a concrete with ethanol<sup>34</sup>) was evaluated for acute dermal toxicity using 7 rabbits (strain not stated).<sup>6</sup> The test substance was administered (protocol not included) at single dermal doses of 0.8 g/kg (2 animals) and 5 g/kg (5 animals). Dosing was followed by a 14-d observation period. There were no mortalities at the 0.8 g/kg dose; moderate redness (2 rabbits) and slight edema (1 rabbit) were observed. All 5 animals dosed with 5 g/kg died on observation day 2; ataxia was reported. Moderate redness (5 rabbits), slight edema (2 rabbits), and moderate edema (3 rabbits) were also observed in the 5 g/kg dose group. An acute dermal LD<sub>50</sub> of > 0.8 g/kg was reported.

## Rosa Centifolia Flower Oil

An acute dermal LD<sub>50</sub> of > 2.5 g/kg for Rosa Centifolia Flower Oil was reported in a study involving rabbits (number and strain not stated).<sup>4</sup> Details relating to the test protocol and study results were not included.

### **Oral**

#### Rosa Centifolia Flower Extract

The acute oral toxicity of a *Rosa centifolia* flower extract (ethanol extract) was evaluated according to Organisation for Economic Cooperation and Development (OECD) Test Guideline (TG) 425.<sup>15</sup> A limit test on a *Rosa centifolia* flower extract (ethanol extract; dose = 2 g/kg body weight; administered as an oral dose by gavage) was performed using 5 male Wistar albino rats. Dosing was followed by a 14-d observation period. None of the animals died during the observation period, and the LD<sub>50</sub> was established at > 2 g/kg body weight.

The acute oral toxicity of Rosa Centifolia Flower Extract (rose absolute) was evaluated using 10 rats (strain not stated).<sup>6</sup> The test substance was administered as a single oral dose of 5 g/kg. Dosing was followed by a 14-d observation period. Three of 10 animals died on day 2 of the observation period; piloerection and lethargy were observed. An LD<sub>50</sub> of > 5 g/kg was reported.

### **Short-Term Toxicity Studies**

### **Oral**

#### Rosa Centifolia Flower Extract

The short-term oral toxicity of *Rosa centifolia* flower extract (ethanol extract) was evaluated according to OECD TG 407.<sup>15</sup> Two groups of 8 male Wistar rats were used. *Rosa centifolia* flower extract was administered orally (method of oral administration was not stated; dose of 640 mg/kg) to one of the groups once daily for 28 d. The control group was dosed orally with normal saline (1 ml/kg). After day 28, the animals were killed, and the heart and liver were examined histologically. Repeated dosing resulted in a statistically significant decrease in hepatic transaminases and an increase in white blood cells. However, it was noted that these changes were within the physiological limits for the rat and not toxicologically relevant. When compared to the control group, no other physiological, biochemical, or histopathological changes were observed in the animals dosed with *Rosa centifolia* flower extract.

### **Subchronic Toxicity Studies**

Data on the subchronic toxicity of the *Rosa centifolia*-derived ingredients reviewed in this safety assessment were neither found in the published literature, nor were these data submitted.

### **Chronic Toxicity Studies**

Data on the chronic toxicity of *Rosa centifolia*-derived ingredients reviewed in this safety assessment were neither found in the published literature, nor were these data submitted.

## **DEVELOPMENTAL AND REPRODUCTIVE TOXICITY STUDIES**

Data on the developmental and reproductive toxicity of *Rosa centifolia*-derived ingredients reviewed in this safety assessment were neither found in the published literature, nor were these data submitted.

## **GENOTOXICITY STUDIES**

The genotoxicity studies summarized below are presented in Table 6.

The genotoxic potential of Rosa Centifolia Stem Extract was evaluated in an Ames test and in 2 in vitro micronucleus assays. Rosa Centifolia Stem Extract (at doses of 5 – 5000 µg/plate) was not mutagenic to *Salmonella typhimurium*, tested with and without metabolic activation.<sup>45</sup> Additionally, of Rosa Centifolia Stem Extract was not genotoxic in a micronucleus assay using cultured human peripheral blood lymphocytes (at concentrations of 200 – 5000 µg/ml),<sup>46</sup> or in an EpiSkin™ micronucleus assay (at concentrations of 25 – 100 mg/ml),<sup>47</sup> with or without metabolic activation.

## **ANTI-MUTAGENICITY STUDIES**

#### Rosa Centifolia Flower Extract

The anti-mutagenicity of aqueous extracts of petals from different cultivars ("passion," "pink noblesse," and "sphinx") of *Rosa centifolia* was studied using the *Escherichia coli* RNA polymerase B (*rpoB*)-based Rif<sup>S</sup>→Rif<sup>R</sup> (rifampicin sensitive to resistant) forward mutation assay against ethyl methanesulfonate-induced mutagenesis.<sup>48</sup> *E. coli* MG1655 cells were used. The cell suspension was mixed with a *Rosa centifolia* flower extract (aqueous extract) and ethyl methanesulfonate (133 mM) and the mixture was incubated. Later, the culture was serially diluted and spread-plated on Luria agar (LA)-rifampicin (100 µg/ml) plates for scoring Rif<sup>R</sup> mutants and LA plates for enumerating viable cells. Mutation frequency was calculated as ratio of total number of Rif<sup>R</sup> mutants per ml to the total number of viable cells in same culture volume. Spontaneous mutation frequency was determined by incubating the cell suspension in the absence of mutagen. The Rif<sup>R</sup> mutation frequency in *E.*

*coli* cells exposed to ethyl methanesulfonate was approximately 1500/10<sup>8</sup> cells, whereas the spontaneous mutation frequency was approximately 1/10<sup>8</sup> cells. Aqueous extracts of rose petals of the 3 cultivars, "passion," "pink noblesse," and "sphinx" (1.5 mg/ml), resulted in reduction in the mutation frequency by 55, 19, and 4%, respectively. Thus, the "passion," cultivar was the most antimutagenic among the rose cultivars that were evaluated. The analysis of antimutagenicity indicated that the blue-colored anthocyanin(s) (for which concentration was maximum in the passion cultivar) was the major contributing bioactive constituent.

### **CARCINOGENICITY STUDIES**

Data on the carcinogenicity of *Rosa centifolia*-derived ingredients reviewed in this safety assessment were neither found in the published literature, nor were these data submitted.

