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

Status:	Draft Report for Panel Review
Release Date:	November 10, 2022
Panel Meeting Date:	December 5-6, 2022

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.

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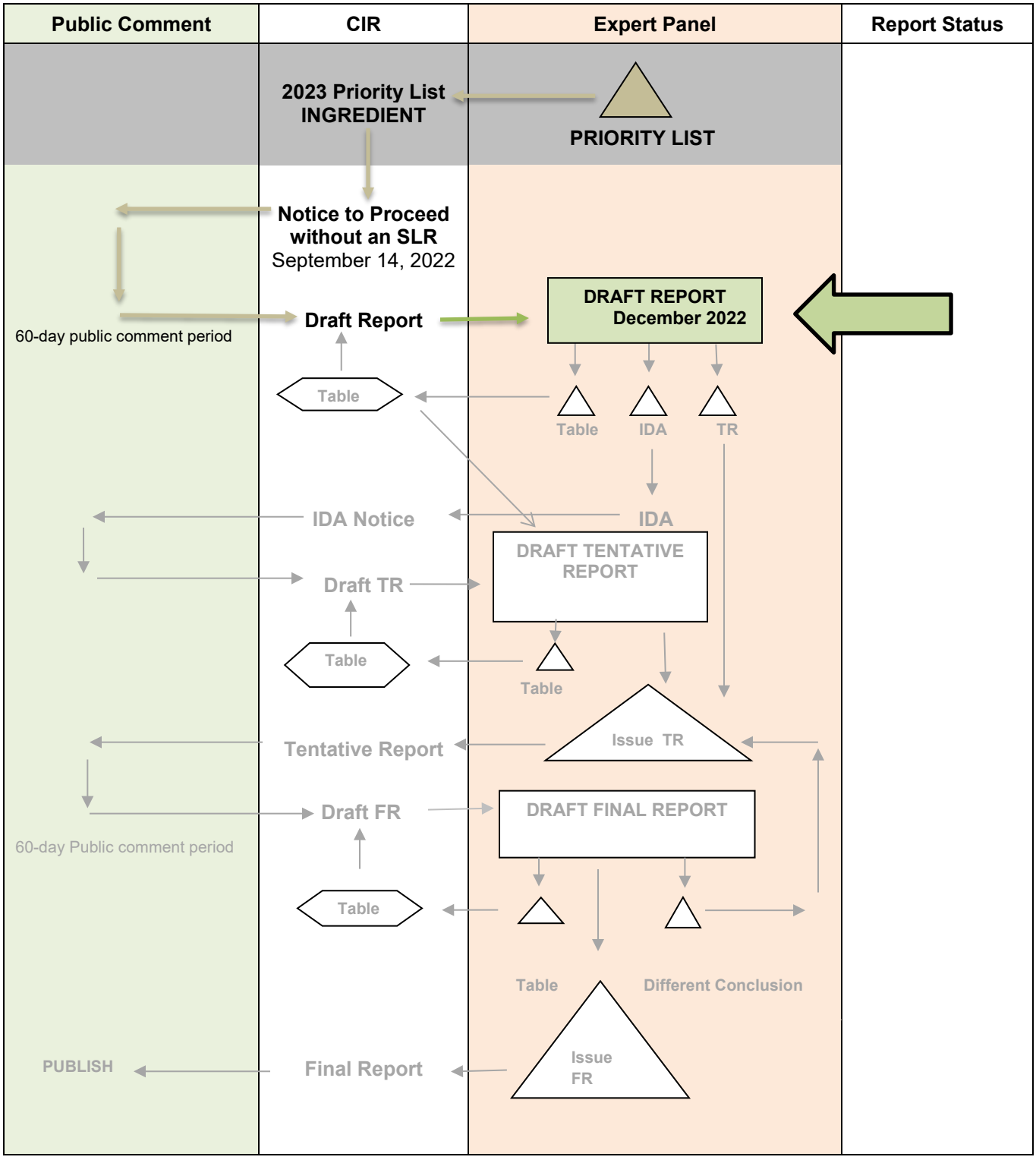
SAFETY ASSESSMENT FLOW CHART

INGREDIENT/FAMILY *Malva sylvestris* (Mallow)-Derived Ingredients

MEETING December 2022



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Memorandum

To: Expert Panel for Cosmetic Ingredient Safety Members and Liaisons

From: Preethi S. Raj, M.Sc.
Senior Scientific Analyst/Writer, CIR

Date: November 10, 2022

Subject: Safety Assessment of *Malva sylvestris* (Mallow)-Derived Ingredients as Used in Cosmetics

Enclosed is the Draft Report of the Safety Assessment of *Malva sylvestris* (Mallow)-Derived Ingredients as Used in Cosmetics (identified as *report_Mallow_122022* in the pdf). This is the first time Panel is seeing a safety assessment of these 8 cosmetic ingredients.

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

Due to a dearth of published data found upon search of these ingredients, a Scientific Literature Review Notice to Proceed (SLR NTP) was announced on September 14, 2022. Information was sought in a wide range of areas, especially chemistry (including method of manufacture, composition, and impurities); toxicity (especially dermal); developmental and reproductive toxicity; genotoxicity; carcinogenicity; and dermal irritation/sensitization data.

Concentration of use data and VCRP data were received from the Council and the FDA, respectively, in 2022 (*data1_Mallow_122022; VCRP_Mallow_122022*). The following unpublished data were also received, and have been incorporated in the report:

data2_Mallow_122022

- CEP-Solabia Group. 2012. Manufacturing process Vegebios® of Mixt Mallow 1.5P (Malva Sylvestris (Mallow) Flower/Leaf Extract)
- CEP-Solabia Group. 2012. Ingredient breakdown Vegebios® of Mixt Mallow 1.5P (Malva Sylvestris (Mallow) Flower/Leaf Extract).
- CEP-Solabia Group. 2015. Specifications data sheet Vegebios® of Mixt Mallow 1.5P (Malva Sylvestris (Mallow) Flower/Leaf Extract)
- CEP-Solabia Group. 2015. Safety data sheet Vegebios® of Mixt Mallow 1.5P (Malva Sylvestris (Mallow) Flower/Leaf Extract)
- CEP-Solabia Group. 2015. Attestations file Vegebios® of Mixt Mallow 1.5P (Malva Sylvestris (Mallow) Flower/Leaf Extract)
- CEP-Solabia Group. 2009. Manufacturing process Glycolysat® of Wild Mallow UP (Malva Sylvestris (Mallow) Leaf Extract)
- CEP-Solabia Group. 2015. Ingredient breakdown Glycolysat® of Wild Mallow UP (Malva Sylvestris (Mallow) Leaf Extract)
- CEP-Solabia Group. 2015. Specifications data sheet Glycolysat® of Wild Mallow UP (Malva Sylvestris (Mallow) Leaf Extract)
- CEP-Solabia Group. 2015. Safety data sheet Glycolysat® of Wild Mallow UP (Malva Sylvestris (Mallow) Leaf Extract).
- CEP-Solabia Group. 2016. Attestation file Glycolysat® of Wild Mallow UP (Malva Sylvestris (Mallow) Leaf Extract)
- CEP-Solabia Group. 2012. Manufacturing process Vegebios® Wild Mallow 1.5P (Malva Sylvestris (Mallow) Leaf Extract)

- CEP-Solabia Group. 2022. Ingredient breakdown Vegebios® Wild Mallow 1.5P (Malva Sylvestris (Mallow) Leaf Extract)
- CEP-Solabia Group. 2022. Specifications data sheet Vegebios® Wild Mallow 1.5P (Malva Sylvestris (Mallow) Leaf Extract)
- CEP-Solabia Group. 2022. Safety data sheet Vegebios® Wild Mallow 1.5P (Malva Sylvestris (Mallow) Leaf Extract)
- CEP-Solabia Group. 2015. Attestations file Vegebios® Wild Mallow 1.5P (Malva Sylvestris (Mallow) Leaf Extract

data3_Mallow_122022

- Anonymous. 2022. Malva Sylvestris (Mallow) Flower Extract (method of manufacture, impurities, example specifications)

data4_Mallow_122022

- Anonymous. 2009. Human repeat insult patch test (product containing 0.0125% Malva Sylvestris (Mallow) Flower/Leaf/Stem Extract)

Also included in this package, for your review, are a flow chart (*flow_Mallow_122022*), a literature search strategy (*search_Mallow_122022*), an ingredient data profile (*dataprofile_Mallow_122022*), and an ingredient history (*history_Mallow_122022*).

After reviewing these documents, if the available data are deemed sufficient to make a determination of safety, the Panel should issue a Tentative Report with a safe as used, safe with qualifications, unsafe, or split conclusion, and Discussion items should be identified. If the available data are insufficient, the Panel should issue an Insufficient Data Announcement (IDA) specifying the data needs therein.

CIR History of:

Malva Sylvestris (Mallow)-Derived Ingredients

January and July 2022

-Frequency of use data obtained

-Concentration of use data submitted by Council

September 2022

-SLR Notice to Proceed was issued

Data received :

September 23, 2022:

Vegebios® of Mixt Mallow 1.5P (Malva Sylvestris (Mallow) Flower/Leaf Extract)

- CEP-Solabia Group. 2012. Manufacturing process, Ingredient breakdown,
- CEP- Solabia Group. 2015. Specifications data sheet, Safety data sheet, Attestations file

Glycolysat® of Wild Mallow UP (Malva Sylvestris (Mallow) Leaf Extract)

- CEP-Solabia Group. 2009. Manufacturing process
- CEP-Solabia Group. 2015. Ingredient breakdown, Specifications data sheet, Safety data sheet
- CEP-Solabia Group. 2016. Attestation file

Vegebios® Wild Mallow 1.5P (Malva Sylvestris (Mallow) Leaf Extract)

- CEP-Solabia Group. 2012. Manufacturing process
- CEP-Solabia Group. 2022. Ingredient breakdown, Specifications data sheet, Safety data sheet
- CEP-Solabia Group. 2015. Attestations file

September 28, 2022:

- Anonymous. 2022. Malva Sylvestris (Mallow) Flower Extract (method of manufacture, impurities, example specifications).

October 12, 2022:

- Anonymous. 2009. Human repeat insult patch test (product containing 0.0125% Malva Sylvestris (Mallow) Flower/Leaf/Stem Extract)

December 2022

-A Draft Report is being presented to the Panel.

Malva Sylvestris (Mallow) Data Profile* – December 5 -6, 2022 – Writer, Preethi Raj																														
					Toxico-kinetics		Acute Tox			Repeated Dose Tox			DART		Genotox		Carci		Dermal Irritation			Dermal Sensitization				Ocular Irritation		Clinical Studies	
	Reported Use	GRAS	Method of Mfg	Constituents/ Impurities	Dermal Penetration	ADME	Dermal	Oral	Inhalation	Dermal	Oral	Inhalation	Dermal	Oral	In Vitro	In Vivo	Dermal	Oral	In Vitro	Animal	Human	In Vitro	Animal	Human	Phototoxicity	In Vitro	Animal	Retrospective/ Multicenter	Case Reports
Malva Sylvestris (Mallow) Extract	X		X	X							X																		
Malva Sylvestris (Mallow) Flower	X																												
Malva Sylvestris (Mallow) Flower Extract	X		X	X																									
Malva Sylvestris (Mallow) Flower/Leaf Extract	X		X	X																	X			X					
Malva Sylvestris (Mallow) Flower/Leaf/Stem Extract	X		X	X																									
Malva Sylvestris (Mallow) Leaf Extract	X		X	X																									
Malva Sylvestris (Mallow) Leaf Powder	X		X																										
Malva Sylvestris (Mallow) Oil	X		X	X																									

* "X" indicates that data were available in a category for the ingredient

Malva Sylvestris (Mallow) derived-Ingredient]

Ingredient	CAS #	InfoB	PubMed	FDA	EU	ECHA	IUCLID	SIDS	ECETOC	HPVIS	NICNAS	NTIS	NTP	WHO	FAO	NIOSH	FEMA	Web
Malva Sylvestris (Mallow) Extract		✓	✓*	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	
Malva Sylvestris (Mallow) Flower		✓	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	
Malva Sylvestris (Mallow) Flower Extract	84082-57-5	✓	✓	NR	NR	✓*	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	✓
Malva Sylvestris (Mallow) Flower/Leaf Extract		✓	✓	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	✓
Malva Sylvestris (Mallow) Flower/Leaf/Stem Extract	84082-57-5	✓	✓	NR	NR	✓*	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	✓
Malva Sylvestris (Mallow) Leaf Extract		✓	✓	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	✓
Malva Sylvestris (Mallow) Leaf Powder		✓	✓	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	
Malva Sylvestris (Mallow) Oil			NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	

✓- data available; ✓*- data available, but not relevant; NR – not reported

Botanical and/or Fragrance Websites (if applicable)

Ingredient	CAS #	Dr. Duke's	Taxonomy	GRIN	Sigma-Aldrich	IFRA	RIFM
Malva Sylvestris (Mallow) Extract		✓*	✓*	✓*	NR	NR	NR
Malva Sylvestris (Mallow) Flower		✓*	✓*	✓*	NR	NR	NR
Malva Sylvestris (Mallow) Flower Extract		✓*	✓*	✓*	NR	NR	NR
Malva Sylvestris (Mallow) Flower/Leaf Extract	84082-57-5	✓*	✓*	✓*	NR	NR	NR
Malva Sylvestris (Mallow) Flower/Leaf/Stem Extract		✓*	✓*	✓*	NR	NR	NR
Malva Sylvestris (Mallow) Leaf Extract	84082-57-5	✓*	✓*	✓*	NR	NR	NR
Malva Sylvestris (Mallow) Leaf Powder		✓*	✓*	✓*	NR	NR	NR
Malva Sylvestris (Mallow) Oil		✓*	✓*	✓*	NR	NR	NR

Search Strategy

[*total # of hits / # hits that were useful*]

PubMed

As of 10/24/2022:

((((((((((((((((((((((((malva sylvestris (mallow) extract) OR (mallow extract)) OR (malva sylvestris (mallow) flower extract)) OR (mallow flower extract)) OR (84082-57-5)) OR (malva sylvestris (mallow) flower)) OR (mallow flower)) OR (common mallow)) OR (malva sylvestris mallow flower leaf extract)) OR (mallow flower leaf extract)) OR (malva

sylvestris mallow flower leaf stem extract)) OR (mallow blossom extract)) OR (vegebios of mixt mallow)) OR (bluemallow)) OR (malva sylvestris (malvenblueten) flower Extract)) OR (phytami common mallow flower)) OR (vitactyl)) OR (glycolysat of wild mallow)) OR (malva sylvestris mallow leaf extract)) OR (mallow leaf powder)) OR (mallow powder)) OR (malva sylvestris mallow leaf powder)) OR (mallow oil)) OR (malva sylvestris oil)) OR (malva sylvestris mallow oil)) OR (malva sylvestris leaf oil)) OR (malva sylvestris flower powder)) OR (mallow flower powder)) OR (malva sylvestris mallow flower leaf stem water)) OR (mallow flower leaf stem water)) OR (mallow water)) OR (mallow leaf water)) OR (malva sylvestris leaf water) – 147/7

