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## Safety Assessment of *Malva sylvestris* (Mallow) – Derived Ingredients as Used in Cosmetics

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*All interested persons are provided 60 days from the above release date (i.e., February 11, 2023) to comment on this safety assessment, and to identify additional published data that should be included or provide unpublished data which can be made public and included. Information may be submitted without identifying the source or the trade name of the cosmetic product containing the ingredient. All unpublished data submitted to the Cosmetic Ingredient Review (CIR) will be discussed in open meetings, will be available for review by any interested party, and may be cited in a peer-reviewed scientific journal. Please submit data, comments, or requests to the CIR Executive Director, Dr. Bart Heldreth.*

The Expert Panel for Cosmetic Ingredient Safety members are: Chair, Wilma F. Bergfeld, M.D., F.A.C.P.; Donald V. Belsito, M.D.; David E. Cohen, M.D.; Curtis D. Klaassen, Ph.D.; Allan E. Rettie, Ph.D.; David Ross, Ph.D.; Thomas J. Slaga, Ph.D.; Paul W. Snyder, D.V.M., Ph.D.; and Susan C. Tilton, Ph.D. The Cosmetic Ingredient Review (CIR) Executive Director is Bart Heldreth, Ph.D. This safety assessment was prepared by Preethi Raj, Senior Scientific Analyst/Writer, CIR.

## ABBREVIATIONS

AD	atopic dermatitis
CAS	Chemical Abstracts Service
cGMPs	current good manufacturing practices
CIR	Cosmetic Ingredient Review
CPSC	Consumer Product Safety Commission
Council	Personal Care Products Council
<i>Dictionary</i>	<i>International Cosmetic Ingredient Dictionary and Handbook</i>
EASI	Eczema Area and Severity Index
FDA	Food and Drug Administration
GAE	gallic acid equivalents
GRAS	generally recognized as safe
HRIPT	human repeated insult patch test
INC	International Nomenclature Committee
MTT	3-(4,5-dimethylthiazol-2-yl)-2,5- diphenyl tetrazolium bromide
NR	not reported/none reported
OECD	Organisation for Economic Co-operation and Development
Panel	Expert Panel for Cosmetic Ingredient Safety
QE	quercetin equivalents
SCORAD	Scoring Atopic Dermatitis
TPA	12- <i>O</i> -tetradecanoylphorbol-acetate
US	United States
UVB	ultraviolet B
VCRP	Voluntary Cosmetic Registration Program

## **ABSTRACT**

The Expert Panel for Cosmetic Ingredient Safety (Panel) assessed the safety of 8 *Malva sylvestris* (mallow)-derived ingredients. The majority of these ingredients are reported to function in cosmetics as skin-conditioning agents, while Malva Sylvestris (Mallow) Leaf Powder is reported to function as an exfoliant. Because final product formulations may contain multiple botanicals, each containing the same constituents of concern, formulators are advised to be aware of these constituents to avoid reaching levels that may be hazardous to consumers. With *Malva sylvestris* (mallow)-derived ingredients, the Panel was concerned about the presence of potential sensitizers (e.g., cinnamal) in cosmetics. Industry should use good manufacturing practices to minimize impurities. The Panel reviewed data relevant to the safety of these ingredients in cosmetic formulations, and concluded 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-sensitizing.

## **INTRODUCTION**

This assessment reviews the safety of 8 *Malva sylvestris* (mallow)-derived ingredients as used in cosmetic formulations:

Malva Sylvestris (Mallow) Extract	Malva Sylvestris (Mallow) Flower/Leaf/Stem Extract
Malva Sylvestris (Mallow) Flower	Malva Sylvestris (Mallow) Leaf Extract
Malva Sylvestris (Mallow) Flower Extract	Malva Sylvestris (Mallow) Leaf Powder
Malva Sylvestris (Mallow) Flower/Leaf Extract	Malva Sylvestris (Mallow) Oil

According to the web-based International *Cosmetic Ingredient Dictionary and Handbook* (wINCI Dictionary), 6 of these ingredients are reported to function in cosmetics as skin-conditioning agents, and one, Malva Sylvestris (Mallow) Leaf Powder, is reported to function as an exfoliant (Table 1).<sup>1</sup> Malva Sylvestris (Mallow) Oil is not included in the *Dictionary*; however, it has reported uses in the 2022 US Food and Drug Administration (FDA) Voluntary Cosmetic Registration Program (VCRP) database, and is thus being reviewed herein.

As indicated in their names, all of these ingredients are derived from the same plant species, *Malva sylvestris*. *Malva sylvestris* may contain hundreds of constituents. Thus, in this assessment, the Panel is evaluating the safety of each of the *Malva sylvestris*-derived ingredients as a whole, complex substance; toxicity from single components may not predict the potential toxicity of botanical ingredients.

Some of the ingredients reviewed in this safety assessment may be consumed as food, and daily exposure from food use would result in much larger systemic exposures than those from use in cosmetic products. The primary focus of the safety assessment of these ingredients as used in cosmetics is on the potential for effects from topical exposure.

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 listing 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 Cosmetic Ingredient Review (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 are provided by the cosmetics industry, as well as by other interested parties.

The cosmetic ingredient names, according to the *Dictionary*, are written as listed above, without italics. In many of the published studies, it is not known how the substance being tested compares to the ingredient as used in cosmetics. Therefore, if it is not known whether the ingredient being discussed is a cosmetic ingredient, the test substance will be identified by the standard taxonomic practice of using italics to identify genus and species (i.e., *Malva sylvestris* extract) or by using its common name (e.g., mallow extract). However, if it is known that the substance is a cosmetic ingredient, the International Nomenclature Committee (INC) terminology (i.e. title case and no italics) “Malva Sylvestris...” (e.g., Malva Sylvestris (Mallow) Extract) will be used. When referring to the plant from which these ingredients are derived, the standard scientific practice of using italics will be followed (i.e., *Malva sylvestris*).

## **CHEMISTRY**

### **Definition and Plant Identification**

The definitions of 7 of the 8 *Malva sylvestris* (mallow)-derived ingredients reviewed in this assessment (Malva Sylvestris (Mallow) Oil is not in the *Dictionary*) are presented in Table 1.<sup>1</sup> Malva Sylvestris (Mallow) Flower Extract and Malva Sylvestris (Mallow) Flower/Leaf/Stem Extract both have the CAS No. 84082-57-5. The remaining ingredients do not have assigned CAS numbers.