### **OTHER RELEVANT STUDIES**

#### **Anti-Inflammatory Activity**

#### **Rosa Centifolia Flower Extract**

Because skin irritation is a sign of dermatitis (skin inflammation), data on anti-inflammatory activity may be useful in evaluating the safety of Rosa Centifolia Flower Extract in the absence of skin irritation data.

The anti-inflammatory activity of a *Rosa centifolia* flower extract (ethanol extract; doses of 32, 64, and 128 mg/kg) was evaluated using the carrageenan-induced paw edema and Freund's complete adjuvant (FCA)-induced arthritis model.<sup>15</sup> The study involved the following 5 groups of 6 male Wistar albino rats, dosed by gavage: group 1 (2 ml/kg of 1% gum acacia suspension; vehicle control), group 2 (3 mg/kg of indomethacin), group 3 (32 mg/kg of *Rosa centifolia* flower extract), group 4 (64 mg/kg of *Rosa centifolia* flower extract), and group 5 (128 mg/kg of *Rosa centifolia* flower extract). At 30 min post-administration, paw inflammation was induced by subcutaneous (s.c.) administration of 0.1 ml of 1% λ-carrageenan in saline into the subplantar surface of the left hind paw. Paw volume was measured at 1, 3, and 6 h after s.c. λ-carrageenan injection. The *Rosa centifolia* flower extract (64 and 128 mg/kg) statistically significantly ( $p < 0.01$ ) inhibited carrageenan-induced paw edema at 1, 3, and 6 h post-carrageenan challenge and demonstrated statistically significant ( $p < 0.01$ ) antiarthritic activity on days 3, 7, 14, and 21 after complete FCA immunization. Treatment with the *Rosa centifolia* flower extract (128 mg/kg) also caused a statistically significant decrease in circulating pro-inflammatory cytokine levels when compared to the control.

### **DERMAL IRRITATION AND SENSITIZATION STUDIES**

The dermal irritation and sensitization studies summarized below are presented in Table 7.

Undiluted Rosa Centifolia Flower Oil was classified as moderately irritating to the skin when applied for 24 h to intact or abraded skin of rabbits (number and strain not stated) using occlusive patches.<sup>4</sup> In a study involving hairless mice (number and strain not stated), undiluted Rosa Centifolia Flower Oil was applied to the back for an unspecified duration; skin irritation was not observed. In human clinical studies, a face mask containing 0.8% Rosa Centifolia Flower (undiluted) was not irritating in a 24-h single insult occlusive patch test involving 20 subjects.<sup>49</sup> Rosa Centifolia Flower Oil (2% in petrolatum) was not irritating in a 48-h closed patch test (number of subjects not stated).<sup>4</sup>

A face mask containing 0.8% Rosa Centifolia Flower was not a sensitizer in a maximization study with sodium lauryl sulfate (SLS) pretreatment in 25 subjects.<sup>50</sup> In human repeated insult patch tests (HRIPT), an eye serum containing 0.1% Rosa Centifolia Flower Extract (49 subjects)<sup>51</sup> and a Rosa Centifolia Flower Extract trade name mixture (tested at 20% in 55 subjects) were not sensitizers.<sup>24,52</sup> Multiple maximization studies with SLS pretreatment were performed with 2% Rosa Centifolia Flower Extract;<sup>7,8,10-13</sup> in 6 studies, involving 22 – 33 subjects per study, the only reaction reported was an incidence of contact sensitization in 1 subject (out of 25).<sup>7</sup> In a maximization test of Rosa Centifolia Flower Oil (2% in petrolatum) involving 24 subjects, no evidence of skin sensitization was found.<sup>4</sup>

### **OCULAR IRRITATION STUDIES**

Data on the ocular irritation potential of *Rosa centifolia*-derived ingredients reviewed in this safety assessment were neither found in the published literature, nor were these data submitted.

### **CLINICAL STUDIES**

#### **Case Report**

#### **Rosa Centifolia Flower Extract and Rosa Centifolia Extract**

A non-atopic female patient with a history of polymorphic light eruption presented with a 2-wk history of a rash after use of a *Rosa centifolia* flower extract (rose absolute eau de parfum) and a non-scented body lotion containing a *Rosa centifolia* extract.<sup>53</sup> Erythema, papules, and edematous plaques were observed on the neck (only perfume application site), upper chest, arms, shoulders, abdomen, and upper thighs. Patch testing (protocol not stated) was performed using van der Bend chambers, and *Rosa centifolia* extract (5% in alcohol) and the body lotion induced the following positive reactions: + (on day 2), ++ (on

day 4), and + (on day 7). Testing with the *Rosa centifolia* flower extract (rose absolute eau de parfum) did not cause a positive reaction on day 2 but did cause positive reactions on days 4 (+ reaction) and 7 (+ reaction).

### Other Clinical Reports

#### Rosa Centifolia Flower Extract

A clinical evaluation (double-blind study) of a shampoo for seborrheic dermatitis was performed using 3 groups of up to 25 patients with this scalp condition.<sup>54</sup> The composition of the shampoo was as follows: 0.01% *Rosa centifolia* flower extract, 0.005% epigallocatechin gallate, 0.3% zinc pyrithione, and 0.45% climbazole. The study was classified as double-blind, and one group of 24 patients was treated with the *Rosa centifolia* flower extract shampoo. The other 2 groups were treated with a 2% ketoconazole shampoo (25 patients) and a 1% zinc pyrithione shampoo (23 patients), respectively. All patients in each group were instructed to massage their scalps for at least 5 min with the assigned shampoo. This was followed by rinsing with water 3 times per wk for 4 wk. A clinical severity score was determined at 2 and 4 wk after shampoo use. Irritation was assessed using a questionnaire, and photographs were taken using a folliscope. In all groups, the clinical severity score improved statistically significantly ( $p < 0.05$ ) relative to baseline at weeks 2 and 4. However, the changes in the clinical severity score at weeks 2 and 4 did not differ statistically significantly between the 3 groups ( $p = 0.39$  and  $p = 0.63$ , respectively). The changes in clinical severity sub-scores (i.e., for erythema, dandruff, and lesion extent) at weeks 2 and 4 did not differ statistically significantly between the 3 groups. Irritation did not differ statistically significantly between the 3 groups ( $p = 0.63$ ). Of the 11 patients who complained of irritation, 9 reported pruritus and 4 reported erythema. These reactions were identified as mild, and the distribution of reactions among the groups was not stated.