- AND mutagenicity – 0/0
- AND carcinogenicity – 0/0
- AND developmental toxicity – 0/0
- AND reproductive toxicity – 2/0
- AND skin lightening/ depigmentation – 0/0
- AND impurities – 0/0
- AND heavy metal limits – 3/0
- AND dermal irritation – 0/0
- AND dermal sensitization – 0/0

Blue mallow toxicity – 0/0
Mallow acute oral toxicity – 98/1
Malva sylvestris acute oral toxicity – 24/2

General Search

Malva sylvestris dermal sensitization – 43/0
Malva sylvestris dermal irritation – 85/2
Wild mallow dermal irritation – 112/0
Wild mallow dermal sensitization – 69/0
Malva sylvestris systemic toxicity – 55/5

0 use ingredients to search:
Malva Sylvestris (Mallow) Flower Powder – 115/0
Malva Sylvestris (Mallow) Flower/Leaf/Stem Water – 101/1
Malva Sylvestris (Mallow) Leaf Water – 154/2

mallow leaf water oral toxicity – 59/0

LINKS

Search Engines

- Pubmed (- http://www.ncbi.nlm.nih.gov/pubmed)
- Toxnet (https://toxnet.nlm.nih.gov/); (includes Toxline; HSDB; ChemIDPlus; DART; IRIS; CCRIS; CPDB; GENE-TOX)
- Scifinder (https://scifinder.cas.org/scifinder)

appropriate qualifiers are used as necessary
search results are reviewed to identify relevant documents

Pertinent Websites

- wINCI - http://webdictionary.personalcarecouncil.org
- FDA databases http://www.ecfr.gov/cgi-bin/ECFR?page=browse
- FDA search databases: http://www.fda.gov/ForIndustry/FDABasicsforIndustry/ucm234631.htm;,
- EAFUS: http://www.accessdata.fda.gov/scripts/fcn/fcnnavigation.cfm?rpt=eafuslisting&displayall=true
- GRAS listing: http://www.fda.gov/food/ingredientspackaginglabeling/gras/default.htm
- SCOGS database: http://www.fda.gov/food/ingredientspackaginglabeling/gras/scogs/ucm2006852.htm
- Indirect Food Additives: http://www.accessdata.fda.gov/scripts/fdcc/?set=IndirectAdditives
- Drug Approvals and Database: http://www.fda.gov/Drugs/InformationOnDrugs/default.htm
- http://www.fda.gov/downloads/AboutFDA/CentersOffices/CDER/UCM135688.pdf
- FDA Orange Book: https://www.fda.gov/Drugs/InformationOnDrugs/ucm129662.htm
- OTC ingredient list: https://www.fda.gov/downloads/aboutfda/centersoffices/officeofmedicalproductsandtobacco/cder/ucm135688.pdf
- (inactive ingredients approved for drugs: http://www.accessdata.fda.gov/scripts/cder/iig/
- HPVIS (EPA High-Production Volume Info Systems) - https://ofmext.epa.gov/hpvis/HPVISlogon
- NIOSH (National Institute for Occupational Safety and Health) - http://www.cdc.gov/niosh/
- NTIS (National Technical Information Service) - http://www.ntis.gov/
- NTP (National Toxicology Program) - http://ntp.niehs.nih.gov/
- Office of Dietary Supplements https://ods.od.nih.gov/
- FEMA (Flavor & Extract Manufacturers Association) - http://www.femaflavor.org/search/apachesolr_search/
- EU CosIng database: http://ec.europa.eu/growth/tools-databases/cosing/
- ECHA (European Chemicals Agency – REACH dossiers) – http://echa.europa.eu/information-on-chemicals;jsessionid=A978100B4E4CC39C78C93A851EB3E3C7.live1
- ECETOC (European Centre for Ecotoxicology and Toxicology of Chemicals) - http://www.ecetoc.org
- European Medicines Agency (EMA) - http://www.ema.europa.eu/ema/
- IUCLID (International Uniform Chemical Information Database) - https://iuclid6.echa.europa.eu/search
- OECD SIDS (Organisation for Economic Co-operation and Development Screening Info Data Sets)- http://webnet.oecd.org/hpv/ui/Search.aspx
- SCCS (Scientific Committee for Consumer Safety) opinions: http://ec.europa.eu/health/scientific_committees/consumer_safety/opinions/index_en.htm
- NICNAS (Australian National Industrial Chemical Notification and Assessment Scheme)- https://www.nicnas.gov.au/
- International Programme on Chemical Safety http://www.inchem.org/
- FAO (Food and Agriculture Organization of the United Nations) - http://www.fao.org/food/food-safety-quality/scientific-advice/jecfa/jecfa-additives/en/
- WHO (World Health Organization) technical reports - http://www.who.int/biologicals/technical_report_series/en/
- www.google.com - a general Google search should be performed for additional background information, to identify references that are available, and for other general information

Botanical Websites, if applicable

- Dr. Duke's - https://phytochem.nal.usda.gov/phytochem/search
- Taxonomy database - http://www.ncbi.nlm.nih.gov/taxonomy
- GRIN (U.S. National Plant Germplasm System) - https://npgsweb.ars-grin.gov/gringlobal/taxon/taxonomysimple.aspx
- Sigma Aldrich plant profiler- http://www.sigmaaldrich.com/life-science/nutrition-research/learning-center/plant-profiler.html
- American Herbal Products Association Botanical Safety Handbook (database) - http://www.ahpa.org/Resources/BotanicalSafetyHandbook.aspx
- European Medicines Agency Herbal Medicines - http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/landing/herbal_search.jsp
- National Agricultural Library NAL Catalog (AGRICOLA) https://agricola.nal.usda.gov/
- The Seasoning and Spice Association List of Culinary Herbs and Spices
- http://www.seasoningandspice.org.uk/ssa/background_culinary-herbs-spices.aspx

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ABBREVIATIONS

AD	atopic dermatitis
CAS	Chemical Abstracts Service
CIR	Cosmetic Ingredient Review
CPSC	Consumer Product Safety Commission
Council	Personal Care Products Council
Dictionary	*International Cosmetic Ingredient Dictionary and Handbook*
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-*O*-tetradecanoylphorbol-acetate
US	United States
UVB	ultraviolet B
VCRP	Voluntary Cosmetic Registration Program

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
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

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).[1] 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.[1] 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.[2,3] 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 and a hydroglycolic and an aqueous Malva Sylvestris (Mallow) Leaf Extract are miscible in water and 50% v/v alcohol, and are not miscible in mineral and vegetal oils.[4-9] 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.[10] 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

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.[11] 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.[12] 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.[13] 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.[4]

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.[14] 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.[15] 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.[16] An aqueous Malva Sylvestris (Mallow) Leaf Extract is produced via steam distillation and filtration.[17] This extract is preserved with 1.5% phenoxyethanol.[6]

In an alternate preparation of a *Malva sylvestris* (mallow) leaf extract, *Malva sylvestris* leaves were cleaned under shade, and ground to a fine powder.[18] 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.[19] 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.[20] 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.[21]

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).[10] 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

A Malva Sylvestris (Mallow) Flower Extract concentrate, in an alcohol base, was tested for the presence of known fragrance allergens.[11] 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 l2-octynoate, and α-isomethyl inone.

Malva Sylvestris (Mallow) Flower Extract concentrate, in a glycerin and water base, was tested for the presence of impurities.[11] 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.[22] The extract was determined to have a total phenolic content of 6.32 ± 0.13 GAE/g, and a total flavonoid content of 1.45 ± 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.[12] 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 ≥ 98% water, 1.5% phenoxyethanol, and ≤ 0.50% *Malva sylvestris* extract.[23] 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.[24] 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.[15] 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 ± 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.[25] An aqueous Malva Sylvestris (Mallow) Leaf Extract comprises 98% water, 1.50% phenoxyethanol, and 0.50% Malva Sylvestris (Mallow) Leaf Extract.[26] 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.[27,28] 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.[29] 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 ± 2.88 mg GAE/g.[30] In another study, *Malva sylvestris* leaves extracted with 70% ethanol were determined to have a total phenolic content of 1.42 ± 0.14 GAE/g, and a total flavonoid content of 0.76 ± 0.19 QE/g.[22]

Malva Sylvestris (Mallow) Oil

In a gas chromatography-mass spectrometry analysis of dried *Malva sylvestris* flowers, the aroma-active compounds were extracted by hydrodistillation.[31] 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.[20] 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).[31]

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.[32] 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 depilatories).[33] Malva Sylvestris (Mallow) Flower Extract also has the highest maximum concentration of use in leave-on dermal formulations; for example, it is reported to be used at 0.1% in non-spray body and hand products. 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 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.[34]

Non-Cosmetic

Malva sylvestris (mallow) is used 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 anaphylactic against heartburn.[35] Due to its high mucilage content, mallow traditionally is used to treat oral or pharyngeal irritations and gastrointestinal discomfort.[21]

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.

Subchronic 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.[18] 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.[18] (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

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

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.[36] The extract was tested at concentrations of 10, 50, 100, 150, or 200 µl 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 µl) 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.[37] 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 (amount not specified). 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 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).[38] 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 ± 6% (3 mg/ear), compared to that of malvidin 3-glucoside (90 ± 3%; 0.2 µmol/ear), and quercetin (55 ± 2%; 3.3 µmol/ear).

DERMAL IRRITATION AND SENSITIZATION STUDIES

Malva Sylvestris (Mallow) Flower/Leaf Extract

The dermal irritation and sensitization potential of a product containing 0.0125% Malva Sylvestris (Mallow) Flower/ Leaf/Stem Extract was evaluated in a human repeated insult patch test (HRIPT) using 101 subjects.[39] 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.

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* flower extract to manage atopic dermatitis (AD) in pediatric patients was evaluated.[40] 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 a herbal alternative to corticosteroids and anti-histamines for the treatment of hand eczema was evaluated in a randomized clinical trial.[41] 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 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-ons. The highest reported concentration of use amongst these ingredients is for Malva Sylvestris (Mallow) Flower Extract at 0.1% in depilatories. It should be noted that although 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 at 30 d of treatment. No significant changes in the weights or cellular morphology of rat testes, genital tract, or heart were observed.

A methanolic extract of *Malva sylvestris* (mallow) leaf extract was cytotoxic when tested at concentrations of 10, 50, 100, 150, 200 µl 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 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 ± 6% (3 mg/ear), compared to that of malvidin 3-glucoside (90 ± 3%; 0.2 µmol/ear), and quercetin (55 ± 2%; 3.3 µmol/ear).

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.

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

To be developed.

CONCLUSION

To be determined.

TABLES

Table 1. Definitions and functions of *Malva sylvestris* (mallow) – derived ingredients[1]*

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

*Malva Sylvestris (Mallow) Oil is not included because it is not an INCI ingredient

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

Property	Value	Reference
Mallow Sylvestris (Mallow) Extract		
Physical Form	liquid	10
Color	dark green	10
Malva Sylvestris (Mallow) Flower Extract (in glycerin and water)		
Physical Form	liquid	11
Color	medium to dark amber	11
Odor	characteristic	11
Density (@ 25 ºC)	1.05 – 1.15	11
pH (@ 25°C)	4 – 6.5	11
Refractive Index (@ 25 °C)	1.3992 – 1.5	11
Solubility	Soluble in any proportion of water	11
Malva Sylvestris (Mallow) Flower/Leaf Extract (aqueous extract)		
Physical Form	liquid	4,7
Color	transparent	4,7
Odor	characteristic	4,7
Density (@ 20 ºC)	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
Miscible	water, 50% v/v alcohol, propylene glycol	
Nonmiscible	mineral oils, vegetal oils	
Malva Sylvestris (Mallow) Leaf Extract (hydroglycolic extract)		
Physical Form	liquid, with possibly a slight precipitate	5,8
Color	brown to yellow brown; translucent	5,8
Odor	characteristic	5,8
Density (@ 20 ºC)	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
Miscible	water, 50% v/v alcohol	
Nonmiscible	mineral oils, vegetal oils	
Malva Sylvestris (Mallow) Leaf Extract (aqueous extract)		
Physical Form	liquid	6,9
Color	colorless, transparent	6,9
Odor	characteristic	6,9
Density (@ 20 ºC)	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
Miscible	water, 50% v/v alcohol, propylene glycol	
Nonmiscible	mineral oils, vegetal oils	

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

Property	Value	Reference
	Malva Sylvestris (Mallow) Oil	
Physical Form	liquid	[31]
Color	light yellow	[31]
Odor	sweet	[31]

Table 3. Constituents across various parts of the *Malva sylvestris* plant[15]

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

Table 4. Frequency (2022)[32] and concentration of use (2022)[33] 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[a]; 35[b]	NR	NR	NR	12[a]; 13[b]	NR
Incidental Inhalation-Powder	2; 35[b]	0.003[c]	NR	NR	6; 13[b]; 1[c]	0.02 – 0.1[c]
Dermal Contact	145	0.0002 – 0.003	1	NR	53	0.002 – 0.1
Deodorant (underarm)	NR	NR	NR	NR	1[a]	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[a]; 2[b]	NR	3[a]	NR	2[b]	NR
Incidental Inhalation-Powder	2[b]	NR	NR	NR	2[b]	NR
Dermal Contact	3	NR	4	NR	4	NR
Deodorant (underarm)	NR	NR	NR	NR	1[a]	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.

[a] It is possible these products are sprays, but it is not specified whether the reported uses are sprays.

[b] 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.

[c] It is possible these products are powders, but it is not specified whether the reported uses are powders.

NR – not reported

REFERENCES

1. Nikitakis J, Kowcz A. Web-Based *International Cosmetic Ingredient Dictionary and Handbook* (wINCI *Dictionary*). http://webdictionary.personalcarecouncil.org/jsp/IngredientSearchPage.jsp. Washington, D.C.: Personal Care Products Council. Last Updated 2022. Accessed 5/26/2022.