Generically, the flower is defined as the reproductive shoot in flowering plants, and is usually composed of sepals, petals, stamens, and pistil(s). The stem is defined as a slender or elongated structure, which supports a plant, fungus, or plant organ. The leaves are defined as the flattened photosynthetic organs of a plant, which are attached to the plant stems.

*Malva sylvestris* is a perennial herbaceous plant, native to Europe, Asia, and Northern Africa, and is colloquially known as blue or common mallow.<sup>2,3</sup> The leaves are green, with rounded or acute apexes, and multiple (mostly seven) lobes. The

flowers of *Malva sylvestris* are odorless, displaying five wedge-shaped, notched petals, mauve to purple in color, with dark veins. A *Malva sylvestris* plant bears 20-35 branches with 50-75 flowers per branch, emerging from leaf axils on each node.

### Chemical Properties

Malva Sylvestris (Mallow) Extract, Malva Sylvestris (Mallow) Flower Extract, Malva Sylvestris (Mallow) Flower/Leaf Extract, Malva Sylvestris (Mallow) Leaf Extract, and Malva Sylvestris (Mallow) Oil are liquids. According to a supplier, an aqueous Malva Sylvestris (Mallow) Flower/Leaf Extract as well as a hydroglycolic and aqueous Malva Sylvestris (Mallow) Leaf Extract are miscible in water and 50% v/v alcohol, and are not miscible in mineral and vegetal oils.<sup>4-9</sup> A summary of chemical properties described for these *Malva sylvestris* (Mallow)-derived ingredients is provided in Table 2.

### Method of Manufacture

Some of the methods of manufacture described herein were submitted by suppliers. However, others are general to the processing of *Malva sylvestris* (mallow), for which it is unknown if these apply to cosmetic ingredient manufacturing.

#### Malva Sylvestris (Mallow) Extract

In a method for producing a methanolic *Malva sylvestris* extract, the whole plant was chopped into small pieces, shade-dried, and ground.<sup>10</sup> This ground plant material was extracted with methanol three times at room temperature and filtered. The filtrate was evaporated under reduced pressure to yield a dark greenish extract that was suspended in water.

#### Malva Sylvestris (Mallow) Flower Extract

One supplier described several methods of manufacture for Malva Sylvestris (Mallow) Flower Extract, via various solvents.<sup>11</sup> Two ethanolic Malva Sylvestris (Mallow) Flower Extracts were produced via extraction of dried *Malva sylvestris* (mallow) flowers with either 30% or 50% v/v ethanolic solution, followed by filtration (other solvents not disclosed). Another ethanolic (30% v/v) Malva Sylvestris (Mallow) Flower Extract was prepared by dissolving the extract of dried *Malva sylvestris* (mallow) flowers with 30% ethanolic solution in squalane, prior to filtration (other solvent not disclosed). A Malva Sylvestris (Mallow) Flower Extract was obtained by filtering the extract of dried *Malva sylvestris* (mallow) flowers with 50% v/v 1, 3-butylene glycolic solution (other solvent not disclosed). Alternatively, an aqueous extract of dried *Malva sylvestris* (mallow) flowers was dissolved in 30% v/v 1,3-butylene glycolic solution prior to filtration.

Malva Sylvestris (Mallow) Flower Extract was extracted using eluents such as water, butylene glycol, carthamus tinctorius (safflower) seed oil, glycerin, and propylene glycol, to yield a concentrate.<sup>12</sup> This concentrate containing the phytochemical constituents is then blended with the desired diluent(s) and preservatives to produce the final ingredient.

During the production of a *Malva sylvestris* flower extract, raw *Malva sylvestris* flowers were crushed to particle size 2-6 mm.<sup>13</sup> The extractions were carried out using the fractional maceration method, with solutions of 10 – 90% v/v ethanol (at room temperature) and with purified water (within 20-100 °C). The obtained extracts were combined and refined with a paper filter.

#### Malva Sylvestris (Mallow) Flower/Leaf Extract

According to a supplier, Malva Sylvestris (Mallow) Flower/Leaf Extract is prepared using the following method.<sup>14</sup> Flowers and leaves of *Malva sylvestris* are extracted via steam distillation, and the resulting extract is filtered to yield Malva Sylvestris (Mallow) Flower/Leaf Extract. This ingredient is preserved with 1.5% phenoxyethanol.<sup>4</sup>

In another preparation of a *Malva sylvestris* (mallow) flower/leaf extract, air-dried plant flowers and leaves of *Malva sylvestris* were extracted using a soxhlet type apparatus with n-hexane, dichloromethane, and methanol, respectively.<sup>15</sup> The extracts were then dried in a vacuum.

#### Malva Sylvestris (Mallow) Flower/Leaf/Stem Extract

A fine dried powder of the flowery stem of *Malva sylvestris* was extracted by stirring with 30 ml of methanol at 25 °C at 150 rpm for 1 h, and then filtered.<sup>16</sup> The residue was then extracted for a second time with an additional 30 ml of methanol. The combined methanolic extracts were evaporated at 35 °C under reduced pressure, re-dissolved in methanol at a concentration of 10 mg/ml, and stored at 4 °C.

#### Malva Sylvestris (Mallow) Leaf Extract

According to supplier-provided data, Malva Sylvestris (Mallow) Leaf Extract can be produced using various solvents. For a hydroglycolic Malva Sylvestris (Mallow) Leaf Extract, *Malva sylvestris* leaves are extracted with a mixture of propylene glycol and water, and the resulting extract is filtered to yield the final product.<sup>17</sup> An aqueous Malva Sylvestris (Mallow) Leaf Extract is produced via steam distillation and filtration.<sup>18</sup> This extract is preserved with 1.5% phenoxyethanol.<sup>6</sup>

In an alternate preparation of a *Malva sylvestris* (mallow) leaf extract, *Malva sylvestris* leaves were cleaned under shade, and ground to a fine powder.<sup>19</sup> The powder (30 g) was then extracted with 500 ml of 50% methanol for 24 h at room temperature with magnetic stirring. The resulting extract was centrifuged at 4500 g for 10 min and lyophilized before being stored at -21 °C.

### Malva Sylvestris (Mallow) Leaf Powder

During the process of making a *Malva sylvestris* (mallow) leaf powder, the green vegetable portion of *Malva sylvestris* was washed and dried in an oven at 60 °C for at least 24 h.<sup>20</sup> This dried sample was crushed into a powder prior to use in extraction.