#### Rosa Centifolia Flower Oil

A randomized, placebo-controlled aromatherapy trial was performed.<sup>55</sup> In the experimental group of 25 female subjects, treatment involved massage into abdominal skin (for 15 min after topical application) of a botanical mixture consisting of *Lavandula officinalis* (lavender, 2 drops), *Salvia sclarea* (clary sage, 1 drop), and a *Rosa centifolia* flower oil (rose, 1 drop) in 5 ml of almond oil. The subjects reported no treatment-related side effects.

### SUMMARY

The safety of 12 *Rosa centifolia*-derived ingredients as used in cosmetics is reviewed in this safety assessment. According to the *Dictionary*, most *Rosa centifolia*-derived ingredients are reported to function as skin conditioning agents in cosmetic products. Other functions associated with ingredients in this group include abrasives, antioxidants, fragrance ingredients, and skin protectants.

The main volatile constituents of *Rosa centifolia* have been identified as citronellol, geraniol, and phenethyl alcohol. UV absorption data indicate an absorption peak at 320 nm (shoulder) for Rosa Centifolia Flower Extract (rose absolute).

According to 2023 VCRP data, Rosa Centifolia Flower Extract has the greatest frequency of use; it is reported to be used in 179 cosmetic products (152 leave-on, 26 rinse-off, and 1 diluted for bath use). The results of a concentration of use survey conducted by the Council in 2021 indicate that Rosa Centifolia Flower Water has the highest concentration of use; it is used at maximum use concentrations up to 0.096%.

Two of the main volatile components of *Rosa centifolia*, citronellol and geraniol, are included in Annex III of Cosmetics Regulation European Commission (EC) No. 1223/2009 (list of substances which cosmetic products must not contain except subject to the restrictions laid down) as fragrance allergens. These ingredients must be on the label if they exceed 0.001% in leave-on and 0.01% in rinse-off products.

According to the US FDA, essential oil, oleoresins (solvent-free), and natural extractives (including distillates) of rose absolute (including *Rosa centifolia* L.), rose buds, and rose flowers are GRAS for use in foods for human consumption and for use in foods, drugs, and related products for animal consumption.

Rosa Centifolia Flower Extract (rose absolute) was evaluated for acute dermal toxicity using 7 rabbits (strain not stated). Single dermal doses of 0.8 g/kg (2 animals) and 5 g/kg (5 animals) were administered. At a dose of 0.8 g/kg, moderate erythema (2 rabbits) and slight edema (1 rabbit) were observed. At 5 g/kg, moderate erythema (5 rabbits), slight edema (2 rabbits), and moderate edema (3 rabbits) were observed. An acute dermal LD<sub>50</sub> of > 0.8 g/kg was reported. An acute dermal LD<sub>50</sub> of > 2.5 g/kg for Rosa Centifolia Flower Oil was reported in a study involving rabbits (number and strain not stated).

The acute oral toxicity of a *Rosa centifolia* flower extract (ethanol extract) was evaluated using 5 male Wistar rats. None of the animals died during the 14-d observation period, and the LD<sub>50</sub> was > 2 g/kg body weight. An acute oral LD<sub>50</sub> of > 5 g/kg was reported for Rosa Centifolia Flower Oil in a study involving rats (number and strain not stated). The acute oral toxicity of Rosa Centifolia Flower extract (rose absolute) was evaluated using 10 rats (strain not stated). Three of 10 rats died, and piloerection and lethargy were observed. An LD<sub>50</sub> of > 5 g/kg was reported.

The short-term (28-d) oral toxicity of Rosa Centifolia Flower Extract (ethanol extract) was evaluated using groups of 8 male Wistar rats (method of oral administration not stated; dose of 640 mg/kg). When compared to the saline control group, no toxicologically relevant findings were observed after dosing with Rosa Centifolia Flower Extract.

The genotoxic potential of Rosa Centifolia Stem Extract was evaluated in an Ames test and in 2 in vitro micronucleus assays. Rosa Centifolia Stem Extract (at doses of 5 - 5000 µg/plate) was not mutagenic to *S. typhimurium*, tested with and without metabolic activation. Additionally, it was not genotoxic in a micronucleus assay using cultured human peripheral blood lymphocytes (at concentrations of 200 - 5000 µg/ml), or in an EpiSkin™ micronucleus assay (at concentrations of 25 - 100 mg/ml), with or without metabolic activation.

The anti-mutagenicity of aqueous extracts of petals from different cultivars ("passion," "pink noblesse," and "sphinx") of *Rosa centifolia* was studied using the *E. coli rpo B*-based Rif<sup>S</sup>→Rif<sup>R</sup> forward mutation assay against ethyl methanesulfonate-induced mutagenesis. The cell suspension was mixed with *Rosa centifolia* flower extract (aqueous extract) and ethyl methanesulfonate (133 mM). Aqueous extracts of rose petals of the 3 cultivars, "passion," "pink noblesse," and "sphinx" (1.5 mg/ml), resulted in reduction in the ethyl methanesulfonate mutation frequency by 55, 19, and 4%, respectively. An anthocyanin, peonidin 3-glucoside, was identified as the major bioactive contributing to rose antimutagenicity.

The anti-inflammatory activity of a *Rosa centifolia* flower extract (ethanol extract; doses of 32, 64, and 128 mg/kg) was evaluated using the carrageenan-induced paw edema and FCA-induced arthritis model. *Rosa centifolia* flower extract (64 and 128 mg/kg) statistically significantly ( $p < 0.01$ ) inhibited carrageenan-induced paw edema at 1, 3, and 6 h post-carrageenan challenge and demonstrated statistically significant ( $p < 0.01$ ) antiarthritic activity on days 3, 7, 14, and 21 after complete FCA immunization.

Undiluted Rosa Centifolia Flower Oil was classified as moderately irritating to the skin when applied for 24 h to intact or abraded skin of rabbits (number and strain not stated) using occlusive patches. In a study involving hairless mice (number and strain not stated), undiluted Rosa Centifolia Flower Oil was applied to the back for an unspecified duration; skin irritation was not observed. In human clinical studies, a face mask containing 0.8% Rosa Centifolia Flower (undiluted) was not irritating in a 24-h single insult occlusive patch test involving 20 subjects. Rosa Centifolia Flower Oil (2% in petrolatum) was not irritating in a 48-h closed patch test (number of subjects not stated).