2. Kumar G, Kadam G, Saha T, K S G, Tiwari A, Kumar R. Studies on floral biology of *Malva sylvestris L*. *Ind J Hort*. 2014;17:295-297.

3. Gasparetto JC, Martins CA, Hayashi SS, Otuky MF, Pontarolo R. Ethnobotanical and scientific aspects of *Malva sylvestris L.*: a millennial herbal medicine. *J Pharm Pharmacol*. 2012;64(2):172-189.

4. CEP-Solabia Group. 2015. Specifications data sheet Vegebios® of Mixt Mallow 1.5P (Malva Sylvestris (Mallow) Flower/Leaf Extract).

5. CEP-Solabia Group. 2015. Specifications data sheet Glycolysat® of Wild Mallow UP (Malva Sylvestris (Mallow) Leaf Extract).

6. CEP-Solabia Group. 2022. Specifications data sheet Vegebios® Wild Mallow 1.5P (Malva Sylvestris (Mallow) Leaf Extract).

7. CEP-Solabia Group. 2015. Safety data sheet Vegebios® of Mixt Mallow 1.5P (Malva Sylvestris (Mallow) Flower/Leaf Extract).

8. CEP-Solabia Group. 2015. Safety data sheet Glycolysat® of Wild Mallow UP (Malva Sylvestris (Mallow) Leaf Extract).

9. CEP-Solabia Group. 2022. Safety data sheet Vegebios® Wild Mallow 1.5P (Malva Sylvestris (Mallow) Leaf Extract).

10. Irfan A, Imran M, Khalid M, et al. Phenolic and flavonoid contents in *Malva sylvestris* and exploration of active drugs as antioxidant and anti-COVID19 by quantum chemical and molecular docking studies. *J Saudi Chem Soc*. 2021;25(8):101277.

11. Anonymous. 2022. Malva Sylvestris (Mallow) Flower Extract (method of manufacture, impurities, example specifications).

12. Beley SY, Hroshovy T, Beley N. Definition of the optimal conditions for wild mallow (*Malva sylvestris*) extraction. *The Pharm Innov*. 2017;6(8, Part F):390.

13. CEP-Solabia Group. 2012. Manufacturing process Vegebios® of Mixt Mallow 1.5P (Malva Sylvestris (Mallow) Flower/Leaf Extract).

14. Razavi S, Zarrini G, Molavi G, Ghasemi G. Bioactivity of *Malva sylvestris* L., a Medicinal Plant from Iran. *Iran J Bas Med Sci*. 2011;14:574-579.

15. Barros L, Carvalho AM, Ferreira IC. Leaves, flowers, immature fruits and leafy flowered stems of *Malva sylvestris*: a comparative study of the nutraceutical potential and composition. *Food Chem Toxicol*. 2010;48(6):1466-1472.

16. CEP-Solabia Group. 2009. Manufacturing process Glycolysat® of Wild Mallow UP (Malva Sylvestris (Mallow) Leaf Extract).

17. CEP-Solabia Group. 2012. Manufacturing process Vegebios® Wild Mallow 1.5P (Malva Sylvestris (Mallow) Leaf Extract).

18. Saad AB, Rjeibi I, Alimi H, et al. Lithium induced, oxidative stress and related damages in testes and heart in male rats: The protective effects of *Malva sylvestris* extract. *Biomed Pharmacother*. 2017;86:127-135.

19. Beghdad MC, Benammar C, Bensalah F, Sabri FZ, Belarbi M, Chemat F. Antioxidant activity, phenolic and flavonoid content in leaves, flowers, stems and seeds of mallow (*Malva sylvestris* L.) from North Western of Algeria. *Afr J Biotech*. 2014;13:486-491.

20. Delfine S, Marrelli M, Conforti F, et al. Variation of *Malva sylvestris* essential oil yield, chemical composition and biological activity in response to different environments across Southern Italy. *Ind Crops Prod*. 2017;98:29-37.

21. European Medicines Agency. Assessment report on *Malva sylvestris* L. and/or *Malva neglecta* Wallr., folium and *Malva sylvestris* L., flos. 2018. https://www.ema.europa.eu/en/documents/herbal-report/final-assessment-report-malva-sylvestris-l/malva-neglecta-wallr-folium-malva-sylvestris-l-flos-first-version_en.pdf. Accessed 05/27/2022.

22. Petkova N, Popova A, Alexieva I. Antioxidant properties and some phytochemical components of the edible medicinal *Malva sylvestris* L. *J Med Plants Stud*. 2019;7(1):96-99.

23. CEP-Solabia Group. 2012. Ingredient breakdown Vegebios®of Mixt Mallow 1.5P (Malva Sylvestris (Mallow) Flower/Leaf Extract.

24. CEP-Solabia Group. 2015. Attestations file Vegebios® of Mixt Mallow 1.5P (Malva Sylvestris (Mallow) Flower/Leaf Extract).

25. CEP-Solabia Group. 2015. Ingredient breakdown Glycolysat® of Wild Mallow UP (Malva Sylvestris (Mallow) Leaf Extract).

26. CEP-Solabia Group. 2022. Ingredient breakdown Vegebios® Wild Mallow 1.5P (Malva Sylvestris (Mallow) Leaf Extract).

27. CEP-Solabia Group. 2016. Attestation file Glycolysat® of Wild Mallow UP (Malva Sylvestris (Mallow) Leaf Extract).

28. CEP-Solabia Group. 2015. Attestations file Vegebios® Wild Mallow 1.5P (Malva Sylvestris (Mallow) Leaf Extract).

29. Reza T, Zeynab Y, Ali A. Chemical composition and antioxidant properties of *Malva sylvestris* L. 2012.

30. Idir M, Djedjiga M, Karima B, Hillal S, Bariz K, Houali K. Evaluation of antioxidant potential of Algerian *Malva sylvestris* aqueous extract. *Int J Sci and Res*. 2020;76.

31. Usami A, Kashima Y, Marumoto S, Miyazawa M. Characterization of aroma-active compounds in dry flower of *Malva sylvestris* L. by GC-MS-O analysis and OAV calculations. *J Oleo Science*. 2013;62(8):563-570.

32. U.S. Food and Drug Administration Center for Food Safety & Applied Nutrition (CFSAN). 2022. Voluntary Cosmetic Registration Program - Frequency of Use of Cosmetic Ingredients (VCRP).

33. Personal Care Products Council. 2022. Concentration of Use by FDA Product Category: *Malva sylvestris*-Derived Ingredients.

34. European Commission. CosIng database; following Cosmetic Regulation No. 1223/2009. http://ec.europa.eu/growth/tools-databases/cosing/. Last Updated 2020. Accessed 1/14/2020.

35. Batsatsashvili K, Mehdiyeva N, Fayvush G, et al. Malva neglecta Wallr. *Malva sylvestris* L. Malvaceae. In: Bussmann Re, ed. *Ethnobotany of the Caucasus, European Ethnobotany.* 2017. 395-403.

36. Rayssan R, Shawkat MS. Cytotoxicity assessment of *Malva sylvestris* crude extract on melanoma and lymphoma cell lines. *J Pharm Sci Res*. 2019;11(1):70-74.

37. Hassan S, Remzi D, Muhammed S, Othman H. Photo protective role of wild edible plants on skin of mice from harmful effects of ultraviolet type-B irradiation. *Br J Appl Sci Technol*. 2016;15:1-10.

38. Prudente AS, Loddi AMV, Duarte MR, et al. Pre-clinical anti-inflammatory aspects of a cuisine and medicinal millennial herb: *Malva sylvestris* L. *Food Chem Toxicol*. 2013;58:324-331.

39. Anonymous. 2009. Human repeat insult patch test (product containing 0.0125% Malva Sylvestris (Mallow) Flower/Leaf/Stem Extract).

40. Meysami M, Hashempur MH, Kamalinejad M, Emtiazy M. Efficacy of short term topical *Malva sylvestris* L. cream in pediatric patients with atopic dermatitis: a randomized double-blind placebo-controlled clinical trial. *Endocr Metab Immune Disord Drug Targets*. 2021;21(9):1673-1678.

41. Barikbin B, Maarefat A, Rahgoshai R, Moravvej H, Mohtasham N, Yousefi M. *Malva sylvestris* in the treatment of hand eczema. *Iran J Derm*. 2010;13(4):131-134.

Concentration of Use by FDA Product Category – *Malva sylvestris*-Derived Ingredients*

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

Ingredient	Product Category	Maximum Concentration of Use
Malva Sylvestris (Mallow) Extract	Skin cleansing (cold creams, cleansing lotions, liquids, and pads)	0.0002%
Malva Sylvestris (Mallow) Extract	Face and neck products Not spray	0.003%
Malva Sylvestris (Mallow) Flower Extract	Bubble baths	0.002%
Malva Sylvestris (Mallow) Flower Extract	Hair dyes and colors	0.00012%
Malva Sylvestris (Mallow) Flower Extract	Foundations	0.02%
Malva Sylvestris (Mallow) Flower Extract	Skin cleansing (cold creams, cleansing lotions, liquids, and pads)	0.02%
Malva Sylvestris (Mallow) Flower Extract	Depilatories	0.1%
Malva Sylvestris (Mallow) Flower Extract	Face and neck products Not spray	0.04%
Malva Sylvestris (Mallow) Flower Extract	Body and hand products Not spray	0.02-0.1%
Malva Sylvestris (Mallow) Flower Extract	Moisturizing products Not spray	0.03%
Malva Sylvestris (Mallow) Flower Extract	Night products Not spray	0.03%
Malva Sylvestris (Mallow) Flower Extract	Other skin care preparations	0.005%

*Ingredients included in the title of the table but not found in the table were included in the concentration of use survey, but no uses were reported.

Information collected in 2022
Table prepared: July 6, 2022

Personal Care Products Council
Committed to Safety, Quality & Innovation

Memorandum

TO: Bart Heldreth, Ph.D.
Executive Director - Cosmetic Ingredient Review

FROM: Carol Eisenmann, Ph.D.
Personal Care Products Council

DATE: September 23, 2022

SUBJECT: Information Malva Sylvestris (Mallow) Flower/Leaf Extract and Malva Sylvestris (Mallow) Leaf Extract

CEP-Solabia Group. 2012. Manufacturing process Vegebios® of Mixt Mallow 1.5P (Malva Sylvestris (Mallow) Flower/Leaf Extract).

CEP-Solabia Group. 2012. Ingredient breakdown Vegebios® of Mixt Mallow 1.5P (Malva Sylvestris (Mallow) Flower/Leaf Extract).

CEP-Solabia Group. 2015. Specifications data sheet Vegebios® of Mixt Mallow 1.5P (Malva Sylvestris (Mallow) Flower/Leaf Extract).

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CEP-Solabia Group. 2015. Attestations file Vegebios® of Mixt Mallow 1.5P (Malva Sylvestris (Mallow) Flower/Leaf Extract).

CEP-Solabia Group. 2009. Manufacturing process Glycolysat® of Wild Mallow UP (Malva Sylvestris (Mallow) Leaf Extract).

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CEP-Solabia Group. 2015. Specifications data sheet Glycolysat® of Wild Mallow UP (Malva Sylvestris (Mallow) Leaf Extract).

CEP-Solabia Group. 2015. Safety data sheet Glycolysat® of Wild Mallow UP (Malva Sylvestris (Mallow) Leaf Extract).

CEP-Solabia Group. 2016. Attestation file Glycolysat® of Wild Mallow UP (Malva Sylvestris (Mallow) Leaf Extract).

CEP-Solabia Group. 2012. Manufacturing process Vegebios® Wild Mallow 1.5P (Malva Sylvestris (Mallow) Leaf Extract).

CEP-Solabia Group. 2022. Ingredient breakdown Vegebios® Wild Mallow 1.5P (Malva Sylvestris (Mallow) Leaf Extract).

CEP-Solabia Group. 2022. Specifications data sheet Vegebios® Wild Mallow 1.5P (Malva Sylvestris (Mallow) Leaf Extract).

CEP-Solabia Group. 2022. Safety data sheet Vegebios® Wild Mallow 1.5P (Malva Sylvestris (Mallow) Leaf Extract).

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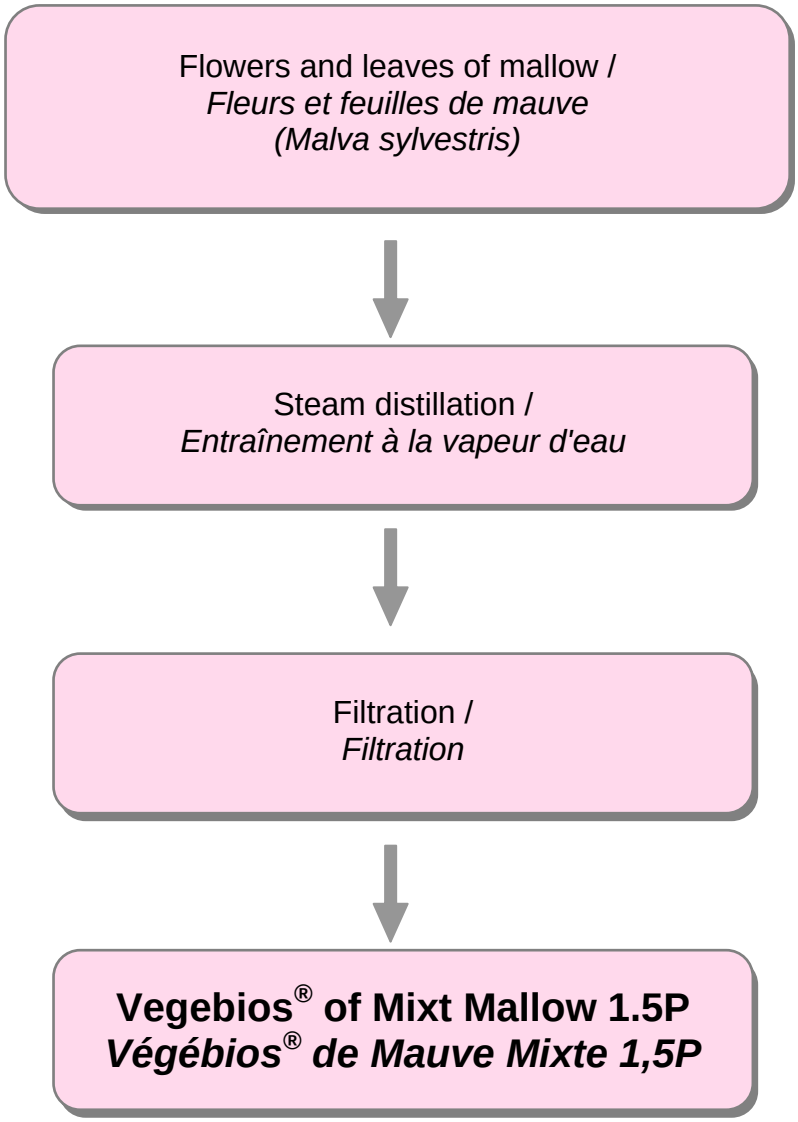
Vegebios® of Mixt Mallow 1.5P
Végébios® de Mauve Mixte 1,5P

Ref. FV670

Malva Sylvestris (Mallow) Flower/Leaf Extract



Produced & Commercialized by CEP - SOLABIA Group
29 Rue Delizy – 93698 Pantin Cedex France
Tel 33 (0)1 48 10 19 40 – Fax 33 (0)1 48 91 18 77 - www.solabia.com

INGREDIENT BREAKDOWN
COMPOSITION CENTESIMALE

Vegebios® of Mixt Mallow 1.5P
Végébios® de Mauve Mixte 1,5P

Ref. FV670

Water ..... ≥ **98.00 %**

Malva sylvestris (mallow) flower/leaf extract .....≤ **0.50%**

Phenoxyethanol ..... **1.50 %**

- Because of the natural origin of the raw material, the centesimal composition is susceptible to slight variations.