### Malva Sylvestris (Mallow) Oil

Aerial portions of the *Malva sylvestris* plant were air-dried in shade at room temperature prior to grinding to a fine powder.<sup>21</sup> These three powder samples (50 g in triplicates) were extracted via hydrodistillation for 3 h, using a Clevenger-type apparatus. The resulting oils were dried over anhydrous sodium sulphate and stored in the dark.

### **Composition and Impurities**

According to a 2018 European Medicines Agency assessment on *Malva sylvestris* L., mucilage, polysaccharides, anthocyanins, flavonoids, fatty acids, organic acids, tocopherols, phenolic derivatives, polyphenols, and terpenoids are among the constituents known to be present in the flowers and leaves of the *Malva sylvestris* plant.<sup>22</sup>

### Malva Sylvestris (Mallow) Extract

The total phenolic content in hexane, dichloromethane, methanol, and aqueous extracts of the whole *Malva sylvestris* plant was determined using the Folin-Ciocalteu assay and expressed in standard gallic acid equivalents (GAE).<sup>10</sup> The phenolic content was 41.73, 73.31, 59.91, and 40.91, respectively. The total flavonoid content in these extracts, using rutin as a positive control, was determined to be 38.13, 69.22, 61.12, and 37.22, respectively. Both the phenolic and flavonoid content were highest for the dichloromethane extract.

### Malva Sylvestris (Mallow) Flower Extract

According to a supplier, an ethanolic (50% v/v) Malva Sylvestris (Mallow) Flower Extract and a Malva Sylvestris (Mallow) Flower Extract obtained using a 1,3-butylene glycolic solution (50% v/v), both comprising tannins and anthocyanins, did not contain more than 20 ppm heavy metals or more than 2 ppm arsenic.<sup>11</sup> Similarly, an ethanolic (30% v/v) Malva Sylvestris (Mallow) Flower Extract comprising tannins, saccharides, and anthocyanins, did not contain more than 20 ppm heavy metals or 2 ppm arsenic. A Malva Sylvestris (Mallow) Flower Extract, extracted in 30% ethanolic solution and dissolved in squalane, was reported to comprise essential oil whilst containing no more than 10 ppm heavy metals and 2 ppm arsenic. An aqueous Malva Sylvestris (Mallow) Flower Extract, dissolved in a 1,3-butylene glycolic solution (30% v/v), comprising tannins and anthocyanins, was reported to contain no more than 20 ppm heavy metals and no more than 2 ppm arsenic.

A Malva Sylvestris (Mallow) Flower Extract concentrate, in an alcohol base, was tested for the presence of known fragrance allergens.<sup>12</sup> All of the following constituents were found to be below the European Union Cosmetic Directive threshold of less than 1 ppm – 0.0001%: amyl cinnamal, benzyl alcohol, cinnamyl alcohol, citral, eugenol, hydroxycitronellal, isoeugenol, amylcinnamyl alcohol, benzyl salicylate, cinnamal, hydroxyisohexyl 3-cyclohexene, carboxaldehyde, coumarin, geraniol, anise alcohol, benzyl cinnamate, farnesol, butylphenyl methylpropional, linalool, benzyl benzoate, citronellol, hexyl cinnamal, limonene, methyl 12-octynoate, and  $\alpha$ -isomethyl inone.

Malva Sylvestris (Mallow) Flower Extract concentrate, in a glycerin and water base, was tested for the presence of impurities.<sup>12</sup> No residual pesticides and none of the following heavy metals were detected: antimony, arsenic, cadmium, chromium, iron, lead, mercury, and nickel.

*Malva sylvestris* (mallow) flowers that were extracted with 70% ethanol were evaluated for phenol and flavonoid content.<sup>23</sup> The extract was determined to have a total phenolic content of  $6.32 \pm 0.13$  GAE/g, and a total flavonoid content of  $1.45 \pm 0.21$  quercetin equivalents (QE)/g. Additionally, the composition and determination of individual constituents found in *Malva sylvestris* (mallow) flower extract, varies considerably depending on extraction solvent and method.<sup>13</sup> For example, maximum polysaccharide and flavonoid content were obtained from wild mallow flowers when extracted with purified water at increased temperatures.

### Malva Sylvestris (Mallow) Flower/Leaf Extract

An aqueous extract of Malva Sylvestris (Mallow) Flower/Leaf Extract was described by a supplier to contain  $\geq 98\%$  water, 1.5% phenoxyethanol, and  $\leq 0.50\%$  *Malva sylvestris* extract.<sup>24</sup> Additionally, the manufacturer of the Malva Sylvestris (Mallow) Flower/Leaf Extract attested that the ingredient was made in accordance with the European Cosmetic Regulation 1223/2009/EC, and that it does not contain any of the 26 allergenic substances listed in this regulation.<sup>25</sup> The manufacturer confirmed the absence of unwanted impurities and attested that this ingredient is devoid of diethylene glycol, dioxin, formaldehyde, formol, gluten, glycol ether, phthalate, and volatile organic compounds (with the exception of phenoxyethanol).

### Malva Sylvestris (Mallow) Flower/Leaf/Stem Extract

Leaves, flowers, immature fruits, and leafy flowered stems of *Malva sylvestris* plant, that were extracted in methanol, were compared for their chemical composition.<sup>16</sup> Leaves contained the highest amounts of phenolics (386.45 mg/g of

extract), flavonoids (210.81 mg/g) and carotenoids (0.19 mg/g). Flowers contained the highest amount of ascorbic acid ( $1.11 \pm 0.07$ ). A comparison of these constituents by plant part can be found in Table 3.

#### Malva Sylvestris (Mallow) Leaf Extract

A hydroglycolic Malva Sylvestris (Mallow) Leaf Extract comprises 67.6% propylene glycol, 30% water, and 2.4% Malva Sylvestris (Mallow) Leaf Extract.<sup>26</sup> An aqueous Malva Sylvestris (Mallow) Leaf Extract comprises 98% water, 1.50% phenoxyethanol, and 0.50% Malva Sylvestris (Mallow) Leaf Extract.<sup>27</sup> Additionally, the manufacturer of these Malva Sylvestris (Mallow) Leaf Extracts attested that these ingredients were made in accordance with the European Cosmetic Regulation 1223/2009/EC, and did not contain any of the 26 allergenic substances listed in this regulation, or unwanted impurities.<sup>28,29</sup> Accordingly, the manufacturer attested that these ingredients are devoid of diethylene glycol, dioxin, formaldehyde, formol, gluten, glycol ether, phthalate, and volatile organic compounds (with the exception of phenoxyethanol).