A face mask containing 0.8% Rosa Centifolia Flower was not a sensitizer in a maximization study with SLS pretreatment in 25 subjects. In HRIPTs, an eye serum containing 0.1% Rosa Centifolia Flower Extract (49 subjects) and a Rosa Centifolia Flower Extract trade name mixture (tested at 20% in 55 subjects) were not sensitizers. Multiple maximization studies with SLS pretreatment were performed with 2% Rosa Centifolia Flower Extract; in 6 studies, involving 22 – 33 subjects per study, the only reaction reported was an incidence of contact sensitization in 1 subject (out of 25). In a maximization test of Rosa Centifolia Flower Oil (2% in petrolatum) involving 24 subjects, no evidence of skin sensitization was found.

A non-atopic female patient presented with a rash after use of a *Rosa centifolia* flower extract (rose absolute eau de parfum) and a non-scented body lotion containing *Rosa centifolia*. Patch testing with *Rosa centifolia* extract (5% in alcohol) and the body lotion induced the following positive reactions: + (on day 2), ++ (on day 4), and + (on day 7). Testing with the *Rosa centifolia* flower extract (rose absolute eau de parfum) did not cause a positive reaction on day 2 but did cause positive reactions on days 4 (+ reaction) and 7 (+ reaction).

A 4-wk clinical evaluation of a shampoo for seborrheic dermatitis containing 0.01% *Rosa centifolia* flower extract was performed using 3 groups of up to 25 patients with this scalp condition; each group used a different shampoo. Of the 11 patients who complained of irritation, 9 reported pruritus and 4 reported erythema. These reactions were identified as mild, and the distribution of reactions among the groups was not stated. Irritation did not differ statistically significantly between the 3 groups.

No treatment-related side effects were observed in an aromatherapy trial involving 25 female subjects. A botanical mixture consisting of *Lavandula officinalis* (lavender, 2 drops), *Salvia sclarea* (clary sage, 1 drop), and *Rosa centifolia* (rose, 1 drop) in 5 ml of almond oil was massaged into abdominal skin for 15 min.

## **DISCUSSION**

This assessment reviews the safety of 12 *Rosa centifolia*-derived ingredients. The Panel concluded that the available data are sufficient for determining the safety of 9 ingredients, i.e., those derived from the flower, bud, and stem, for use in cosmetic products when formulated to be non-sensitizing, and that the data are insufficient for determining safety of the remaining 3 ingredients. The Panel noted that the flower- and bud-derived ingredients that are reviewed in this safety assessment are found in foods that are generally recognized as safe (GRAS). Composition and other data on the stem extract denote similarities to both the flower and the bud and obviate the need for additional toxicological data.

Because final product formulations may contain multiple botanicals, each possibly containing similar constituents of concern, formulators are advised to be aware of these constituents and to avoid reaching levels that may be hazardous to consumers. For *Rosa centifolia*-derived ingredients, the Panel was concerned about the presence of citronellol and geraniol in cosmetics, which could result in sensitization reactions. Therefore, when formulating products, manufacturers should avoid reaching levels of plant constituents that may cause sensitization or other adverse health effects.

The Panel also expressed concern about pesticide residues, heavy metals, and other plant species that may be present in botanical ingredients. They stressed that the cosmetics industry should continue to use current good manufacturing practices (cGMPs) to limit impurities in cosmetic formulations.

For the 3 *Rosa centifolia*- derived ingredients for which the Panel determined the data were insufficient, the Panel felt that there may be differences in the methods of manufacturing, compositions and impurities, and other data points, as compared to the ingredients that had sufficient data. Thus, it was unclear if inferences from the flower, bud, and stem could be applied to the callus culture, leaf cell, and whole plant extract. Accordingly, the additional data needed to determine the safety of these ingredients in cosmetics are:

- Method of manufacture
- Composition and impurities data
- 28-day dermal toxicity data
- if positive additional toxicological endpoints may be needed
- Dermal irritation and sensitization data at expected maximum concentration of use

The Panel discussed the issue of incidental inhalation exposure resulting from these ingredients (for example, Rosa Centifolia Flower Extract is reported to be used at up to 0.025% in spray fragrance preparations and at up to 0.0001% in face powders). Inhalation toxicity data were not available. However, the Panel noted that in aerosol products, the majority of droplets/particles would not be respirable to any appreciable amount. Furthermore, droplets/particles deposited in the nasopharyngeal or tracheobronchial 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 low concentrations at which these ingredients are used (or expected to be used) in potentially inhaled products, 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 <https://www.cir-safety.org/cir-findings>.

Finally, the Panel's respiratory exposure resource document (see link above) notes that airbrush technology presents a potential safety concern, and that no data are available for consumer habits and practices thereof. As a result of deficiencies in these critical data needs, the safety of cosmetic ingredients applied by airbrush delivery systems cannot be assessed by the Panel. Therefore, the Panel has found the data insufficient to support the safe use of cosmetic ingredients applied via an airbrush delivery system.

### CONCLUSION

The Expert Panel for Cosmetic Ingredient Safety concluded that the following 9 *Rosa centifolia*-derived ingredients are safe in cosmetics in the present practices of use and concentration described in this safety assessment when formulated to be non-sensitizing:

Rosa Centifolia Bud Extract*	Rosa Centifolia Flower Powder
Rosa Centifolia Flower	Rosa Centifolia Flower Water
Rosa Centifolia Flower Extract	Rosa Centifolia Flower Wax
Rosa Centifolia Flower Juice*	Rosa Centifolia Stem Extract*
Rosa Centifolia Flower Oil	

*\*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 the product categories and at concentrations comparable to others in this group.*

Additionally, the Panel also concluded the available data are insufficient to make a determination that the following 3 *Rosa centifolia*-derived ingredients are safe under the intended conditions of use in cosmetic formulations:

Rosa Centifolia Callus Culture Extract\*\*  
Rosa Centifolia Extract\*\*  
Rosa Centifolia Leaf Cell Extract \*\*