  En raison de l'origine naturelle des matières premières, la composition centésimale est susceptible de subir une légère variation.

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SPECIFICATIONS DATA SHEET

Vegebios® of Mixt Mallow 1.5P

Ref. FV670

DEFINITION

Vegebios® of Mixt Mallow 1.5P is an aqueous extract obtained by steam distillation of flowers and leaves of mallow *(Malva sylvestris).*

PRESENTATION

• **Sample**	plastic flask - 125 mL
• **Code / Packaging** *to be mentioned with your order*	FV670KC – can 5 kg FV670KE – can 20 kg

ORGANOLEPTIC CHARACTERISTICS

• **Appearance**	transparent solution
• **Color**	colorless
• **Odor**	characteristic

ANALYTICAL CHARACTERISTICS

• **pH**	4.7 – 6.7
• **Refractive index at 20°C**	1.332 - 1.339
• **Density at 20°C**	0.999 - 1.002

MICROBIOLOGICAL CHARACTERISTICS

• **Total aerobic microbial count** *Eur. Ph. 8th ed. § 2.6.12 – 2.6.13*	≤ 100 C.F.U/g

Vegebios® of Mixt Mallow 1.5P

SOLUBILITIES (10% DILUTED)

• **Water**	miscible	• **Mineral oils**	non miscible
• **Alcohol 50% v/v**	miscible	• **Vegetal oils**	non miscible

STORAGE

• **Shelf life**	3 years in closed original packaging
• **Preservative system**	1.5% of phenoxyethanol
• **Storage conditions**	store at room temperature

LEGISLATIVE INFORMATION

• **INCI**	Aqua / Malva sylvestris extract	
• **CTFA**	Water (and) Malva sylvestris (mallow) flower/leaf extract	
• **CAS**	Aqua	7732-18-5
	Malva sylvestris extract	84082-57-5
• **EINECS**	Aqua	231-791-2
	Malva sylvestris extract	282-003-9

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Malva Sylvestris (Mallow) Flower/Leaf Extract

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Product form : Mixture

Trade name : Vegebios® of Mixt Mallow 1.5P

Name : Aqua / Malva sylvestris extract; Preserved with 1.5% phenoxyethanol

Product code : FV670

Product group : Raw material

1.2. Relevant identified uses of the substance or mixture and uses advised against

1.2.1. Relevant identified uses

Main use category : Industrial use,Professional use

Use of the substance/mixture : Cosmetics, personal care products

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

CEP - SOLABIA GROUP
29 rue Delizy
93698 Pantin Cedex - FRANCE
T 0033 1 48 10 19 40 - F 0033 1 48 91 18 77
info.fds@solabia.fr - www.solabia.com

1.4. Emergency telephone number

No additional information available

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP]

Not classified

2.2. Label elements

Safety data sheet available on request.

2.3. Other hazards

Adverse physicochemical, human health and environmental effects : May cause moderate irritation to the eyes. Repeated or prolonged contact may cause skin irritation. May be harmful if swallowed.

SECTION 3: Composition/information on ingredients

3.1. Substance

Not applicable

3.2. Mixture

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Aqua	(CAS No) 7732-18-5 (EC no) 231-791-2	>= 98	Not classified
phenoxyethanol	(CAS No) 122-99-6 (EC no) 204-589-7 (EC index no) 603-098-00-9	1,5	Acute Tox. 4 (Oral), H302 Eye Irrit. 2, H319
Malva sylvestris extract	(CAS No) 84082-57-5 (EC no) 282-003-9	<= 0,5	Not classified

Full text of H-phrases: see section 16

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures after inhalation : Not applicable.

First-aid measures after skin contact : Wash with plenty of soap and water.

First-aid measures after eye contact : Rinse cautiously with water for several minutes. If eye irritation persists: Get medical advice/attention.

First-aid measures after ingestion : Rinse mouth. Do not induce vomiting. Call a POISON CENTER or doctor/physician if you feel unwell.

4.2. Most important symptoms and effects, both acute and delayed

No additional information available

4.3. Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media : Water spray. Dry powder. Foam.

5.2. Special hazards arising from the substance or mixture

Hazardous decomposition products in case of fire : None.

5.3. Advice for firefighters

Protection during firefighting : Do not attempt to take action without suitable protective equipment. Wear respiratory protection. Complete protective clothing.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

Protective equipment : Wear personal protective equipment. For further information refer to section 8: "Exposure controls/personal protection".

6.1.2. For emergency responders

Protective equipment : Do not attempt to take action without suitable protective equipment. For further information refer to section 8: "Exposure controls/personal protection".

6.2. Environmental precautions

Avoid release to the environment.

6.3. Methods and material for containment and cleaning up

For containment : Collect spillage.

Methods for cleaning up : Take up liquid spill into absorbent material, e.g.: sand, saw dust.

6.4. Reference to other sections

No additional information available

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : Wear personal protective equipment. For further information refer to section 8: "Exposure controls/personal protection".

Hygiene measures : Always wash hands after handling the product.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Store at ambient temperature.

7.3. Specific end use(s)

No additional information available

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

No additional information available

8.2. Exposure controls

Materials for protective clothing	: Wear suitable protective clothing
Hand protection	: Wear suitable gloves
Eye protection	: Safety glasses with side guards should be worn to prevent injury from airborne particles and/or other eye contact with this product
Skin and body protection	: Wear suitable protective clothing
Respiratory protection	: Not applicable

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Liquid
Appearance	: Transparent solution.
Colour	: Colourless.
Odour	: characteristic.
Odour threshold	: No data available
pH	: 4,7 - 6,7 (in the state of delivery)
Relative evaporation rate (butylacetate=1)	: No data available
Melting point	: No data available
Freezing point	: No data available
Boiling point	: No data available
Flash point	: No data available
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
Flammability (solid, gas)	: No data available
Vapour pressure	: No data available
Relative vapour density at 20 °C	: No data available
Relative density	: 0,999 - 1,002 (20°C)
Solubility	: Soluble in water. Soluble in ethanol 50% v/v. Soluble in propyleneglycol. Insoluble in: mineral or vegetable oils.
Log Pow	: No data available
Viscosity, kinematic	: No data available
Viscosity, dynamic	: No data available
Explosive properties	: No data available
Oxidising properties	: No data available
Explosive limits	: No data available

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

No additional information available

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

No additional information available

10.4. Conditions to avoid

No additional information available

10.5. Incompatible materials

No additional information available

10.6. Hazardous decomposition products

No additional information available

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity : Not classified
No data available

Skin corrosion/irritation : Not classified
No data available
pH: 4,7 - 6,7 (in the state of delivery)

Serious eye damage/irritation : Not classified
No data available
pH: 4,7 - 6,7 (in the state of delivery)

Respiratory or skin sensitisation : Not classified
No data available

Germ cell mutagenicity : Not classified
No data available

Carcinogenicity : Not classified
No data available

Reproductive toxicity : Not classified
No data available

Specific target organ toxicity (single exposure) : Not classified
No data available

Specific target organ toxicity (repeated exposure) : Not classified
No data available

Aspiration hazard : Not classified
No data available

SECTION 12: Ecological information

12.1. Toxicity

Ecology - general : No data available.

12.2. Persistence and degradability

Persistence and degradability No data available.

12.3. Bioaccumulative potential

Bioaccumulative potential Not established.

12.4. Mobility in soil

Ecology - soil No data available.

12.5. Results of PBT and vPvB assessment

No additional information available

12.6. Other adverse effects

Other adverse effects : No data available.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste disposal recommendations : Dispose in a safe manner in accordance with local/national regulations. Incineration, disposal or recycling at specific offsite provider.

Ecology - waste materials : Avoid release to the environment.

SECTION 14: Transport information

In accordance with ADR / RID / IMDG / IATA / ADN

14.1. UN number

Not regulated for transport

14.2. UN proper shipping name

Proper Shipping Name (ADR) : Not applicable

Proper Shipping Name (IMDG) : Not applicable

Proper Shipping Name (IATA) : Not applicable
Proper Shipping Name (ADN) : Not applicable
Proper Shipping Name (RID) : Not applicable

14.3. Transport hazard class(es)

ADR
Transport hazard class(es) (ADR) : Not applicable

IMDG
Transport hazard class(es) (IMDG) : Not applicable

IATA
Transport hazard class(es) (IATA) : Not applicable

ADN
Transport hazard class(es) (ADN) : Not applicable

RID
Transport hazard class(es) (RID) : Not applicable

14.4. Packing group

Packing group (ADR) : Not applicable
Packing group (IMDG) : Not applicable
Packing group (IATA) : Not applicable
Packing group (ADN) : Not applicable
Packing group (RID) : Not applicable

14.5. Environmental hazards

Dangerous for the environment : No
Marine pollutant : No
Other information : No supplementary information available

14.6. Special precautions for user

- Overland transport
No data available

- Transport by sea
No data available

- Air transport
No data available

- Inland waterway transport
Carriage prohibited (ADN) : No
Not subject to ADN : No

- Rail transport
Carriage prohibited (RID) : No

14.7. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

15.1.1. EU-Regulations

Contains no REACH substances with Annex XVII restrictions
Contains no substance on the REACH candidate list
Contains no REACH Annex XIV substances

15.1.2. National regulations

No additional information available

15.2. Chemical safety assessment

No additional information available

SECTION 16: Other information

Full text of H- and EUH-statements:

Acute Tox. 4 (Oral)	Acute toxicity (oral), Category 4
Eye Irrit. 2	Serious eye damage/eye irritation, Category 2
H302	Harmful if swallowed
H319	Causes serious eye irritation

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product

ATTESTATIONS FILE

Vegebios® of Mixt Mallow 1.5P
Végébios® de Mauve Mixte 1,5P

Malva Sylvestris (Mallow) Flower/Leaf Extract

Ref. FV670

Pantin, September 7th, 2015

ORIGIN / *ORIGINE*

We undersigned, CEP - SOLABIA Group, certify that the above product is an aqueous extract of **vegetal origin** obtained by steam distillation from **flowers and leaves of mallow** (*Malva sylvestris)*.

Nous soussignés, CEP - Groupe SOLABIA, certifions que le produit désigné ci-dessus est un extrait aqueux ***d'origine végétale*** *obtenu par hydrodistillation à partir* ***de fleurs et des feuilles de mauve*** *(Malva sylvestris).*

GMO / *OGM*

According to our knowledge about possible GMO plants, we undersigned, CEP - SOLABIA Group, certify that the above product does not come from plants being or having been submitted to a program of genetic modification.

Nous soussignés, CEP - Groupe SOLABIA, certifions que dans l'état actuel de nos connaissances sur les plantations OGM, le produit désigné ci-dessus ne provient pas de plantes faisant ou ayant fait l'objet d'un programme de modification génétique.

BSE / *ESB*

According to our knowledge of BSE epidemic, we undersigned, CEP - SOLABIA Group, certify that the above product does not contain any ovine, bovine or caprine origin materials and is free from Bovine Spongiform Encephalopathy risk.

Nous soussignés, CEP - Groupe SOLABIA, certifions que dans l'état actuel de nos connaissances sur l'épidémie d'ESB, le produit désigné ci-dessus ne renferme pas de composants d'origine bovine, ovine ou caprine et est exempt de risque d'Encéphalopathie Spongiforme Bovine.

Alexandre LEGER
Technical Marketing
Marketing technique

ATTESTATIONS FILE

Vegebios® of Mixt Mallow 1.5P
Végébios® de Mauve Mixte 1,5P

Ref. FV670

Pantin, September 7th, 2015

ALLERGENIC SUBSTANCES / *SUBSTANCES ALLERGENES*

Data collected within the framework of UNITIS studies / *Informations recueillies dans le cadre des études menées par UNITIS*

We undersigned, CEP - SOLABIA Group, certify that the bibliographical study realized on *Malva sylvestris* revealed that none of the 26 allergenic substances listed in the European Cosmetic Regulation 1223/2009/EC is quoted in the plant bibliography.

Nous soussignés, CEP - Groupe SOLABIA, certifions que l'étude bibliographique réalisée sur Malva sylvestris a révélé qu'aucune des 26 substances allergènes listées dans le Règlement Cosmétique Européen 1223/2009/CE n'est citée dans la bibliographie de la plante.

CMR - HAZARDOUS SUBSTANCES / *CMR - SUBSTANCES DANGEREUSES*

Data collected within the framework of UNITIS studies / *Informations recueillies dans le cadre des études menées par UNITIS*

We undersigned, CEP - SOLABIA Group, certify that in accordance with the European Cosmetic Regulation 1223/2009/EC, the above product does not contain any of the substances mentioned in the lists *1A, 1B or 2*, *or* classified hazardous, according to Regulation 1272/2008/EC (known as CLP) and its adaptations.

Nous soussignés, CEP - Groupe SOLABIA, certifions que conformément au Règlement Cosmétique Européen 1223/2009/CE, le produit-désigné ci-dessus ne contient pas de substances répertoriées dans les listes CMR 1A, 1B ou 2, ou classées dangereuses, selon le Règlement 1272/2008/CE (dit CLP) et ses adaptations.

EUROPEAN COSMETIC REGULATION 1223/2009/EC
REGLEMENT COSMETIQUE EUROPEEN 1223/2009/CE

We undersigned, CEP - SOLABIA Group, certify that the above product is in accordance with the European Cosmetic Regulation 1223/2009/EC.