In a phytochemical analysis of *Malva sylvestris* leaves, different samples contained 82.80-86.23% moisture, 13.10-14.85% ash, 0.16-0.30% fat, 2.95-5% fiber, and 2.49-3.22% protein.<sup>30</sup> Various fatty acids, including linolenic acid and palmitic acid, as well as minerals (calcium, sodium, magnesium, iron, phosphorus, zinc, and copper, in descending order by quantity) were also found in the leaves.

The total phenolic content of an aqueous *Malva sylvestris* (mallow) leaf extract was determined to be  $153.02 \pm 2.88$  mg GAE/g.<sup>31</sup> In another study, *Malva sylvestris* leaves extracted with 70% ethanol were determined to have a total phenolic content of  $1.42 \pm 0.14$  GAE/g, and a total flavonoid content of  $0.76 \pm 0.19$  QE/g.<sup>23</sup>

#### Malva Sylvestris (Mallow) Oil

In a gas chromatography-mass spectrometry analysis of dried *Malva sylvestris* flowers, the aroma-active compounds were extracted by hydrodistillation.<sup>32</sup> This extraction produced a light yellow oil with a sweet odor and 143 identifiable volatile compounds. The main compounds found were hexadecenoic acid (10.1%), pentacosane (4.8%), and 6,10,14-trimethyl-2-pentadecanone (4.1%). The essential oil mainly comprised hydrocarbons (25.40%), alcohols (18.78%), acids (16.66%), ethers (5.01%), ketones (7.28%), esters (12.43%), aldehydes (2.3%), and others (2%).

Phenolic compounds, carbonyl compounds, oxygenated sesquiterpenes, fatty acids and esters, and hydrocarbons were identified as the main constituent categories for oil obtained from the aerial parts of several *Malva sylvestris* plants.<sup>21</sup> In another study, a few of the aroma-active compounds found in oil extracted from dry *Malva sylvestris* flowers were identified as phenanthrene (2090 µg/kg), 2,3-dihydrobenzofuran (1440 µg/kg), menthol (1030 µg/kg), borneol (620 µg/kg), and limonene (440 µg/kg).<sup>32</sup>

### USE Cosmetic

The safety of the cosmetic ingredients addressed in this assessment is evaluated based on data received from the US 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 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 2022 VCRP survey data, all of the ingredients named in this assessment are reported to be in use.<sup>33</sup> Malva Sylvestris (Mallow) Extract is reported to be used in 198 formulations, 184 of which are leave-on products, and Malva Sylvestris (Mallow) Flower Extract is reported to be used in 72 formulations (Table 4). The other ingredients have 5 or fewer reported uses. The results of the concentration of use survey conducted by the Council in 2022 indicate Malva Sylvestris (Mallow) Flower Extract has the highest reported maximum concentration of use at 0.1% in non-spray body and hand products and in depilatories.<sup>34</sup> Although VCRP frequency of use data were reported for all ingredients, concentration of use data were only received for Malva Sylvestris (Mallow) Extract and Malva Sylvestris (Mallow) Flower Extract.

Malva Sylvestris (Mallow) Extract is reported to be used in products that can result in incidental ingestion, such as 52 lipstick formulations (concentration of use not provided). Malva Sylvestris (Mallow) Extract and Malva Sylvestris (Mallow) Flower Extract are reported to be used in products applied near the eye, in 6 and 2 other eye makeup preparations, respectively (concentrations of use not provided). Of note, Malva Sylvestris (Mallow) Flower Extract has reported uses in baby shampoo, lotions, oils, powders and creams (2 reported uses; concentrations of use not provided).

Furthermore, some of the *Malva sylvestris* (mallow)-derived ingredients are used in powder formulations, and could possibly be inhaled. For example, Malva Sylvestris (Mallow) Extract and Malva Sylvestris (Mallow) Flower Extract are reported to be used in 2 and 5 face powder formulations, respectively (concentrations of use not provided). 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 cosmetics 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.

All of the ingredients named in the report are not restricted from use in any way under the rules governing cosmetic products in the European Union.<sup>35</sup>

### **Non-Cosmetic**

*Malva sylvestris* (mallow) leaves, flowers, seeds, stems, and buds are consumed across cultures as a traditional herb and food, with a multitude of traditional medicine uses, including as a mild laxative, anti-inflammatory agent, a liver cleansing tonic, and prophylactic against heartburn.<sup>36</sup> Due to its high mucilage content, mallow traditionally is used to treat oral or pharyngeal irritations and gastrointestinal discomfort.<sup>22</sup>

## **TOXICOKINETIC STUDIES**

No relevant toxicokinetic studies were found in the published literature, and unpublished data were not 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**

No acute toxicity studies were found in the published literature, and unpublished data were not submitted.

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

#### **Malva Sylvestris (Mallow) Leaf Extract**

The effects of a *Malva sylvestris* (mallow) leaf extract upon male Wistar rat heart and testes were evaluated.<sup>19</sup> Six male Wistar rats were orally administered 0.2 g/kg bw *Malva sylvestris* (mallow) leaf extract for 60 d, during which the animals received an intraperitoneal (i.p.) injection of distilled water (0.5 ml/100 g bw) for the last 30 d of treatment. No significant changes were seen in the weights of the testis, genital tract (seminal vesicles, epididymis, prostate), or heart of rats treated with the leaf extract. Normal cellular morphology of seminiferous tubules and lumen with mature spermatozoa were seen in the testes, and myocardial sections of rats treated with the *Malva sylvestris* (mallow) leaf extract showed slightly separated myocardial fibers with small focus of inflammatory mononuclear collections with the absence of necrotic damage.

## **DEVELOPMENTAL AND REPRODUCTIVE TOXICITY STUDIES**

A short-term toxicity study of a *Malva sylvestris* (mallow) leaf extract (described previously) examined the effects on the testes and genital tract of male rats.<sup>19</sup> (See the Short-Term Toxicity section for results.) No full developmental or reproductive toxicity studies were found in the published literature, and unpublished data were not submitted.