*\*\*There are currently no uses reported for these ingredients.*

## TABLES

**Table 1.** Definitions and reported functions of the ingredients in this safety assessment.<sup>1</sup>

<b>Ingredient/CAS No.</b>	<b>Definition &amp; Structures</b>	<b>Function(s)</b>
Rosa Centifolia Bud Extract	Rosa Centifolia Bud Extract is the extract of the buds of <i>Rosa centifolia</i> .	Skin-Conditioning Agents - Emollient
Rosa Centifolia Callus Culture Extract	Rosa Centifolia Callus Culture Extract is the extract of a culture of the callus of <i>Rosa centifolia</i> .	Skin Protectants
Rosa Centifolia Extract	Rosa Centifolia Extract is the extract of the whole plant, <i>Rosa centifolia</i> .	Skin-Conditioning Agents - Miscellaneous
Rosa Centifolia Flower	Rosa Centifolia Flower are the flowers of <i>Rosa centifolia</i> .	Fragrance Ingredients; Skin-Conditioning Agents - Miscellaneous
Rosa Centifolia Flower Extract 84604-12-6	Rosa Centifolia Flower Extract is the extract of the flowers of <i>Rosa centifolia</i> .	Fragrance Ingredients; Skin-Conditioning Agents - Miscellaneous
Rosa Centifolia Flower Juice	Rosa Centifolia Flower Juice is the juice expressed from the flower of <i>Rosa centifolia</i> .	Skin-Conditioning Agents - Miscellaneous
Rosa Centifolia Flower Oil	Rosa Centifolia Flower Oil is the volatile oil obtained from the flowers of <i>Rosa centifolia</i> .	Fragrance Ingredients
Rosa Centifolia Flower Powder	Rosa Centifolia Flower Powder is the powder obtained from the dried, ground flowers of <i>Rosa centifolia</i> .	Abrasives
Rosa Centifolia Flower Water	Rosa Centifolia Flower Water is an aqueous solution of the steam distillate obtained from the flowers of the rose, <i>Rosa centifolia</i> .	Skin-Conditioning Agents - Miscellaneous
Rosa Centifolia Flower Wax	Rosa Centifolia Flower Wax is a wax obtained from the flower of <i>Rosa centifolia</i> .	Skin-Conditioning Agents - Miscellaneous
Rosa Centifolia Leaf Cell Extract	Rosa Centifolia Leaf Cell Extract is the extract of a culture of the leaf cells of <i>Rosa centifolia</i> .	Antioxidants; Skin Protectants
Rosa Centifolia Stem Extract	Rosa Centifolia Stem Extract is the extract of the stems of <i>Rosa centifolia</i> .	Skin-Conditioning Agents - Emollient

**Table 2.** Chemical properties

Property	Value/Results	Reference
<b>Rosa Centifolia Bud Extract</b>		
Form	Solid or liquid; appearance is related to components of the extract	18
Solubility	Solubility is related to components of extract and solvent used for extraction	18
<b>Rosa Centifolia Callus Culture Extract</b>		
Form	Solid or liquid; appearance is related to components of the extract	19
Solubility	Solubility is related to components of extract and solvent used for extraction	19
<b>Rosa Centifolia Extract</b>		
Form	Yellowish to light-brown viscous liquid	16
<b>Rosa Centifolia Flower Extract</b>		
Form	Solid or liquid; appearance is related to components of the extract	20
Solubility	Solubility is related to components of extract and solvent used for extraction	20
<b>Rosa Centifolia Flower Extract (trade mixture)</b>		
Form (at 20°C)	translucent solution with possibly a slight precipitate (brown, orange color)	37
Density (at 20°C)	1.053 – 1.065	37
Refractive index (at 20°C)	1.412 – 1.423	37
Solubility	Miscible in water and alcohol (50% v/v); immiscible in mineral oils and vegetable oils	37
Flash point	≥ 100°C	22
<b>Rosa Centifolia Flower Juice (trade mixture)</b>		
Form (20°C)	liquid to opalescent liquid with an orange to brown color	26
Density (at 20°C)	1.130 – 1.150	26
Refractive index (at 20°C)	1.390 – 1.410	26
Solubility	Miscible in water and alcohol (50% v/v); immiscible in mineral oils and vegetable oils	26
<b>Rosa Centifolia Flower Oil</b>		
Form	Colorless or yellow liquid	21
Solubility	Miscible with chloroform	21
Specific gravity (at 30° C/15° C)	0.848 – 0.863	21
Refractive index (at 30° C)	1.457 – 1.463	21
<b>Rosa Centifolia Flower Extract (rose absolute)</b>		
UV absorption peak (nm)	320 (shoulder)	5
<b>Rosa Centifolia Flower Water (trade name material)</b>		
Form (at 20°C)	Colorless, transparent liquid.	27
Density (at 20°C)	0.999 – 1.002	27
Refractive index (at 20°C)	1.332 – 1.339	27
Solubility	Miscible in water and alcohol (50% v/v) and immiscible in mineral oils and vegetable oils; soluble in propylene glycol	27,56
<b>Rosa Centifolia Flower Wax</b>		
Form	Solid	17
Solubility	Insoluble in water	17