Nous soussignés, CEP - Groupe SOLABIA, certifions que le produit désigné ci-dessus est conforme au Règlement Cosmétique Européen 1223/2009/CE.

Alexandre LEGER
Technical Marketing
Marketing technique

ATTESTATIONS FILE

Vegebios® of Mixt Mallow 1.5P
Végébios® de Mauve Mixte 1,5P

Ref. FV670

Pantin, September 7th, 2015

ANIMAL TESTING / *TESTS SUR ANIMAUX*

We undersigned, CEP - SOLABIA Group, certify that the above product has not been the subject of animal testing for cosmetic purposes by or behalf of SOLABIA Group.

Nous soussignés, CEP - Groupe SOLABIA, certifions que le produit désigné ci-dessus n'a pas fait l'objet de tests sur animaux à des fins cosmétiques, par ou pour le compte du Groupe SOLABIA.

SAFETY / *INNOCUITÉ*

We undersigned, CEP - SOLABIA Group, certify that no incident following the use of the above product that can be interpreted as being a sign of toxicity has been brought to our attention. In light of our experience acquired by the sale of this raw material in the cosmetic area, we declare that it is not harmful in normal concentrations and normal conditions of use.

Nous soussignés, CEP - Groupe SOLABIA, certifions qu'aucun incident consécutif à l'utilisation du produit désigné ci-dessus et pouvant être interprété comme un signe de toxicité, n'a été porté à notre connaissance. Compte tenu de notre expérience acquise par la vente de cette matière première dans l'industrie cosmétique, nous déclarons qu'elle n'est pas nocive aux concentrations et dans les conditions normales d'utilisation.

We undersigned, CEP - SOLABIA Group, certify that the above product is free from: /
Nous soussignés, CEP - Groupe SOLABIA, certifions que le produit désigné ci-dessus est exempt de :

- Diethylene glycol / *Diéthylène glycol*
- Dioxin / *Dioxine*
- Formaldehyde / *Formaldéhyde*
- Formol
- Gluten
- Glycol ether / *Ether de glycol (except phenoxyethanol / excepté phénoxyéthanol)*
- Phthalate
- Volatile Organic Compound (VOC) / *Composé Organique Volatile (COV) (except phenoxyethanol / excepté phénoxyéthanol)*

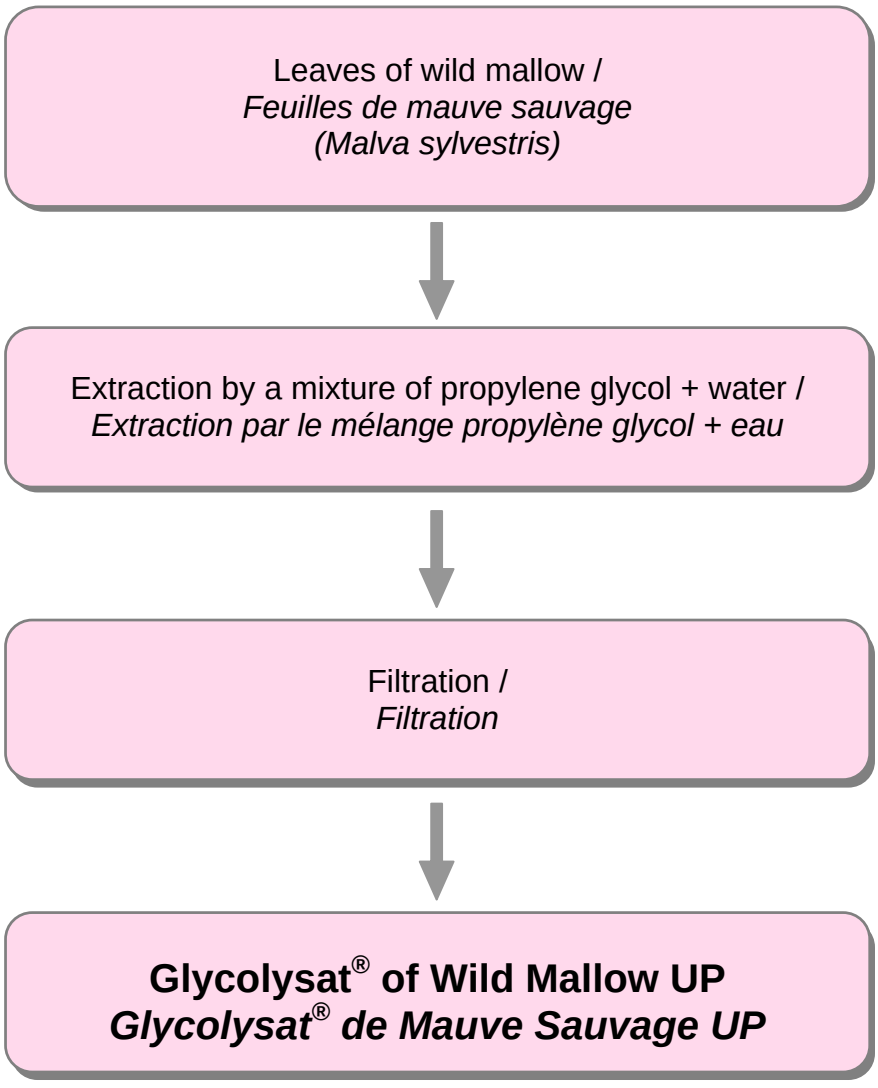
Alexandre LEGER
Technical Marketing
Marketing technique

MANUFACTURING PROCESS
PROCEDE DE FABRICATION

Glycolysat® of Wild Mallow UP
Glycolysat® de Mauve Sauvage UP

Ref. FG669

Malva Sylvestris (Mallow) Leaf Extract



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29 Rue Delizy – 93698 Pantin Cedex France
Tel 33 (0)1 48 10 19 40 – Fax 33 (0)1 48 91 18 77 - www.solabia.com

INGREDIENT BREAKDOWN
COMPOSITION CENTESIMALE

Glycolysat® of Wild Mallow UP
Glycolysat® de Mauve Sauvage UP

Ref. FG669

Propylene glycol..... **67.60 %**

Water ..... **30.00 %**

Malva sylvestris (mallow) leaf extract..... **2.40 %**
3g under halogen, 1 hour at 110°C

Notes - *Remarques :*

- Because of the natural origin of the raw material, the centesimal composition is susceptible to slight variations.

  En raison de l'origine naturelle des matières premières, la composition centésimale est susceptible de subir une légère variation.

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SPECIFICATIONS DATA SHEET

Glycolysat® of Wild Mallow UP

Ref. FG669

Malva Sylvestris (Mallow) Leaf Extract

DEFINITION

Glycolysat® of Wild Mallow UP is an hydroglycolic extract obtained from the leaves of mallow *(Malva sylvestris).* It is obtained by controlled extraction using propylene glycol and water.

PRESENTATION

• **Sample**	plastic flask - 125 mL
• **Code / Packaging** *to be mentioned with your order*	FG669KC - can 5 kg FG669KE - can 20 kg

ORGANOLEPTIC CHARACTERISTICS

• **Appearance**	translucent solution with possibly a slight precipitate
• **Color**	brown to yellow brown
• **Odor**	characteristic

ANALYTICAL CHARACTERISTICS

• **pH**	4.6 – 5.7
• **Refractive index at 20°C**	1.410 – 1.420
• **Density at 20°C**	1.047 – 1.060
• **Dry extract** *3 g under halogen, 1 hour at 110°C*	1.7% – 2.7%

MICROBIOLOGICAL CHARACTERISTICS

• **Total aerobic microbial count** *Eur. Ph. 8th ed. § 2.6.12 – 2.6.13*	≤ 100 C.F.U/g

Glycolysat® of Wild Mallow UP

SOLUBILITIES (10% DILUTED)

• **Water**	miscible	• **Mineral oils**	non miscible
• **Alcohol 50% v/v**	miscible	• **Vegetal oils**	non miscible

STORAGE AND USE

- **Shelf life** — 3 years in closed original packaging
- **Preservative system** — preservative free
- **Storage conditions** — store at room temperature
- **Use conditions** — mix before use if necessary

LEGISLATIVE INFORMATION

- **INCI** — Propylene glycol / Aqua / Malva sylvestris extract
- **CTFA** MODIFICATION — Propylene glycol (and) Water (and) Malva sylvestris (mallow) leaf extract
- **CAS**

Propylene glycol	57-55-6
Aqua	7732-18-5
Malva sylvestris extract	84082-57-5

- **EINECS**

Propylene glycol	200-338-0
Aqua	231-791-2
Malva sylvestris extract	282-003-9

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SAFETY DATA SHEET

IN ACCORDANCE WITH REGULATION 1907/2006/EC
MODEL RECOMMENDED BY OSHA (Occupational Health and Safety Administration, USA)

Glycolysat® of Wild Mallow UP

Malva Sylvestris (Mallow) Leaf Extract

Réf. FG669

I. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE SOCIETY/COMPANY

- **Commercial name** — Glycolysat® of Wild Mallow UP
- **Recommended used** — Cosmetic
- **Supplier** — CEP – SOLABIA Group
  29 Rue Delizy – 93698 Pantin Cedex
  Tel +33 1.48.10.19.40 Fax +33 1.48.91.18.77 – www.solabia.com
  info.fds@solabia.fr

II. IDENTIFICATION OF THE DANGERS

- **Human health hazards** — harmful in case of accidental ingestion. Potentially irritant for eyes
- **Environment hazards** — not available
- **Physico-chemical hazards** — not available

III. COMPOSITION / INFORMATION ON THE INGREDIENTS

- **Designation** — Propylene glycol / Aqua / Malva sylvestris extract ; unpreserved
- **CAS**

Propylene glycol	57-55-6
Aqua	7732-18-5
Malva sylvestris extract	84082-57-5

- **Hazardous components** — none

IV. FIRST AIDS PROCEDURE

- **Inhalation** — no danger. In case of dizzy spell after prolonged accidental inhalation, bring the person to fresh air. As a precaution, consult a doctor
- **Ingestion** — harmful in case of accidental ingestion. Do not induce vomiting. Consult a doctor
- **Skin contact** — no danger. Wash with plenty of water and soap and flush
- **Eye contact** — potentially irritant. Flush with plenty of water. Consult a doctor in case of irritation

V. FIRE SAFETY PRECAUTIONS

- **Extinguishing media** — sprayed water, CO_2, pulverulent material

VI. MEASURES TO BE TAKEN IN CASES OF ACCIDENTAL SPILLAGE

- **Individual precautions** — wear protective goggles and gloves
- **Precautions for protecting the environment** — avoid discharge into sewer / the natural environment
- **Methods of cleansing** — pump or soak up with an inert absorbent (sand, sawdust...)

VII. MANIPULATION AND STORAGE

- **Manipulation** — wear protective goggles and gloves
- **Storage conditions** — store at room temperature
- **Separation of incompatible materials** — hazardous reactions with strong acids
- **Recommended packaging materials** — no restriction currently known

VIII. CONTROL OF EXPOSURE / INDIVIDUAL PROTECTION

- **Individual protection equipment** — wear protective goggles and gloves Wash hands before breaks and at the end of work

IX. PHYSICAL AND CHEMICAL CHARACTERISTICS

- **Physical state at 20°C** — translucent solution with possibly a slight precipitate
- **Color** — brown to yellow brown
- **Odor** — characteristic
- **pH** (state on delivery) — 4.6 – 5.7
- **Flash point** — ≥ 100°C
- **Explosion characteristics** — not available
- **Density at 20°C** — 1.047 – 1.060
- **Solubility**

water	miscible
alcohol 50% v/v	miscible
mineral / vegetal oils	non miscible

X. STABILITY AND REACTIVITY

- **Stability** — stable in storing conditions mentioned in § VII
- **Conditions to avoid** — none currently known
- **Materials to avoid** — hazardous reactions with strong acids
- **Hazardous decomposition products** — an incomplete combustion of propylene glycol can induce carbon monoxide and other toxic gas

XI. TOXICOLOGICAL INFORMATION

- **Acute toxicity** — no case of toxicity has been noticed yet under normal conditions of use
- **Local effects** — no case of intolerance has been noticed yet under normal conditions of use

XII. ECOLOGICAL INFORMATION

- **Ecotoxicity** — avoid discharge into sewer / the natural environment comply with regulations and prefectorial decrees in force
- **Other ecological information** — in case of suitable handling and use, no ecological problem is to expect

XIII. DISPOSAL CONSIDERATIONS

- **Residues disposal** — comply with national and community regulations in force
- **Tainted packaging** — comply with national and community regulations in force

XIV. INFORMATION CONCERNING TRANSPORT

- IMDG class (by sea), ICAO/IATA (by air), RID/ADR/ADNR (by land): not dangerous

XV. REGULATORY INFORMATION

- Non-hazardous product – no specific community regulation application relative to this product needs to be mentioned

XVI. OTHER INFORMATION

- This form supplements the directions for use but does not replace them. The data are based on the current state of our knowledge. They are given in good faith. The attention of users is particularly drawn to the possible risks encountered when a product is used under conditions other than those for which it has been developed.
  It does not exempt, in no case, the user to know and apply all the texts regulating its activity. He will take under his own responsibility the precautions related to the use he makes of the product.

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ATTESTATIONS FILE

Glycolysat® of Wild Mallow UP
Glycolysat® de Mauve Sauvage UP

Ref. FG669

Malva Sylvestris (Mallow) Leaf Extract

Pantin, February 8th, 2016

ORIGIN / *ORIGINE*

We undersigned, CEP - SOLABIA Group, certify that the above product is a hydroglycolic extract of **vegetal origin** obtained from the **leaves of wild mallow** (*Malva sylvestris*).

Nous soussignés, CEP - Groupe SOLABIA, certifions que le produit désigné ci-dessus est un extrait hydroglycolique ***d'origine végétale*** *obtenu à partir* ***de feuilles*** *de* ***mauve sauvage*** *(Malva sylvestris).*

GMO / *OGM*

According to our knowledge about possible GMO plants, we undersigned, CEP - SOLABIA Group, certify that the above product does not come from plants being or having been submitted to a program of genetic modification.

Nous soussignés, CEP - Groupe SOLABIA, certifions que dans l'état actuel de nos connaissances sur les plantations OGM, le produit désigné ci-dessus ne provient pas de plantes faisant ou ayant fait l'objet d'un programme de modification génétique.

BSE / *ESB*

According to our knowledge of BSE epidemic, we undersigned, CEP - SOLABIA Group, certify that the above product does not contain any ovine, bovine or caprine origin materials and is free from Bovine Spongiform Encephalopathy risk.