## **GENOTOXICITY STUDIES**

#### **Malva Sylvestris (Mallow) Flower Extract**

A Malva Sylvestris (Mallow) Flower Extract (extracted with 50% v/v 1,3-butylene glycolic solution, other solvent not disclosed) was not genotoxic when tested at concentrations up to 10,000 µg/0.1 ml/plate in *Salmonella typhimurium* TA98, TA100, TA1535, TA1537, and *Escherichia coli* WP2 uvrA strains in an Ames test.<sup>11</sup> No further details were provided. Another Malva Sylvestris (Mallow) Flower Extract (aqueous, further dissolved in 30% v/v 1,3-butylene glycolic solution) was also not genotoxic when tested in the same *S. typhimurium* and *E. coli* strains at concentrations up to 5000 µg/0.1 ml/plate. No further details were provided.

## **CARCINOGENICITY STUDIES**

No carcinogenicity studies were found in the published literature, and unpublished data were not submitted.

## **OTHER RELEVANT STUDIES**

### **Cytotoxicity**

#### **Malva Sylvestris (Mallow) Leaf Extract**

The cytotoxic potential of a methanolic *Malva sylvestris* (mallow) leaf extract against melanoma and lymphoma cell lines was evaluated in a 3-(4,5-dimethylthiazol-2-yl)-2,5-diphenyltetrazolium bromide (MTT) assay.<sup>37</sup> The extract was tested at concentrations of 10, 50, 100, 150, or 200 µg/ml in both cell lines. The cytotoxic effect increased in a concentration-dependent manner; the extract was cytotoxic to melanoma at a higher rate (76.53%) than lymphoma (68.65%) at the maximum test concentration (200 µg/ml) of the extract. Also, a minimal cytotoxic effect (7%) was observed against the normal cell line at the same concentration.

### **Photoprotective Effects**

#### **Malva Sylvestris (Mallow) Extract**

Groups of 5 male and 5 female albino BALB/c mice were used in an experiment to determine the photoprotective potential of orally ingested and topically applied *Malva sylvestris* (mallow) extract upon ultraviolet B (UVB) radiation on mice skin.<sup>38</sup> The animals were divided into 4 groups: (1) a control group which was neither exposed to UVB irradiation nor the *Malva sylvestris* (mallow) extract, (2) a group which was exposed to UVB irradiation only, (3) a group which was orally administered 1 ml of *Malva sylvestris* (mallow) extract before UVB irradiation, (4) and a group which had the *Malva sylvestris* (mallow) extract applied dermally 5 min prior to irradiation with UVB light (further details not provided). With the exception of the controls, all groups were exposed to UVB irradiation for 20 min, 4 d/wk, for a month, on shaved back skin (2 x 5 cm). UVB irradiation was shown to create changes in the epidermis, including keratinocyte proliferation, leading to epidermal thickness, which was most evident in the UVB-irradiation-only group (group 2). Compared to group 2, epidermal thickness was slight to mild-moderate for the groups which were either orally or topically administered the *Malva sylvestris* (mallow) extract. While the epidermal thickness (measured in µm) for group 2 was 12.93 times greater than in controls, the epidermal thickness for group 3 (oral exposure of *Malva sylvestris* (mallow) extract) was 3.75 times that of controls. Furthermore, the oral administration of *Malva sylvestris* (mallow) extract, as well as topical administration (topical-specific results not provided) was shown to significantly decrease the inflammatory cell infiltration associated with UVB irradiation.

### **Topical Anti-Inflammatory Effects**

#### **Malva Sylvestris (Mallow) Leaf Extract**

The ability of a hydroalcoholic *Malva sylvestris* (mallow) leaf extract to reduce 12-*O*-tetradecanoylphorbol-acetate (TPA) – induced inflammation was examined in female Swiss mice (number not specified).<sup>39</sup> Edema was induced on the right ears of the mice by topically applying 2.5 µg/ear of TPA dissolved in 20 µl of acetone. Shortly after inducing inflammation, hydroalcoholic extract of *Malva sylvestris* leaves (0.001-3.0 mg/ear), or other compounds, such as malvidin 3,5-glucoside (0.0004–0.1 µmol/ear), malvidin 3-glucoside (0.0002–0.2 µmol/ear), scopoletin (0.0001–1.5 µmol/ear), quercetin (0.003–3.3 µmol/ear) and dexamethasone (0.05 mg/ear, used as a positive control) were dissolved in 20 µl and applied directly on the induction site. Thickness of the ears was measured before and 6 h after induction of inflammation. The edema reduction caused by the hydroalcoholic extract was  $77 \pm 6\%$  (3 mg/ear), compared to that of malvidin 3-glucoside ( $90 \pm 3\%$ ; 0.2 µmol/ear), and quercetin ( $55 \pm 2\%$ ; 3.3 µmol/ear).

## **DERMAL IRRITATION AND SENSITIZATION STUDIES**

### **Irritation**

#### **Animal**

##### **Malva Sylvestris (Mallow) Flower Extract**

A *Malva Sylvestris* (Mallow) Flower Extract (extracted with 50% v/v 1,3-butylene glycolic solution) was not irritating when tested at 10% and 100% in a primary skin irritation test using 3 rabbits.<sup>11</sup> No further details were provided.

#### **Human**

##### **Malva Sylvestris (Mallow) Flower Extract**

A *Malva Sylvestris* (Mallow) Flower Extract (aqueous, further dissolved in 30% v/v 1,3-butylene glycolic solution) was non-irritating when tested at 10% in a closed patch test using 34 subjects.<sup>11</sup> No further details were provided.

### **Sensitization**

#### **Human**

##### **Malva Sylvestris (Mallow) Flower Extract**

The sensitizing potential of a *Malva Sylvestris* (Mallow) Flower Extract (aqueous, further dissolved in 30% v/v 1,3-butylene glycolic solution) was evaluated at 10% in a modified Marzulli-Maibach human repeated insult patch test (HRIPT) using 54 subjects.<sup>11</sup> The ingredient was described as a mild material which did not induce delayed contact sensitization. No further details were provided.



### Malva Sylvestris (Mallow) Flower/Leaf/Stem Extract

The dermal irritation and sensitization potential of a product containing 0.0125% Malva Sylvestris (Mallow) Flower/Leaf/Stem Extract was evaluated in an HRIPT using 101 subjects.<sup>40</sup> Nine occlusive induction applications of 20 µl were applied to the back under Finn chambers over 3 wk. After a 2-wk non-treatment period, a 48-h occlusive challenge application was made to the original test site and to a new test site on the opposite side of the back. Test sites were evaluated 30 min and 48 and 96 h after application. One adverse event was reported, which was unrelated to the test article. The test article was determined to not be a dermal irritant or sensitizer.