**Table 3.** Constituents of *Rosa centifolia*

<b>Constituents</b>	<b>Concentration</b>
<b><i>Essential Oil</i></b>	
$\alpha$ -pinene	not stated. <sup>14</sup>
$\beta$ -phenethyl alcohol	0.09%. <sup>34</sup>
$\beta$ -pinene	not stated. <sup>14</sup>
<i>cis</i> -rose oxide	0.07%. <sup>34</sup>
citral	not stated. <sup>14</sup>
citronellol	1200 ppm. <sup>14</sup>
citronellol	9.22%. <sup>34</sup>
<i>n</i> -eicosane C <sub>20</sub>	0.55%. <sup>34</sup>
eugenol	0.74%. <sup>34</sup>
farnesol	3.48%. <sup>34</sup>
geranic acid	not stated. <sup>14</sup>
geraniol	17.60%. <sup>34</sup>
geraniol aldehyde	not stated. <sup>14</sup>
<i>n</i> -heneicosane C <sub>21</sub>	6.31%. <sup>34</sup>
<i>n</i> -heptacosane C <sub>27</sub>	1.79%. <sup>34</sup>
<i>n</i> -heptadecane	1.07%. <sup>34</sup>
limonene	0.05%. <sup>34</sup>
linalool	1.03%. <sup>34</sup>
methyl eugenol	0.56%. <sup>34</sup>
myrcene	not stated. <sup>14</sup>
nerol	4.36%. <sup>34</sup>
<i>n</i> -nonadecane C <sub>19</sub>	8.10%. <sup>34</sup>
nonadecene C <sub>19:1</sub>	2.28%. <sup>34</sup>
<i>n</i> -pentacosane C <sub>25</sub>	2.86%. <sup>34</sup>
<i>trans</i> -rose oxide	0.04%. <sup>34</sup>
<i>n</i> -tricosane C <sub>23</sub>	5.90%. <sup>34</sup>
<b><i>Flower</i></b>	
cyanin	not stated <sup>14</sup>
EO (undefined)	2000 ppm <sup>14</sup>
eusupinin A	not stated <sup>33</sup>
gallic acid	not stated <sup>14</sup>
malic acid	not stated <sup>14</sup>
methionine sulfoxide	not stated <sup>14</sup>
pectin	not stated <sup>14</sup>
quercitrin	not stated <sup>14</sup>
resin	not stated <sup>14</sup>
rugosin A	not stated <sup>33</sup>
rugosin B	not stated <sup>33</sup>
rugosin D	not stated <sup>33</sup>
saponin	13,000 ppm <sup>14</sup>
shisonin-A	not stated <sup>14</sup>
sugar	not stated <sup>14</sup>
tannins	100,000 - 240,000 ppm <sup>14</sup>
tartaric acid	not stated <sup>14</sup>
tellimagrandin I	not stated <sup>33</sup>
wax	not stated <sup>14</sup>
<b><i>Leaf</i></b>	
saponin (in leaf)	85,000 ppm <sup>14</sup>
<b><i>Stem</i></b>	
ash content	< 20%. <sup>35</sup>
benzyl alcohol	< 4 ppm <sup>35</sup>
limonene	< 1 ppm <sup>35</sup>
lipid content	< 1%. <sup>35</sup>
polyphenols	> 20%. <sup>35</sup>
water content	2 - 6%. <sup>35</sup>
<b><i>Whole plant (main volatile constituents)</i></b>	
citronellol	not stated <sup>16</sup>
geraniol	not stated <sup>16</sup>
phenethyl alcohol	not stated <sup>16</sup>
<b><i>Whole plant (constituent levels potentially present)</i></b>	
citral	< 8 ppm <sup>27</sup>
citronellol	< 250 ppm <sup>26</sup>
citronellol	< 100 ppm <sup>27</sup>
eugenol	< 6 ppm <sup>27</sup>
geraniol	< 250 ppm <sup>26</sup>
geraniol	< 150 ppm <sup>27</sup>
farnesol	< 4 ppm <sup>27</sup>

**Table 4. Frequency (2023) and concentration (2021) of use according to likely duration and exposure and by product category.**

	# of Uses	Max Conc of Use (%)	# of Uses	Max Conc of Use (%)	# of Uses	Max Conc of Use (%)
	Rosa Centifolia Flower		Rosa Centifolia Flower Extract		Rosa Centifolia Flower Oil	
<b>Totals</b>	<b>16</b>	<b>NR</b>	<b>179</b>	<b>0.0001-0.025</b>	<b>30</b>	<b>0.001-0.002</b>
<b>summarized by likely duration and exposure*</b>						
<b>Duration of Use</b>						
Leave-On	7	NR	152	0.0001-0.025	22	0.001-0.002
Rinse-Off	2	NR	26	0.0001-0.002	6	NR
Diluted for (Bath) Use	7	NR	1	0.0001-0.002	2	NR
<b>Exposure Type**</b>						
Eye Area	NR	NR	5	0.0005-0.02	NR	NR
Incidental Ingestion	NR	NR	7	0.002	1	0.001
Incidental Inhalation-Spray	3 <sup>a</sup> ; 4 <sup>b</sup>	NR	2; 57 <sup>a</sup> ; 63 <sup>b</sup>	0.0005-0.025; 0.01 <sup>b</sup>	9 <sup>a</sup> ; 8 <sup>b</sup>	NR
Incidental Inhalation-Powder	3 <sup>a</sup>	NR	57 <sup>a</sup> ; 1 <sup>c</sup>	0.0001; 0.00013-0.002 <sup>c</sup>	9 <sup>a</sup>	0.001-0.002 <sup>c</sup>
Dermal Contact	15	NR	160	0.0001-0.025	26	0.001-0.002
Deodorant (underarm)	NR	NR	NR	NR	NR	NR
Hair - Non-Coloring	NR	NR	12	0.001-0.002	3	NR
Hair-Coloring	NR	NR	NR	NR	NR	NR
Nail	NR	NR	NR	NR	NR	NR
Mucous Membrane	8	NR	10	0.0001-0.002	4	0.001
Baby Products	NR	NR	1	NR	NR	NR
<b>as reported by product category</b>						
<b>Baby Products</b>						
Baby Lotions/Oils/Powders/Creams			1	NR		
<b>Bath Preparations (diluted for use)</b>						
Bath Oils, Tablets, and Salts	5	NR			2	NR
Bubble Baths			1	0.0001		
Other Bath Preparations	2	NR	NR	0.002		
<b>Eye Makeup Preparations</b>						
Eye Lotion			2	0.0005		
Eye Makeup Remover			1	NR		
Mascara			NR	0.02		
Other Eye Makeup Preparations			2	NR		
<b>Fragrance Preparations</b>						
Cologne and Toilet Water			NR	0.0005-0.025		
Perfumes			1	NR		
Other Fragrance Preparation			1	0.025		
<b>Hair Preparations (non-coloring)</b>						
Hair Conditioner			4	0.001	1	NR
Hair Spray (aerosol fixatives)						
Rinses (non-coloring)					1	NR
Shampoos (non-coloring)			5	0.001-0.002	1	NR
Tonics, Dressings, and Other Hair Grooming Aids			2	NR		
Other Hair Preparations			1	NR		
<b>Hair Coloring Preparations</b>						
Hair Dyes/Colors (all types requiring caution statements and patch tests)						
<b>Makeup Preparations</b>						
Blushers			2	NR		
Face Powders			NR	0.0001		
Foundations			NR	0.0001		
Lipstick			7	0.002	1	0.001
Makeup Bases			2	NR		
Other Makeup Preparations			1	NR		
<b>Personal Cleanliness Products</b>						
Bath Soaps and Detergents			1	0.0001-0.001	1	NR
Douches	1	NR				
Other Personal Cleanliness Products			1	0.0001		
<b>Skin Care Preparations</b>						
Cleansing			9	0.002	1	NR
Face and Neck (exc shave)	4	NR	39	0.00013-0.002	7	0.002
Body and Hand (exc shave)			24	0.001-0.002	1	0.001
Moisturizing	3	NR	52	0.001	8	0.002
Night					1	NR
Paste Masks (mud packs)	1	NR	5	NR	1	NR
Skin Fresheners			3	0.01		
Other Skin Care Preparations			12	0.001	4	0.001