Nous soussignés, CEP - Groupe SOLABIA, certifions que dans l'état actuel de nos connaissances sur l'épidémie d'ESB, le produit désigné ci-dessus ne renferme pas de composants d'origine bovine, ovine ou caprine et est exempt de risque d'Encéphalopathie Spongiforme Bovine.

Alexandre LEGER
Technical Marketing
Marketing technique

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ATTESTATIONS FILE

Glycolysat® of Wild Mallow UP
Glycolysat® de Mauve Sauvage UP

Ref. FG669

Pantin, February 8th, 2016

ALLERGENIC SUBSTANCES / *SUBSTANCES ALLERGENES*

Data collected within the framework of UNITIS studies / *Informations recueillies dans le cadre des études menées par UNITIS*

We undersigned, CEP - SOLABIA Group, certify that the bibliographical study realized on *Malva sylvestris* revealed that none of the 26 allergenic substances listed in the European Cosmetic Regulation 1223/2009/EC is quoted in the plant bibliography.

Nous soussignés, CEP - Groupe SOLABIA, certifions que l'étude bibliographique réalisée sur Malva sylvestris a révélé qu'aucune des 26 substances allergènes listées dans le Règlement Cosmétique Européen 1223/2009/CE n'est citée dans la bibliographie de la plante.

CMR - HAZARDOUS SUBSTANCES / *CMR - SUBSTANCES DANGEREUSES*

Data collected within the framework of UNITIS studies / *Informations recueillies dans le cadre des études menées par UNITIS*

We undersigned, CEP - SOLABIA Group, certify that in accordance with the European Cosmetic Regulation 1223/2009/EC, the above product does not contain any of the substances mentioned in the lists *1A, 1B or 2*, *or* classified hazardous, according to Regulation 1272/2008/EC (known as CLP) and its adaptations.

Nous soussignés, CEP - Groupe SOLABIA, certifions que conformément au Règlement Cosmétique Européen 1223/2009/CE, le produit-désigné ci-dessus ne contient pas de substances répertoriées dans les listes CMR 1A, 1B ou 2, ou classées dangereuses, selon le Règlement 1272/2008/CE (dit CLP) et ses adaptations.

EUROPEAN COSMETIC REGULATION 1223/2009/EC
REGLEMENT COSMETIQUE EUROPEEN 1223/2009/CE

We undersigned, CEP - SOLABIA Group, certify that the above product is in accordance with the European Cosmetic Regulation 1223/2009/EC.

Nous soussignés, CEP - Groupe SOLABIA, certifions que le produit désigné ci-dessus est conforme au Règlement Cosmétique Européen 1223/2009/CE.

Alexandre LEGER
Technical Marketing
Marketing technique

ATTESTATIONS FILE

Glycolysat® of Wild Mallow UP
Glycolysat® de Mauve Sauvage UP

Ref. FG669

Pantin, February 8th, 2016

ANIMAL TESTING / *TESTS SUR ANIMAUX*

We undersigned, CEP - SOLABIA Group, certify that the above product has not been the subject of animal testing for cosmetic purposes by or behalf of SOLABIA Group.

Nous soussignés, CEP - Groupe SOLABIA, certifions que le produit désigné ci-dessus n'a pas fait l'objet de tests sur animaux à des fins cosmétiques, par ou pour le compte du Groupe SOLABIA.

SAFETY / *INNOCUITÉ*

We undersigned, CEP - SOLABIA Group, certify that no incident following the use of the above product that can be interpreted as being a sign of toxicity has been brought to our attention. In light of our experience acquired by the sale of this raw material in the cosmetic area, we declare that it is not harmful in normal concentrations and normal conditions of use.

Nous soussignés, CEP - Groupe SOLABIA, certifions qu'aucun incident consécutif à l'utilisation du produit désigné ci-dessus et pouvant être interprété comme un signe de toxicité, n'a été porté à notre connaissance. Compte tenu de notre expérience acquise par la vente de cette matière première dans l'industrie cosmétique, nous déclarons qu'elle n'est pas nocive aux concentrations et dans les conditions normales d'utilisation.

We undersigned, CEP - SOLABIA Group, certify that the above product is free from: /
Nous soussignés, CEP - Groupe SOLABIA, certifions que le produit désigné ci-dessus est exempt de :

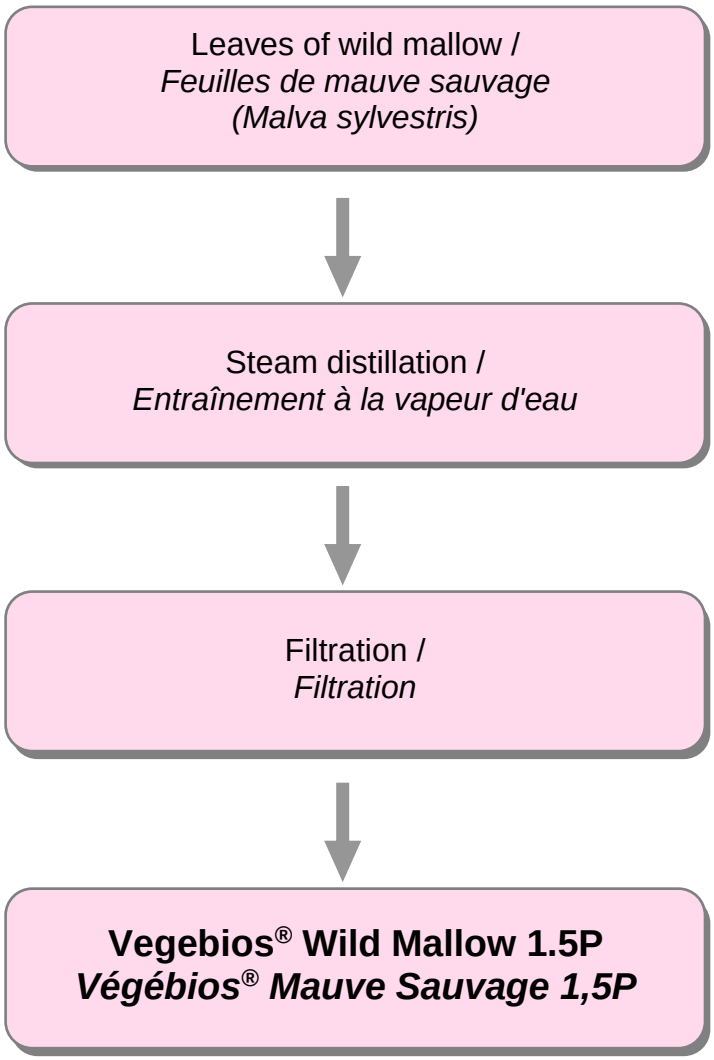
- Diethylene glycol / *Diéthylène glycol*
- Dioxin / *Dioxine*
- Formaldehyde / *Formaldéhyde*
- Formol
- Gluten
- Glycol ether / *Ether de glycol*
- Phthalate
- Volatile Organic Compound (VOC) / *Composé Organique Volatile (COV) (except propylene glycol considered as one in California / excepté le propylène glycol considéré comme tel en Californie)*

Alexandre LEGER
Technical Marketing
Marketing technique

Vegebios® Wild Mallow 1.5P
Végébios® Mauve Sauvage 1,5P

Malva Sylvestris (Malva) Leaf Extract

Réf. FV509



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INGREDIENT BREAKDOWN
COMPOSITION CENTESIMALE

Vegebios® Wild Mallow 1.5P
Végébios® Mauve Sauvage 1,5P

Réf. FV509

INCI

Aqua ..... **98.00 %**

Phenoxyethanol ..... **1.50 %**

Malva sylvestris leaf extract ..... **0.50 %**

CTFA

Water ..... **98.00 %**

Phenoxyethanol ..... **1.50 %**

Malva sylvestris (mallow) leaf extract..... **0.50 %**

Notes - *Remarques :*

- Because of the natural origin of the raw material, the centesimal composition is susceptible to slight variations.

  En raison de l'origine naturelle des matières premières, la composition centésimale est susceptible de subir une légère variation.

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SPECIFICATIONS DATA SHEET

Vegebios® Wild Mallow 1.5P

Ref. FV509

Malva Sylvestris (Mallow) Leaf Extract

DEFINITION

Vegebios® Wild Mallow 1.5P is an aqueous extract obtained by steam distillation of leaves of wild mallow *(Malva sylvestris)*.

PRESENTATION

• **Sample**	plastic flask - 125 mL
• **Code / Packaging** *to be mentioned with your order*	FV509KC – can 5 kg FV509KE – can 20 kg

ORGANOLEPTIC CHARACTERISTICS

• **Appearance**	transparent solution
• **Color**	colorless
• **Odor**	characteristic

ANALYTICAL CHARACTERISTICS

• **pH**	5.2 – 7.2
• **Refractive index at 20°C**	1.332 - 1.339
• **Density at 20°C**	0.999 - 1.002

MICROBIOLOGICAL CHARACTERISTICS

• **Total aerobic microbial count** *Eur. Ph. § 2.6.12 – 2.6.13*	≤ 100 C.F.U/g

Vegebios® Wild Mallow 1.5P

SOLUBILITIES (10% DILUTED)

• **Water**	miscible	• **Mineral oils**	non miscible
• **Alcohol 50%v/v**	miscible	• **Vegetal oils**	non miscible

STORAGE

- **Shelf life** — 3 years in closed original packaging
- **Preservative system** — 1.5% of phenoxyethanol
- **Storage conditions** — store at room temperature

LEGISLATIVE INFORMATION

- **INCI** MODIFICATION — Aqua / Malva sylvestris leaf extract
- **CTFA** MODIFICATION — Water (and) Malva sylvestris (mallow) leaf extract
- **CAS**

Aqua	7732-18-5
Malva sylvestris leaf extract	84082-57-5

- **EINECS**

Water	231-791-2
Malva sylvestris (mallow) leaf extract	282-003-9

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Vegebios® Wild Mallow 1.5P

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2020/878
Issue date: 01/02/2022 Revision date: 01/02/2022 Supersedes version of: 28/07/2021 Version: 1.2

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Product form	:	Mixture
Trade name	:	Vegebios® Wild Mallow 1.5P
Name	:	Aqua (and) Malva sylvestris leaf extract (and) phenoxyethanol
Product code	:	FV509
Product group	:	Raw material

1.2. Relevant identified uses of the substance or mixture and uses advised against

1.2.1. Relevant identified uses

Main use category	:	Industrial use,Professional use
Use of the substance/mixture	:	Cosmetics, personal care products

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

CEP - SOLABIA
41 rue Delizy
93692 Pantin Cedex - FRANCE
T 0033 1 48 10 19 40 - F 0033 1 48 91 18 77
info.fds@solabia.fr - www.solabia.com

1.4. Emergency telephone number

Country	Organisation/Company	Address	Emergency number	Comment
United Kingdom	Guy's & St Thomas' Poisons Unit Medical Toxicology Unit, Guy's & St Thomas' Hospital Trust	Avonley Road SE14 5ER London	+44 20 7188 7188	

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP]

Not classified

Adverse physicochemical, human health and environmental effects

May cause moderate irritation to the eyes. Repeated or prolonged contact may cause skin irritation. May be harmful if swallowed.

2.2. Label elements

Safety data sheet available on request.
No labelling applicable

2.3. Other hazards

Contains no PBT/vPvB substances ≥ 0.1% assessed in accordance with REACH Annex XIII

The mixture does not contain substance(s) included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or is not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605

SECTION 3: Composition/information on ingredients

3.1. Substances

Not applicable

Vegebios® Wild Mallow 1.5P

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2020/878

3.2. Mixtures

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Aqua	CAS-No.: 7732-18-5 EC-No.: 231-791-2	≥ 98	Not classified
phenoxyethanol	CAS-No.: 122-99-6 EC-No.: 204-589-7 EC Index-No.: 603-098-00-9	1,5	Acute Tox. 4 (Oral), H302 Eye Irrit. 2, H319
Malva sylvestris extract	CAS-No.: 84082-57-5 EC-No.: 282-003-9	≤ 0,5	Not classified

Full text of H- and EUH-statements: see section 16

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures after inhalation : Not applicable.

First-aid measures after skin contact : Wash with plenty of water/….

First-aid measures after eye contact : Rinse cautiously with water for several minutes. If eye irritation persists: Get medical advice/attention.

First-aid measures after ingestion : Rinse mouth. Do not induce vomiting. Call a POISON CENTER/doctor if you feel unwell.

4.2. Most important symptoms and effects, both acute and delayed

No additional information available

4.3. Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media : Water spray. Dry powder. Foam.

5.2. Special hazards arising from the substance or mixture

Hazardous decomposition products in case of fire : None.

5.3. Advice for firefighters

Protection during firefighting : Do not attempt to take action without suitable protective equipment. [In case of inadequate ventilation] wear respiratory protection. Complete protective clothing.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

Protective equipment : Wear personal protective equipment. For further information refer to section 8: "Exposure controls/personal protection".

6.1.2. For emergency responders

Protective equipment : Do not attempt to take action without suitable protective equipment. For further information refer to section 8: "Exposure controls/personal protection".

6.2. Environmental precautions

Avoid release to the environment.

6.3. Methods and material for containment and cleaning up

For containment : Collect spillage.

Methods for cleaning up : Take up liquid spill into absorbent material, e.g.: sand, saw dust.

6.4. Reference to other sections

No additional information available

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : Wear personal protective equipment. For further information refer to section 8: "Exposure controls/personal protection".

Hygiene measures : Always wash hands after handling the product.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Store at ambient temperature.