### **Photosensitization/Phototoxicity**

#### **Animal**

#### Malva Sylvestris (Mallow) Flower Extract

A Malva Sylvestris (Mallow) Flower Extract (aqueous, further dissolved in 30% v/v 1,3-butylene glycolic solution) was not phototoxic to the skin of guinea pigs (n = 5) when tested at 1 and 10%.<sup>11</sup> No further details were provided. Similarly, the same extract was not photosensitizing to guinea pigs (n = 5) when tested at 10% during induction and at 1 and 10% during challenge. No further details were provided.

### **OCULAR IRRITATION STUDIES**

No ocular irritation studies were found in the published literature, and unpublished data were not submitted.

### **CLINICAL STUDIES**

#### **Treatment of Atopic Dermatitis**

#### Malva Sylvestris (Mallow) Flower Extract

In a double-blind randomized clinical trial, the efficacy of a topical cream containing a *Malva sylvestris* (mallow) flower extract to manage atopic dermatitis (AD) in pediatric patients was evaluated.<sup>41</sup> Fifty-one children with AD were randomized to either be treated with a single fingertip unit, twice a day, of a topical cream containing a *Malva sylvestris* (mallow) flower extract or a cream base placebo, for 4 wk. Both creams were instructed to be applied as to completely cover lesions. No adverse events occurred in either study group. The primary measured outcome of this study was the severity of AD as assessed using the SCORing Atopic Dermatitis (SCORAD) questionnaire, which was filled out by the study investigator biweekly. SCORAD scores were based on 3 aspects of AD: redness, skin thickening, and crusting. A significant reduction of the severity of dermatitis was seen in the *Malva sylvestris* cream group, regarding the mean difference scores and the SCORAD total scores compared with the baseline after 2 and 4 wk of treatment. Additionally, there was a significant improvement in the skin thickening score, redness score and total SCORAD score for the *Malva sylvestris* cream group, when compared with the placebo group.

#### **Treatment of Hand Eczema**

#### Malva Sylvestris (Mallow) Extract

The safety and effectiveness of *Malva sylvestris* as an herbal alternative to corticosteroids and anti-histamines for the treatment of hand eczema was evaluated in a randomized clinical trial.<sup>42</sup> (Details on the plant part used to make the ointment were not provided.) Fifty subjects with hand eczema were randomized to either receive a single finger tip unit, twice daily (for both hands, everyday), of an ointment containing 4% *Malva sylvestris* or the same amount of a placebo for 6 wk. Therapeutic results for erythema, excoriation, lichenification, edema, dryness, itching, and oozing were compared between the two groups 3 and 6 wk after beginning of treatment. Erythema, excoriation, and lichenification were assessed using the Eczema Area and Severity Index (EASI) scoring system; edema, dryness, itching, and oozing were also scored similarly. There was a statistically significant difference between both groups for all measured scores at the first and second follow-up. No therapeutic adverse effects were seen in either group.

### **SUMMARY**

According to the *Dictionary*, 6 of these 8 ingredients are reported to function as skin-conditioning agents and one ingredient, Malva Sylvestris (Mallow) Leaf Powder, is reported to be an exfoliant. Malva Sylvestris (Mallow) Oil is not included in the *Dictionary*; however, it has reported uses in the 2022 VCRP database, and is thus being reviewed herein.

Malva Sylvestris (Mallow) Extract is reported to have the greatest frequency of use in 198 formulations, 184 of which are leave-on formulations. The highest reported concentration of use amongst these ingredients is for Malva Sylvestris (Mallow) Flower Extract at 0.1% in non-spray body and hand products and in depilatories. It should be noted that all ingredients have use reported in the VCRP, but concentration of use data were only reported for 2 ingredients.

Six male Wistar rats were orally administered 0.2 g/kg bw *Malva sylvestris* (mallow) leaf extract for 60 d, with an i.p. dose of 0.5 ml/100 g bw distilled water for the last 30 d of treatment. No significant changes in the weights or cellular morphology of rat testes, genital tract, or heart were observed.

In an Ames test, a *Malva Sylvestris* (Mallow) Flower Extract, obtained via extraction with 50% v/v 1,3-butylene glycol solution, was not genotoxic when tested at concentrations of up to 10,000 µg/0.1 ml/plate in *S. typhimurium* TA98, TA100, TA1535, TA1537 and *E. coli* WP2 uvrA strains. Similarly, an aqueous *Malva Sylvestris* (Mallow) Flower Extract, further dissolved in 30% v/v 1,3-butylene glycol solution, was not genotoxic when tested at concentrations of up to 5000 µg/0.1 ml/ plate in another Ames test using the same bacterial strains.

A methanolic extract of *Malva sylvestris* (mallow) leaf extract was cytotoxic when tested at concentrations of 10, 50, 100, 150, 200 µg/ml against melanoma and lymphoma cell lines in an MTT assay. The extract was cytotoxic in a dose-dependent manner and showed a higher rate of cytotoxicity against the melanoma cell line (76.53%) than the lymphoma cell line (68.65%).

Groups of 5 male and 5 female albino BALB/c mice were exposed to UVB-irradiation, in the presence and absence of orally administered (1 ml) or dermally applied *Malva sylvestris* (mallow) extract. The epidermal changes, skin thickness, and inflammatory response caused by UVB irradiation were especially reduced by oral and topical administration of the *Malva sylvestris* (mallow) extract.

*Malva sylvestris* (mallow) leaf extract was applied, along with other compounds, to female mouse ears after inducing topical inflammation with TPA. Edema reduction caused by the hydroalcoholic *Malva sylvestris* (mallow) extract was  $77 \pm 6\%$  (3 mg/ear), compared to that of malvidin 3-glucoside ( $90 \pm 3\%$ ; 0.2 µmol/ear), and quercetin ( $55 \pm 2\%$ ; 3.3 µmol/ear).

A *Malva Sylvestris* (Mallow) Flower Extract (extracted with 50% v/v 1,3-butylene glycol solution) was not irritating when tested at 10 and 100% in a primary skin irritation test using 3 rabbits. A *Malva Sylvestris* (Mallow) Flower Extract (aqueous, further dissolved in 30% v/v 1,3-butylene glycol solution) was non-irritating at 10% in a closed patch test using 34 subjects, and non-irritating and non-sensitizing when tested at 10% in a modified Marzulli-Maibach HRIPT using 54 subjects. A product containing 0.0125% *Malva Sylvestris* (Mallow) Flower/Leaf/Stem Extract was not irritating or sensitizing in an HRIPT of 101 subjects. One adverse event was reported, which was deemed unrelated to the test article.