**Table 4. Frequency (2023) and concentration (2021) of use according to likely duration and exposure and by product category.**

	# of Uses	Max Conc of Use (%)	# of Uses	Max Conc of Use (%)	# of Uses	Max Conc of Use (%)
	Rosa Centifolia Flower Powder		Rosa Centifolia Flower Water		Rosa Centifolia Flower Wax	
<b>Totals</b>	<b>10</b>	<b>NR</b>	<b>72</b>	<b>0.0000096-0.096</b>	<b>10</b>	<b>NR</b>
<b>summarized by likely duration and exposure*</b>						
<b>Duration of Use</b>						
Leave-On	8	NR	62	0.000096-0.096	9	NR
Rinse-Off	1	NR	10	0.0000096-0.023	1	NR
Diluted for (Bath) Use	1	NR	NR	0.0048	NR	NR
Eye Area	NR	NR	8	NR	1	NR
Incidental Ingestion	NR	NR	3	NR	2	NR
Incidental Inhalation-Spray	1 <sup>a</sup> ;6 <sup>b</sup>	NR	1; 24 <sup>a</sup> ; 24 <sup>b</sup>	0.00096; 0.00096 <sup>b</sup>	1 <sup>a</sup> ; 3 <sup>b</sup>	NR
Incidental Inhalation-Powder	1;1 <sup>a</sup>	NR	24 <sup>a</sup>	0.096 <sup>c</sup>	1 <sup>a</sup>	NR
Dermal Contact	10	NR	67	0.0000096-0.096	7	NR
Deodorant (underarm)	NR	NR	NR	NR	NR	NR
Hair - Non-Coloring	NR	NR	2	0.00096-0.023	NR	NR
Hair-Coloring	NR	NR	NR	0.0096	NR	NR
Nail	NR	NR	NR	NR	NR	NR
Mucous Membrane	1	NR	6	0.0048	3	NR
Baby Products	1	NR	NR	NR	NR	NR
<b>as reported by product category</b>						
<b>Baby Products</b>						
Baby Lotions/Oils/Powders/Creams	1	NR				
<b>Bath Preparations (diluted for use)</b>						
Bath Oil, Tablets, and Salts	1	NR	NR	0.0048		
<b>Bubble Baths</b>						
<b>Other Bath Preparations</b>						
<b>Eye Makeup Preparations</b>						
Eye Lotion			1	NR		
Eye Makeup Remover			3	NR		
Mascara					1	NR
<b>Other Eye Makeup Preparations</b>						
<b>Fragrance Preparations</b>						
<b>Cologne and Toilet Water</b>						
<b>Perfumes</b>						
Other Fragrance Preparation			1	NR		
<b>Hair Preparations (non-coloring)</b>						
Hair Conditioner			1	0.023		
Hair Spray (aerosol fixatives)			NR	0.00096		
Rinses (non-coloring)						
Shampoos (non-coloring)			1	0.0096		
Tonics, Dressings, and Other Hair Grooming Aids			NR	0.00096		
<b>Other Hair Preparations</b>						
<b>Hair Coloring Preparations</b>						
Hair Dyes/Colors (all types requiring caution statements and patch tests)			NR	0.0096		
<b>Makeup Preparations</b>						
<b>Face Powders</b>						
<b>Foundations</b>						
Lipstick			3	NR	2	NR
<b>Makeup Bases</b>						
<b>Other Makeup Preparations</b>						
<b>Personal Cleanliness Products</b>						
Bath Soaps and Detergents			2	NR	1	NR
Douches						
<b>Other Personal Cleanliness Products</b>						
<b>Skin Care Preparations</b>						
Cleansing			2	0.0000096		
Face and Neck (exc shave)	5	NR	21	0.096	1	NR
Body and Hand (exc shave)	1	NR	3	0.096	2	NR
Moisturizing	1	NR	21	0.096	1	NR
Night			2	0.000096		
Paste Masks (mud packs)	1	NR		NR		
<b>Skin Fresheners</b>						
Other Skin Care Preparations			5	0.02	2	NR

NR – not reported

\*likely duration and exposure is derived based on product category (see Use Categorization <https://www.cir-safety.org/cir-findings>)

\*\*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.

<sup>a</sup> Not 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.

<sup>b</sup> It is possible these products are sprays, but it is not specified whether the reported uses are sprays.

<sup>c</sup> It is possible these products are powders, but it is not specified whether the reported uses are powders.

**Table 5.** *Rosa centifolia*-derived ingredients with no reported uses.<sup>39,40</sup>

Rosa Centifolia Bud Extract
Rosa Centifolia Callus Culture Extract
Rosa Centifolia Extract
Rosa Centifolia Flower Juice
Rosa Centifolia Leaf Cell Extract
Rosa Centifolia Stem Extract

**Table 6. Genotoxicity studies**

Test Article	Concentration/Dose	Vehicle/Solvent	Test System	Procedure	Results	Reference
<b>IN VITRO</b>						
Rosa Centifolia Stem Extract	5 – 5000 200 ug/plate	Vehicle – water	<i>Salmonella typhimurium</i> (TA98, TA100, TA1535, TA1537, TA102)	OECD TG 471; Ames test, with and without metabolic activation. Vehicle and appropriate positive controls were used.	not mutagenic Positive control caused statistically significant increase	<sup>45</sup>
Rosa Centifolia Stem Extract	1000 – 5000 µg/ml (3 h exposure) and 200 – 800 µg/ml (24 h exposure) without activation 2000 – 5000 µg/ml with activation (3 h)	Vehicle – water	cultured human peripheral blood lymphocytes	In vitro mammalian cell micronucleus test: cells were exposed to the test article for 3 or 24 h and for 3 h without metabolic activation	not genotoxic Positive control induced statistically significant increases	<sup>46</sup>
Rosa Centifolia Stem Extract	25 – 100 mg/ml	normal saline	12 reconstructed epidermal units	EpiSkin™ micronucleus assay Mitomycin was used as the positive control	not genotoxic Positive control caused statistically significant increase	<sup>47</sup>