7.3. Specific end use(s)

No additional information available

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

8.1.1. National occupational exposure and biological limit values

No additional information available

8.1.2. Recommended monitoring procedures

No additional information available

8.1.3. Air contaminants formed

No additional information available

8.1.4. DNEL and PNEC

No additional information available

8.1.5. Control banding

No additional information available

8.2. Exposure controls

8.2.1. Appropriate engineering controls

No additional information available

8.2.2. Personal protection equipment

Personal protective equipment symbol(s):

8.2.2.1. Eye and face protection

Eye protection:
Safety glasses with side guards should be worn to prevent injury from airborne particles and/or other eye contact with this product

8.2.2.2. Skin protection

Skin and body protection:
Wear suitable protective clothing

Hand protection:
Wear suitable gloves

Other skin protection

Materials for protective clothing:
Wear suitable protective clothing

8.2.2.3. Respiratory protection

Respiratory protection:
Not applicable

8.2.2.4. Thermal hazards

No additional information available

8.2.3. Environmental exposure controls

No additional information available

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	:	Liquid
Colour	:	Colourless.
Appearance	:	Transparent solution.
Odour	:	characteristic.
Odour threshold	:	Not available
Melting point	:	Not available
Freezing point	:	Not available
Boiling point	:	Not available
Flammability	:	Not available
Explosive limits	:	Not available
Lower explosion limit	:	Not available
Upper explosion limit	:	Not available
Flash point	:	Not available
Auto-ignition temperature	:	Not available
Decomposition temperature	:	Not available
pH	:	5,2 – 7,2 (in the state of delivery)
Viscosity, kinematic	:	Not available
Solubility	:	Soluble in water. Soluble in ethanol 50% v/v. Soluble in propyleneglycol. Insoluble in: mineral or vegetable oils.
Partition coefficient n-octanol/water (Log Kow)	:	Not available
Vapour pressure	:	Not available
Vapour pressure at 50 °C	:	Not available
Density	:	Not available
Relative density	:	0,999 – 1,002 (20°C)
Relative vapour density at 20 °C	:	Not available
Particle size	:	Not applicable
Particle size distribution	:	Not applicable
Particle shape	:	Not applicable
Particle aspect ratio	:	Not applicable
Particle aggregation state	:	Not applicable
Particle agglomeration state	:	Not applicable
Particle specific surface area	:	Not applicable
Particle dustiness	:	Not applicable

9.2. Other information

9.2.1. Information with regard to physical hazard classes

No additional information available

9.2.2. Other safety characteristics

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

No additional information available

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

No additional information available

10.4. Conditions to avoid

No additional information available

10.5. Incompatible materials

No additional information available

10.6. Hazardous decomposition products

No additional information available

SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Acute toxicity (oral)	:	Not classified
Acute toxicity (dermal)	:	Not classified
Acute toxicity (inhalation)	:	Not classified
Additional information	:	No data available
Skin corrosion/irritation	:	Not classified pH: 5,2 – 7,2 (in the state of delivery)
Additional information	:	No data available
Serious eye damage/irritation	:	Not classified pH: 5,2 – 7,2 (in the state of delivery)
Additional information	:	No data available
Respiratory or skin sensitisation	:	Not classified
Additional information	:	No data available
Germ cell mutagenicity	:	Not classified
Additional information	:	No data available
Carcinogenicity	:	Not classified
Additional information	:	No data available
Reproductive toxicity	:	Not classified
Additional information	:	No data available
STOT-single exposure	:	Not classified
Additional information	:	No data available
STOT-repeated exposure	:	Not classified
Additional information	:	No data available
Aspiration hazard	:	Not classified
Additional information	:	No data available

11.2. Information on other hazards

No additional information available

SECTION 12: Ecological information

12.1. Toxicity

Ecology - general	:	No data available.
Hazardous to the aquatic environment, short-term (acute)	:	Not classified
Hazardous to the aquatic environment, long-term (chronic)	:	Not classified

12.2. Persistence and degradability

Vegebios® Wild Mallow 1.5P	
Persistence and degradability	No data available.

12.3. Bioaccumulative potential

Vegebios® Wild Mallow 1.5P	
Bioaccumulative potential	Not established.

12.4. Mobility in soil

Vegebios® Wild Mallow 1.5P	
Ecology - soil	No data available.

12.5. Results of PBT and vPvB assessment

No additional information available

12.6. Endocrine disrupting properties

No additional information available

12.7. Other adverse effects

Other adverse effects : No data available

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Product/Packaging disposal recommendations : Dispose in a safe manner in accordance with local/national regulations. Incineration, disposal or recycling at specific offsite provider.

Ecology - waste materials : Avoid release to the environment.

SECTION 14: Transport information

In accordance with ADR / IMDG / IATA / ADN / RID

14.1. UN number or ID number

UN-No. (ADR) : Not applicable
UN-No. (IMDG) : Not applicable
UN-No. (IATA) : Not applicable
UN-No. (ADN) : Not applicable
UN-No. (RID) : Not applicable

14.2. UN proper shipping name

Proper Shipping Name (ADR) : Not applicable
Proper Shipping Name (IMDG) : Not applicable
Proper Shipping Name (IATA) : Not applicable
Proper Shipping Name (ADN) : Not applicable
Proper Shipping Name (RID) : Not applicable

14.3. Transport hazard class(es)

ADR
Transport hazard class(es) (ADR) : Not applicable

IMDG
Transport hazard class(es) (IMDG) : Not applicable

IATA
Transport hazard class(es) (IATA) : Not applicable

ADN

Transport hazard class(es) (ADN) : Not applicable

RID

Transport hazard class(es) (RID) : Not applicable

14.4. Packing group

Packing group (ADR) : Not applicable
Packing group (IMDG) : Not applicable
Packing group (IATA) : Not applicable
Packing group (ADN) : Not applicable
Packing group (RID) : Not applicable

14.5. Environmental hazards

Dangerous for the environment : No
Marine pollutant : No
Other information : No supplementary information available

14.6. Special precautions for user

Overland transport

No data available

Transport by sea

No data available

Air transport

No data available

Inland waterway transport

No data available

Rail transport

No data available

14.7. Maritime transport in bulk according to IMO instruments

Not applicable

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

15.1.1. EU-Regulations

Contains no REACH substances with Annex XVII restrictions
Contains no substance on the REACH candidate list
Contains no REACH Annex XIV substances
Contains no substance subject to Regulation (EU) No 649/2012 of the European Parliament and of the Council of 4 July 2012 concerning the export and import of hazardous chemicals.
Contains no substance subject to Regulation (EU) No 2019/1021 of the European Parliament and of the Council of 20 June 2019 on persistent organic pollutants

15.1.2. National regulations

Germany

Water hazard class (WGK) : Not classified according to Regulation Governing Systems for Handling Substances Hazardous to Waters (AwSV)
Hazardous Incident Ordinance (12. BImSchV) : Is not subject of the Hazardous Incident Ordinance (12. BImSchV)

Netherlands

SZW-lijst van kankerverwekkende stoffen : None of the components are listed
SZW-lijst van mutagene stoffen : None of the components are listed
SZW-lijst van reprotoxische stoffen – Borstvoeding : None of the components are listed
SZW-lijst van reprotoxische stoffen – Vruchtbaarheid : None of the components are listed

SZW-lijst van reprotoxische stoffen – Ontwikkeling : None of the components are listed

Switzerland

Storage class (LK) : LK 10/12 - Liquids

15.2. Chemical safety assessment

No additional information available

SECTION 16: Other information

Indication of changes			
Section	**Changed item**	**Change**	**Comments**
	Issue date	Modified	
	Revision date	Modified	
	Supersedes	Modified	
1.1	Trade name	Modified	
1.1	Name	Modified	

Full text of H- and EUH-statements	
Acute Tox. 4 (Oral)	Acute toxicity (oral), Category 4
Eye Irrit. 2	Serious eye damage/eye irritation, Category 2
H302	Harmful if swallowed.
H319	Causes serious eye irritation.

COSMETIQUE FDS UE (Annexe II REACH)

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.

ATTESTATIONS FILE

Vegebios® of Wild Mallow 1.5P
Végébios® de Mauve Sauvage 1,5P

Ref. FV509

Malva Sylvestris (Mallow) Leaf Extract

Pantin, September 7th, 2015

ORIGIN / *ORIGINE*

We undersigned, CEP - SOLABIA Group, certify that the above product is an aqueous extract from **vegetal origin** obtained by steam distillation of **leaves of wild mallow** (*Malva sylvestris*).

*Nous soussignés, CEP - Groupe SOLABIA, certifions que le produit désigné ci-dessus est un extrait aqueux d'**origine végétale** obtenu par hydrodistillation des **feuilles de mauve sauvage** (Malva sylvestris).*

GMO / *OGM*

According to our knowledge about possible GMO plants, we undersigned, CEP - SOLABIA Group, certify that the above product does not come from plants being or having been submitted to a program of genetic modification.

Nous soussignés, CEP - Groupe SOLABIA, certifions que dans l'état actuel de nos connaissances, le produit désigné ci-dessus ne provient pas de plantes faisant ou ayant fait l'objet d'un programme de modification génétique.

BSE / *ESB*

According to our knowledge of BSE epidemic, we undersigned, CEP - SOLABIA Group, certify that the above product does not contain any ovine, bovine or caprine origin materials and is free from Bovine Spongiform Encephalopathy risk.

Nous soussignés, CEP - Groupe SOLABIA, certifions que le produit désigné ci-dessus ne renferme pas de composants d'origine bovine, ovine ou caprine et est exempt de risques d'Encéphalopathie Spongiforme Bovine.

Alexandre LEGER
Marketing Assistant
Assistant Marketing

Produced & Commercialised by CEP - SOLABIA Group
29 Rue Delizy - 93698 Pantin Cedex
Tel 33 (0)1 48 10 19 40 - Fax 33 (0)1 48 91 18 77 - www.solabia.com

ATTESTATIONS FILE

Vegebios® of Wild Mallow 1.5P
Végébios® de Mauve Sauvage 1,5P

Ref. FV509

Pantin, September 7th, 2015

ALLERGENIC SUBSTANCES / *SUBSTANCES ALLERGÈNES*

Data collected within the framework of UNITIS studies / *Informations recueillies dans le cadre des études menées par UNITIS*

We undersigned, CEP - SOLABIA Group, certify that the bibliographical study realized on *Malva sylvestris* revealed that none of the 26 allergenic substances listed in the European Cosmetic Regulation 1223/2009/EC is quoted in the plant bibliography.

Nous soussignés, CEP - Groupe SOLABIA, certifions que l'étude bibliographique réalisée sur Malva sylvestris a révélé qu'aucune des 26 substances allergènes listées dans le Règlement Cosmétique Européen 1223/2009/CE n'est citée dans la bibliographie de la plante.

CMR - HAZARDOUS SUBSTANCES / *CMR - SUBSTANCES DANGEREUSES*

Data collected within the framework of UNITIS studies / *Informations recueillies dans le cadre des études menées par UNITIS*

We undersigned, CEP - SOLABIA Group, certify that in accordance with the European Cosmetic Regulation 1223/2009/EC, the above product does not contain any of the substances mentioned in the lists *1A, 1B or 2*, *or* classified hazardous, according to Regulation 1272/2008/EC (known as CLP) and its adaptations.

Nous soussignés, CEP - Groupe SOLABIA, certifions que conformément au Règlement Cosmétique Européen 1223/2009/CE, le produit désigné ci-dessus ne contient pas de substances répertoriées dans les listes CMR 1A, 1B ou 2, ou classées dangereuses, selon le Règlement 1272/2008/CE (dit CLP) et ses adaptations.

EUROPEAN COSMETIC REGULATION 1223/2009/EC
REGLEMENT COSMETIQUE EUROPEEN 1223/2009/CE

We undersigned, CEP - SOLABIA Group, certify that the above product is in accordance with the European Cosmetic Regulation 1223/2009/EC.

Nous soussignés, CEP - Groupe SOLABIA, certifions que le produit désigné ci-dessus est conforme au Règlement Cosmétique Européen 1223/2009/CE.

Alexandre LEGER
Marketing Assistant
Assistant Marketing

ATTESTATIONS FILE

Vegebios® of Wild Mallow 1.5P
Végébios® de Mauve Sauvage 1,5P

Ref. FV509

Pantin, September 7th, 2015

ANIMAL TESTING / *TESTS SUR ANIMAUX*

We undersigned, CEP - SOLABIA Group, certify that the above product has not been the subject of animal testing for cosmetic purposes by or behalf of SOLABIA Group.

Nous soussignés, CEP - Groupe SOLABIA, certifions que la matière première citée ci-dessus n'a pas fait l'objet de tests sur animaux à des fins cosmétiques, par ou pour le compte du Groupe SOLABIA.

SAFETY / *INNOCUITÉ*

We undersigned, CEP - SOLABIA Group, certify that no incident following the use of the above product that can be interpreted as being a sign of toxicity has been brought to our attention. In light of our experience acquired by the sale of this starting material, we declare that it is not harmful in normal concentrations and normal conditions of use.

Nous soussignés, CEP - Groupe SOLABIA, certifions qu'aucun incident consécutif à l'utilisation de la matière première désignée ci-dessus et pouvant être interprété comme un signe de toxicité, n'a été porté à notre connaissance. Compte tenu de notre expérience acquise par la vente de cette matière première dans l'industrie cosmétique, nous déclarons qu'elle n'est pas nocive aux concentrations et dans les conditions normales d'utilisation.

We undersigned, CEP - SOLABIA Group, certify that the above product is free from: /
Nous soussignés, CEP - Groupe SOLABIA, certifions que le produit désigné ci-dessus est exempt de :

- Diethylene glycol / *Diéthylène glycol*
- Dioxin / *Dioxine*
- Formaldehyde / *Formaldéhyde*
- Formol
- Gluten
- Glycol ether / *Ether de glycol (except phenoxyethanol / excepté phénoxyéthanol)*
- Phthalate
- Volatile Organic Compounds (VOC) / *Composés Organiques Volatiles (COV) (except phenoxyethanol / excepté phénoxyéthanol)*

Alexandre LEGER
Marketing Assistant
Assistant Marketing

Personal Care Products Council
Committed to Safety, Quality & Innovation

Memorandum

TO: Bart Heldreth, Ph.D.
Executive Director - Cosmetic Ingredient Review

FROM: Carol Eisenmann, Ph.D.
Personal Care Products Council

DATE: September 28, 2022

SUBJECT: Information Malva Sylvestris (Mallow) Flower Extract

Anonymous. 2022. Malva Sylvestris (Mallow) Flower Extract (method of manufacture, impurities, example specifications).

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

Manufacturing Process:

The **flower** is extracted with specified **eluent(s) under appropriate temperature conditions,** to yield a **concentrate**. The concentrate containing the phytochemical constituents is then blended with the desired diluent(s) and preservation system to produce the final ingredient. The ingredient is evaluated for physiochemical properties according to the specification requirements for the batch to be released. In addition, the concentrate is also evaluated for contaminants and physiochemical properties as needed.

Typical eluents include Water, Butylene Glycol, Carthamus Tinctorius (Safflower) Seed Oil, Glycerin, and Propylene Glycol.