A *Malva Sylvestris* (Mallow) Flower Extract (aqueous, further dissolved in 30% v/v 1,3-butylene glycol solution) was not phototoxic to guinea pig skin when tested at 1 and 10%. The same extract was also not photosensitizing to guinea pig skin when tested at 10% during induction and at 1 and 10% during challenge.

In a double-blind, randomized clinical trial, the efficacy of a topical cream containing *Malva sylvestris* extract to manage atopic dermatitis (AD) was evaluated in 51 pediatric patients for 4 wk. A significant reduction of the severity of dermatitis was seen in the *Malva sylvestris* cream group, regarding the mean difference scores and the SCORAD total scores compared with the baseline after 2 and 4 wk of treatment. Additionally, there was a significant improvement in the skin thickening score, redness score and total SCORAD score for the *Malva sylvestris* cream group, when compared with the placebo group.

An ointment containing 4% *Malva sylvestris* was tested as an herbal alternative to corticosteroids and anti-histamines in a randomized clinical trial of 50 subjects. Erythema, excoriation, and lichenification were assessed using the EASI scoring system; edema, dryness, itching, and oozing were also scored similarly. There was a statistically significant difference between both groups for all measured scores at the first and second follow-up. No therapeutic adverse effects were seen in either group.

## **DISCUSSION**

The Panel reviewed the safety of 8 *Malva sylvestris* (mallow)-derived ingredients, and concluded that the available data are sufficient for determining that all 8 ingredients are safe in cosmetics in the present practices of use and concentration when formulated to be non-sensitizing. The Panel acknowledged the absence of systemic toxicity data, but noted that *Malva sylvestris* (mallow) leaves, flowers, seeds, stems, and buds are consumed as food. Accordingly, these food exposures would likely result in much larger systemic exposure compared to that resulting from use in cosmetic products, mitigating the need for systemic toxicity data.

*Malva sylvestris* (mallow)-derived ingredients are used (or assumed to be used) at low concentrations in cosmetic formulations. Additionally, *Malva Sylvestris* (Mallow) Flower Extract and *Malva Sylvestris* (Mallow) Flower/Leaf/Stem Extract were not irritating or sensitizing in HRIPTs. However, because final product formulations may contain multiple botanicals, each possibly containing the same constituents of concern, formulators are advised to be aware of these constituents and to avoid reaching levels that may be hazardous to consumers. For *Malva sylvestris* (mallow)-derived ingredients, the Panel was concerned about the presence of cinnamal in cosmetics, which could result in sensitization. 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.

The Panel discussed the issue of incidental inhalation exposure resulting from these ingredients (e.g., Malva Sylvestris (Mallow) Extract and Malva Sylvestris (Mallow) Flower Extract are reported to be used face powder formulations (concentrations of use not provided)). Inhalation toxicity data were not available. However, the Panel noted that the majority of 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>.

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 determined by the Panel. Therefore, the Panel has concluded the data are 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 8 *Malva sylvestris* (mallow)-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:

Malva Sylvestris (Mallow) Extract  
Malva Sylvestris (Mallow) Flower  
Malva Sylvestris (Mallow) Flower Extract  
Malva Sylvestris (Mallow) Flower/Leaf Extract

Malva Sylvestris (Mallow) Flower/Leaf/Stem Extract  
Malva Sylvestris (Mallow) Leaf Extract  
Malva Sylvestris (Mallow) Leaf Powder  
Malva Sylvestris (Mallow) Oil

## TABLES

**Table 1. Definitions and functions of *Malva sylvestris* (mallow) – derived ingredients<sup>1\*</sup>**

<b>Ingredient/CAS No.</b>	<b>Definition</b>	<b>Function</b>
Malva Sylvestris (Mallow) Extract	Malva Sylvestris (Mallow) Extract is the extract of the whole plant, <i>Malva sylvestris</i> .	Skin-conditioning agents-miscellaneous
Malva Sylvestris (Mallow) Flower	Malva Sylvestris (Mallow) Flower is the flowers of <i>Malva sylvestris</i> .	Skin-conditioning agents-miscellaneous
Malva Sylvestris (Mallow) Flower Extract 84082-57-5	Malva Sylvestris (Mallow) Flower Extract is the extract of the flowers of <i>Malva sylvestris</i> .	Skin-conditioning agents-miscellaneous
Malva Sylvestris (Mallow) Flower/Leaf Extract	Malva Sylvestris (Mallow) Flower/Leaf Extract is the extract of the flowers and leaves of <i>Malva sylvestris</i> .	Skin-conditioning agents-miscellaneous
Malva Sylvestris (Mallow) Flower/Leaf/Stem Extract 84082-57-5	Malva Sylvestris (Mallow) Flower/Leaf/Stem Extract is the extract of the flowers, leaves, and stems of <i>Malva sylvestris</i> .	Skin-conditioning agents-miscellaneous
Malva Sylvestris (Mallow) Leaf Extract	Malva Sylvestris (Mallow) Leaf Extract is the extract of the leaves of <i>Malva sylvestris</i> .	Skin-conditioning agents-miscellaneous
Malva Sylvestris (Mallow) Leaf Powder	Malva Sylvestris (Mallow) Leaf Powder is the powder obtained from the dried, ground leaves of <i>Malva sylvestris</i> .	Exfoliants

\*Malva Sylvestris (Mallow) Oil is not included in this table because it is not an INCI ingredient