**Table 7. Dermal irritation and sensitization studies**

Test Article	Concentration/Dose	Test Population	Procedure	Results	Reference
<b>IRRITATION</b>					
<b>ANIMAL</b>					
Rosa Centifolia Flower Oil	Undiluted	Hairless mice (number and strain not stated)	Applied to the back for an unspecified duration. Additional study details not included	No evidence of skin irritation	4
Rosa Centifolia Flower Oil	Undiluted	Rabbits (number and strain not stated)	Applied for 24 h to intact or abraded skin using occlusive patches. Additional study details not included	Test substance classified as moderately irritating to the skin	4
<b>HUMAN</b>					
Face mask containing 0.8% Rosa Centifolia Flower	Undiluted	20 subjects	Single-insult occlusive patch test; 24 h patch. Irritation scores determined at time of patch removal	No evidence of skin irritation	49
Rosa Centifolia Flower Oil	2% in petrolatum	number of subjects not stated	48-h closed patch test	No evidence of skin irritation	4
<b>SENSITIZATION</b>					
<b>HUMAN</b>					
Face mask containing 0.8% Rosa Centifolia Flower	tested neat (0.05 ml)	25 subjects (20 females, 5 males)	Maximization test. Test article (0.05 ml) applied under 15 mm occlusive patch to SLS (0.25%) pretreated site on upper outer arm or back. Procedure involved five 48-h induction patches (72 h on weekends). After a 10 - 14 d non-treatment period, a -h occlusive patch with 5% aq. SLS was applied to a previously untreated site, and an occlusive patch with the test substance was applied for 48 h. Challenge site evaluated for reactions at time of patch removal and 24 h later.	No adverse or unexpected reactions during induction phase. No evidence of contact allergy at time of challenge patch removal or 24 later. Concluded that the test article does not possess a detectable contact-sensitizing potential and, hence, is not likely to cause contact sensitivity reactions under normal use conditions.	50
Eye serum containing 0.1% Rosa Centifolia Flower Extract	tested neat (0.1 – 0.15 g) approximately 25 – 38 mg/cm <sup>2</sup> test material	49 subjects	HRIPT. Occlusive patches were applied 3x/wk for 3 wk, for a total of 9 induction applications. (The test material was volatilized for 30 – 90 min on the patch prior to application.) After a 2-wk non-treatment period, a challenge patch was applied to a new site, and 24 to 72 h after, the site was scored.	No reactions were observed during induction or challenge and the researchers concluded that the test article was not associated with skin irritation or allergic contact dermatitis.	51
Rosa Centifolia Flower Extract trade name mixture	20%	55 subjects (45 females, 10 males)	HRIPT (modified Shelanski method). Total of 9 induction patches (occlusive patches) applied over 3-wk period. Induction phase followed by 10- to 21-d non-treatment period. Occlusive challenge patch applied to new site on lower back.	No dermal reactions observed during induction or challenge phase. Test substance did not induce delayed contact sensitization.	24,52
Rosa Centifolia Flower Extract (concrete rose)	2%	28 subjects	Maximization test. Test substance applied, under occlusion, to volar aspect of forearm for 5 alternate-day 48-h periods. Test site pretreated for 24 h with 5% aqueous SLS (under occlusion). After 10- to 14-d non-treatment period, challenge phase. Single challenge application preceded by 30-min application of SLS (under occlusion). Another challenge application (different site, no pretreatment) also made	Moderate degree of irritation observed at SLS-treated site. No other significant or allergic reactions observed.	8
Rosa Centifolia Flower Extract (concrete rose)	2%	25 subjects	Modified maximization test procedure. Test substance applied, under occlusion, to volar aspect of forearm for 5 alternate 48-h periods. Initial patch test site pretreated for 24 h with 5% aqueous SLS (under occlusion). After 10- to 14-d non-treatment period, test substance (under occlusive challenge patch) applied for 48 h to new test site. Challenge applications preceded by 30-min application of 5% aqueous SLS (under occlusion). Additional challenge site not pretreated with SLS.	Approximately 1/3 of subjects tested developed irritation at SLS-treated site. No other significant irritation or allergic reactions observed. Test substance produced no reactions that were considered significantly irritating or allergic in nature	10

**Table 7. Dermal irritation and sensitization studies**

<b>Test Article</b>	<b>Concentration/Dose</b>	<b>Test Population</b>	<b>Procedure</b>	<b>Results</b>	<b>Reference</b>
Rosa Centifolia Flower Extract (concrete rose)	2%	22 subjects	Modified maximization test procedure, as described above	Test substance produced no reactions that were considered significantly irritating or allergic in nature	<sup>11</sup>
Rosa Centifolia Flower Extract (rose centifolia concrete)	2%	33 subjects	Modified maximization test procedure, as described above.	Sweat retention response observed in 1 subject. Test substance produced no reactions that were considered significantly irritating or allergic in nature	<sup>12</sup>
Rosa Centifolia Flower Extract (rose absolute)	2%	24 subjects	Modified maximization test procedure, as described above, except, challenge applications preceded by 30-min application of 2% aqueous SLS (under occlusion). Additional challenge site not pretreated with SLS.	A 3+ reaction observed in 1 subject after initial patch application. Retesting of subject did not yield positive reaction. Test substance did not induce skin sensitization	<sup>13</sup>
Rosa Centifolia Flower Extract (rose absolute)	2%	25 subjects	Maximization test. Test substance applied, under occlusion, to volar forearm for 5 alternate-day 48-h periods. Patch test sites pretreated for 24 h with 5% aqueous SLS (under occlusion). After 10-d non-treatment period, test substance, under occlusive challenge patch, applied for 48 h to new test site. Challenge applications preceded by 1-h application of 10% aqueous SLS (under occlusion). Challenge sites evaluated at time of patch removal and 24 h later.	Test substance induced contact sensitization (mild reaction) in 1 subject; therefore, the researcher concluded the test material is a mild sensitizer	<sup>7</sup>
Rosa Centifolia Flower Oil	2% in petrolatum	24 subjects	Maximization test. Protocol details not included	No evidence of skin sensitization	<sup>4</sup>

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