**Table 2. Chemical properties of *Malva sylvestris* (mallow)-derived ingredients**

<b>Property</b>	<b>Value</b>	<b>Reference</b>
<b>Mallow Sylvestris (Mallow) Extract</b>		
Physical Form	liquid	10
Color	dark green	10
<b>Malva Sylvestris (Mallow) Flower Extract (in glycerin and water)</b>		
Physical Form	liquid	12
Color	medium to dark amber	12
Odor	characteristic	12
Density (@ 25 °C)	1.05 – 1.15	12
pH (@ 25°C)	4 – 6.5	12
Refractive Index (@ 25 °C)	1.3992 – 1.5	12
Solubility	Soluble in any proportion of water	12
<b>Malva Sylvestris (Mallow) Flower/Leaf Extract (aqueous extract)</b>		
Physical Form	liquid	4,7
Color	transparent	4,7
Odor	characteristic	4,7
Density (@ 20 °C)	0.999 – 1.002	4,7
pH (°C not specified)	4.7 – 6.7	4,7
Refractive index (@ 20°C)	1.332 – 1.339	4
Solubility (10% diluted)		4,7
<i>Miscible</i>	water, 50% v/v alcohol, propylene glycol	
<i>Nonmiscible</i>	mineral oils, vegetal oils	
<b>Malva Sylvestris (Mallow) Leaf Extract (hydroglycolic extract)</b>		
Physical Form	liquid, with possibly a slight precipitate	5,8
Color	brown to yellow brown; translucent	5,8
Odor	characteristic	5,8
Density (@ 20 °C)	1.047 – 1.060	5,8
Flash point (° C)	≥ 100	5,8
pH (°C not specified)	4.6- 5.7	5,8
Refractive index (@ 20 °C)	1.410 – 1.420	5
Solubility (10% diluted)		5,8
<i>Miscible</i>	water, 50% v/v alcohol	
<i>Nonmiscible</i>	mineral oils, vegetal oils	
<b>Malva Sylvestris (Mallow) Leaf Extract (aqueous extract)</b>		
Physical Form	liquid	6,9
Color	colorless, transparent	6,9
Odor	characteristic	6,9
Density (@ 20 °C)	0.999 – 1.002	6,9
pH (°C not specified)	5.2 – 7.2	6,9
Refractive index (@ 20 °C)	1.332 – 1.339	6
Solubility (10% diluted)		6,9
<i>Miscible</i>	water, 50% v/v alcohol, propylene glycol	
<i>Nonmiscible</i>	mineral oils, vegetal oils	

**Table 2. Chemical properties of *Malva sylvestris* (mallow)-derived ingredients**

Property	Value	Reference
<b>Malva Sylvestris (Mallow) Oil</b>		
Physical Form	liquid	32
Color	light yellow	32
Odor	sweet	32

**Table 3. Constituents across various parts of the *Malva sylvestris* plant (mg/g methanolic extract)<sup>16</sup>**

	Leaves	Flowers	Immature fruits	Leafy flowered stems
<b>Phenolics</b>	386.45 ± 8.54	258.65 ± 26.04	56.76 ± 2.01	317.93 ± 2.61
<b>Flavonoids</b>	210.81 ± 7.99	46.55 ± 5.26	25.35 ± 2.72	143.40 ± 7.86
<b>Ascorbic Acid</b>	0.17 ± 0.05	1.11 ± 0.07	0.27 ± 0.00	0.20 ± 0.04
<b>Carotenoids</b>	0.19 ± 0.00	0.03 ± 0.00	0.01 ± 0.00	0.11 ± 0.00

**Table 4. Frequency (2022)<sup>33</sup> and concentration of use (2022)<sup>34</sup> of *Malva sylvestris* (mallow)-derived ingredients according to duration and exposure**

	# of Uses      Max Conc of Use (%)		# of Uses      Max Conc of Use (%)		# of Uses      Max Conc of Use (%)	
	Malva Sylvestris (Mallow) Extract		Malva Sylvestris (Mallow) Flower		Malva Sylvestris (Mallow) Flower Extract	
Totals*	198	0.0002 – 0.003	1	NR	72	0.00012 – 0.1
Duration of Use						
Leave-On	184	0.003	NR	NR	43	0.005 – 0.1
Rinse-Off	10	0.0002	NR	NR	28	0.00012 – 0.1
Diluted for (Bath) Use	4	NR	1	NR	1	0.002
Exposure Type						
Eye Area	13	NR	NR	NR	2	NR
Incidental Ingestion	52	NR	NR	NR	NR	NR
Incidental Inhalation-Spray	40 <sup>a</sup> ; 35 <sup>b</sup>	NR	NR	NR	12 <sup>a</sup> ; 13 <sup>b</sup>	NR
Incidental Inhalation-Powder	2; 35 <sup>b</sup>	0.003 <sup>c</sup>	NR	NR	6; 13 <sup>b</sup> ; 1 <sup>c</sup>	0.02 – 0.1 <sup>c</sup>
Dermal Contact	145	0.0002 – 0.003	1	NR	53	0.002 – 0.1
Deodorant (underarm)	NR	NR	NR	NR	1 <sup>a</sup>	NR
Hair - Non-Coloring	1	NR	NR	NR	19	NR
Hair-Coloring	NR	NR	NR	NR	NR	0.00012
Nail	NR	NR	NR	NR	NR	NR
Mucous Membrane	58	NR	1	NR	2	0.002
Baby Products	NR	NR	NR	NR	2	NR
	Malva Sylvestris (Mallow) Flower/Leaf Extract		Malva Sylvestris (Mallow) Flower/Leaf/Stem Extract		Malva Sylvestris (Mallow) Leaf Extract	
Totals*	4	NR	5	NR	4	NR
Duration of Use						
Leave-On	4	NR	4	NR	4	NR
Rinse Off	NR	NR	1	NR	NR	NR
Diluted for (Bath) Use	NR	NR	NR	NR	NR	NR
Exposure Type						
Eye Area	1	NR	NR	NR	NR	NR
Incidental Ingestion	NR	NR	NR	NR	NR	NR
Incidental Inhalation-Spray	1 <sup>a</sup> ; 2 <sup>b</sup>	NR	3 <sup>a</sup>	NR	2 <sup>b</sup>	NR
Incidental Inhalation-Powder	2 <sup>b</sup>	NR	NR	NR	2 <sup>b</sup>	NR
Dermal Contact	3	NR	4	NR	4	NR
Deodorant (underarm)	NR	NR	NR	NR	1 <sup>a</sup>	NR
Hair - Non-Coloring	1	NR	1	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
	Malva Sylvestris (Mallow) Leaf Powder		Malva Sylvestris (Mallow) Oil			
Totals*	1	NR	2	NR		
Duration of Use						
Leave-On	NR	NR	NR	NR		
Rinse-Off	1	NR	2	NR		
Diluted for (Bath) Use	NR	NR	NR	NR		
Exposure Type						
Eye Area	NR	NR	NR	NR		
Incidental Ingestion	NR	NR	NR	NR		
Incidental Inhalation-Spray	NR	NR	NR	NR		
Incidental Inhalation-Powder	NR	NR	NR	NR		
Dermal Contact	NR	NR	2	NR		
Deodorant (underarm)	NR	NR	NR	NR		
Hair - Non-Coloring	NR	NR	NR	NR		
Hair-Coloring	1	NR	NR	NR		
Nail	NR	NR	NR	NR		
Mucous Membrane	NR	NR	2	NR		
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.

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

<sup>b</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 categories.

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

NR – not reported

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