Heavy Metal & Pesticides/ Allergens/ Impurities:

The following heavy metal testing was conducted on the concentrate in a Glycerin and Water base:

	Heavy Metal	Detection	Reporting Limit	Heavy Metal	Detection	Reporting Limit
Heavy metals:	Antimony	Not Detected	0.005 mg/l	Iron	Not Detected	0.1 mg/l
	Arsenic	Not Detected	0.01 mg/l	Lead	Not Detected	0.025 mg/l
	Cadmium	Not Detected	0.001 mg/l	Mercury	Not Detected	0.0002 mg/l
	Chromium	Not Detected	0.002 mg/l	Nickel	Not Detected	0.002 mg/l

There were no residual pesticides detected. (Parameters: 8081 GCS Pesticides and 8141 GCS, O/P Pesticides)

The following Allergen testing was conducted on the concentrate in an Alcohol base:

	Fragrance Ingredient	Threshold	Fragrance Ingredient	Threshold
Presence of the 26 allergens defined by the 7th amendment to the EU Cosmetic Directive:	Amyl Cinnamal	<1ppm-0.0001%	Anise Alcohol	<1ppm-0.0001%
	Benzyl Alcohol	<1ppm-0.0001%	Benzyl Cinnamate	<1ppm-0.0001%
	Cinnamyl Alcohol	<1ppm-0.0001%	Farnesol	<1ppm-0.0001%
	Citral	<1ppm-0.0001%	Butylphenyl Methylpropional	<1ppm-0.0001%
	Eugenol	<1ppm-0.0001%	Linalool	<1ppm-0.0001%
	Hydroxycitronellal	<1ppm-0.0001%	Benzyl Benzoate	<1ppm-0.0001%
	Isoeugenol	<1ppm-0.0001%	Citronellol	<1ppm-0.0001%
	Amylcinnamyl Alcohol	<1ppm-0.0001%	Hexyl Cinnamal	<1ppm-0.0001%
	Benzyl Salicylate	<1ppm-0.0001%	Limonene	<1ppm-0.0001%
	Cinnamal	<1ppm-0.0001%	Methyl l2-octynoate	<1ppm-0.0001%
	Hydroxyisohexyl 3-Cyclohexene Carboxaldehyde	<1ppm-0.0001%	Alpha-Isomethyl Inone (Other Name: Methyl Lonone Gamma)	<1ppm-0.0001%
	Coumarin	<1ppm-0.0001%	Evernia Prunastri (Oak Moss) Extract	Not Tested
	Geraniol	<1ppm-0.0001%	Evernia Furfuracea (Tree Moss) Extract	Not Tested

*The given values correspond to the limit of determination OR *Results have been calculated form highest reported values published.

Additional information:

- A typical product with the **Malva Sylvestris (Mallow) Flower Extract** prepared in Glycerin and Water has the following specifications:

Analysis:

Specification	Range	Actual
APPEARANCE	Medium to dark amber liquid	PASS
MICROBIAL PLATE COUNT	Less than 100 organisms per gram	PASS
ODOR	Characteristic	PASS
PH	4.0 - 6.5 at 25° C	4.8
REFRACTIVE INDEX	1.3920 - 1.5000 at 25° C	1.3992
SOLUBILITY	Soluble in any proportion in water	PASS
SPECIFIC GRAVITY	1.05 - 1.15 at 25° C	1.13

Personal Care Products Council
Committed to Safety, Quality & Innovation

Memorandum

TO: Bart Heldreth, Ph.D.
Executive Director - Cosmetic Ingredient Review

FROM: Carol Eisenmann, Ph.D.
Personal Care Products Council

DATE: October 12, 2022

SUBJECT: HRIPT Product Containing Malva Sylvestris (Mallow) Flower/Leaf Extract

Anonymous. 2009. Human repeat insult patch test (product containing 0.0125% Malva Sylvestris (Mallow) Flower/Leaf/Stem Extract).

[redacted]

Human Repeat Insult Patch Test with Challenge

tested product contains 0.0125% Malva Sylvestris (Mallow) Flower/Leaf/ Stem Extract

Sponsor: [redacted]

Document type:

Investigational Product:

Batch No.:

Product Type:

Study Monitor:

Investigator:

Document Version: Final Date: January 30, 2009

[redacted]

[redacted]

Study Title: Human Repeat Insult Patch Test with Challenge

Sponsor: [redacted]

Protocol #:

Contract Research Organization:

[redacted]

Study Sites:

Dates of Study: November 3, 2008 – December 12, 2008

STUDY PERSONNEL

Principal Investigator

Clinical Research Coordinator,
Director, Dermatological Safety Testing

Assistant Clinical Research Coordinator

[redacted]

[redacted]

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[redacted]

SUMMARY

One investigational product, [redacted] was evaluated as supplied to determine if the application of the investigational product, [redacted] did not cause a delayed contact allergic response in volunteer subjects with normal skin using an occlusive human repeat insult patch test. One hundred one (101) subjects completed the study.

Under the conditions employed in this study, there was no evidence of sensitization or significant irritation to [redacted]

1 INTRODUCTION

The test consists in the repeated dermal application of the investigational product to human volunteer subjects under conditions which exaggerate the normal conditions of product use.

2 STUDY OBJECTIVE

The main objective of this study was to confirm that the application of a cosmetic product to volunteer subjects under maximized conditions according to the "modified Marzulli and Maibach" method did not cause a delayed contact allergic response.

Secondarily, skin compatibility of certain products may have been evaluated during the induction phase.

3 STUDY DESIGN

3.1 OVERALL STUDY DESIGN

This was a single center, within-subject comparison study of the investigational product. All subjects had sites designated for the investigational product on the infrascapular area of the back for the purpose of determining sensitization potential.

During the induction phase of the study, the study products were applied to 1 side of the infrascapular area of the back. Evaluation of dermal reactions at the application sites was assessed clinically using a visual scale that rated the degree of erythema, edema, and other signs of cutaneous irritation. A total of 9 applications were made during the induction phase.

Following induction, subjects had a 2-week rest phase, after which they entered the challenge phase that consisted of one 48-hour patch application to the original site and a naive site on the opposite side of the back. Observations at the naive site during challenge and the patterns of reactivity during the induction period provided a basis for an interpretation of contact allergic response.

If a cutaneous response observed in the challenge phase indicated possible sensitization, or at the discretion of the dermatologist investigator, a rechallenge was performed. In such cases, a narrative description of reactions in the challenge and rechallenge phases were reported together with the opinion of the dermatologist investigator as to whether such reactions were felt to be indicative of contact allergic response.

A total of 10 patch applications were made over a period of 6 weeks.

3.2 DISCUSSION OF DESIGN

This study design is based on the Modified Draize procedure (Marzulli & Maibach 1974), and is accepted standard methodology used for assessment of skin sensitization [2, 3].

Substances that come into contact with human skin need to be evaluated for their propensity to irritate and/or sensitize. Once an appropriate pre-clinical safety evaluation has been performed, a reproducible, standardized, quantitative patch evaluation procedure must be used to demonstrate that

[redacted]

a particular investigational product can be applied safely to human skin without significant risk of adverse reactions [4].

Repeated insult patch test (RIPT) evaluation is a predictive patch study that can detect weak sensitizers that require multiple applications to induce a cell-mediated (Type IV) immune response sufficient to cause an allergic reaction. Irritant reactions may also be detected using this evaluation method, although this is not the primary purpose of this procedure.

3.3 STUDY PROCEDURES

3.3.1 Screening / Day 1

At screening, the subjects were informed of the study procedures and the informed consent of each volunteer was obtained. Background information, including the date of birth, gender, and race, and a medical history for each subject was reviewed and recorded at screening. Eligibility was determined by review of the inclusion/non-inclusion criteria. If the subject fulfilled all the inclusion and none of the non-inclusion criteria, he/she was allowed to participate in the study, and received a unique enrollment number in order to preserve the subject's confidentiality. Qualified subjects were given oral and written instructions as follows:

- When bathing, avoid getting the patches and the application areas wet by taking a low tub bath or shower the front of your body only.
- No swimming is permitted during the study.
- You must notify staff if patches come off.
- Do not engage in activities (especially sports) that cause excessive sweating.
- Throughout the entire study, and for 2 weeks after study completion, avoid exposure to the sun or tanning beds.
- Avoid excessive scrubbing around patch area, which may cause irritation and may remove patch site markings.
- Do not apply any products in or around the patch area (including sunscreens). You must notify the staff if you do.
- Inform the staff of any vaccinations and/or use of medications during the study.
- Notify the staff if anything unusual occurs at any time during the study or within 2 weeks of completing the study. Please bear in mind that if [redacted] discontinues your participation in this study due to an adverse experience or severe reaction, you will be paid for your participation.
- Please inform us if you experience any discomfort beyond mild itching. Contact us as soon as possible at [redacted]
- During the entire study, including rest week, we ask that you not participate in any other patch or photopatch study with any research company.
- Do not participate in a similar study within 3 months of completing this study.

3.3.2 Induction

The induction phase consisted of a series of 9 applications of the investigational product and subsequent evaluations of the application sites. Patches were applied on Mondays, Wednesdays, and Fridays for 3 consecutive weeks. The subjects returned to the facility at 48-hour intervals to have the patches removed. Using a tissue, the dermatologist investigator-trained evaluator removed any remaining excess investigational product to avoid transference of products between sites. The sites were evaluated 15 to 30 minutes after patch removal by a dermatologist investigator-trained evaluator

[redacted]

using the scoring system detailed in Table 3.1 in Appendix I. Scores were entered into the data sheets by the evaluator. Identical patches were then applied to the same sites. Patches applied on a Friday remained in place for 72 hours until Monday.

3.3.3 Rest Period

During the 2-week rest period, subjects did not receive any application of the investigational product.

3.3.4 Challenge

At challenge, subjects who completed the induction phase and the rest period had identical patches applied to the original sites and to naive sites. Patches remained in place for 48 hours. The sites were graded at least 30 minutes as well as 48 hours following patch removal (ie, 48 and 96 hours after patch application) using the procedures described above for the induction phase.

3.3.5 Rechallenge

At the discretion of the dermatologist investigator and after discussion with the sponsor, a subject may have been rechallenged to the investigational product in the event of a doubtful reaction during the challenge phase. Rechallenge patches would be applied as soon as challenge reactions had resolved. The investigational product would be applied to naive sites on the back for 48 hours and graded at 48, 72, and 96 hours after application and if necessary, every day until resolution.

A similar or more severe response observed at rechallenge would have been considered indicative of a sensitization reaction. At the dermatologist investigator's discretion, further follow-up or retesting may have been necessary to confirm an interpretation of the finding.

3.3.6 Study Flow Chart

Week 1
1 Obtain informed consent, review completed medical screening form, apply patches
3 Staff removes patches, grades, applies patches
5 Staff removes patches, grades, applies patches

Week 2
1 Staff removes patches, grades, applies patches
3 Staff removes patches, grades, applies patches
5 Staff removes patches, grades, applies patches

Week 3
1-7 Same as Week 2

Week 4
1 Staff removes patches, grades
2-7 Begin rest period

Week 5
1-7 Rest period

Week 6

[redacted]

1 Staff applies patches
3 Staff removes patches, grades
5 Staff grades

3.4 SELECTION OF SUBJECTS

A sufficient number of subjects were enrolled in order to provide 100 completed subjects evaluable for analysis; an individual subject was allowed to participate in the study 1 time only.

To be considered a **completed case**, a subject must have had 9 applications of the investigational product and 9 subsequent readings during induction and 1 application followed by 2 subsequent readings during challenge. Only completed cases were used to assess sensitization.

3.4.1 Inclusion Criteria

Subjects included in the study were those who:

1. were healthy males or females, 18 to 65 years of age (no more than 10% ages 60-65), with a permanent address,

2. were able to give written consent,

3. were informed of the test procedures, were capable of reading the documents presented to them, and were capable of understanding them in the language used,

4. were subjects who benefited from social security or medical insurance (according to the legislation in force in the country where the test takes place),

5. were subjects selected according to the procedures established by the Investigating Laboratory. These criteria will be evaluated using the questionnaires recorded in the Investigator's CRF.

3.4.2 Non-inclusion Criteria

Subjects excluded from the study were those who:

1. refused to undertake to refrain from participating simultaneously in other bio-medical studies,

2. did not comply with the non-inclusion period stipulated at the time of their participation in the previous test,

3. had been deprived of their freedom by a legal or administrative decision, or people undergoing an emergency medical treatment (article L 209-5 French Law),

4. were minors or subjects protected by law, as well as those admitted into a health, social, or mental institution (article L 209-6 French law),

5. refused to give their agreement by not signing the informed consent declaration,

[redacted]

6. had an organ removed (kidney, lung, spleen, hepatic lobe, etc), a transplant, or suffered from a cranial trauma with after-effects,

7. were pregnant or nursing women, or those who have not taken contraceptive precautions,

8. presented a condition which is considered unacceptable for the study: such as skin marks at the test site that may interfere with the evaluation of the skin reactions (pigmentation problems, scarring, excessive hair growth, excessive numbers of freckles and moles, sunburn, etc), an immune deficiency, a previous history of contact allergies, immediate allergic reactions currently under treatment (asthma, periodic spasmodic rhinitis, conjunctivitis, etc), a fever lasting for more than 24 hours, in the 8 days preceding the product application,

9. had undergone long-term treatment or who were currently undergoing long-term treatment involving insulin, antihistamines, corticoids, beta-blockers (including eye drops), antibiotics, immunosuppressive drugs (cyclosporine), and/or in a period of de-sensitization,

10. had treatment with vitamin A or its derivatives less than 3 months before the beginning of the study,

11. had been vaccinated in the 3 weeks prior to the study or intend to be vaccinated during the study,

12. had been presenting cutaneous hyperactivity or skin disorder,

13. had strong reactions to sticking plaster of patches,

14. had been exposed to natural sunshine or UV lamp on the test area, during the month preceding the study,

15. showed a disorder due to excessive alcohol or drug use.

3.4.3 Informed Consent

A properly executed informed consent document in compliance with FDA regulations (21 CFR Part 50) and the Helsinki Declaration (1964) and subsequent amendments [5] was obtained from each subject prior to entering the study. Each subject dated and signed an informed consent document, which was witnessed and dated and signed by the dermatologist investigator's designee. The signed informed consent document is maintained in the study file. In addition, the subject was provided with a copy of the informed consent document (see Appendix III).

3.4.4 Interruption or Discontinuation of Treatment

In accordance with legal requirements and ICH-GCP guidelines, every subject or his/her legal representative had the right to refuse further participation in the study at any time and without providing reasons. A subject's participation was terminated immediately upon his/her request. The dermatologist investigator or designee was to seek to obtain and record the reason.

The termination of an individual's participation was to be considered in the case of a serious adverse event (SAE). If the subject, during the course of the study, developed a condition(s) which would

[redacted]

have prevented his/her entry into the study according to the safety-related medical non-inclusion criteria, he/she was to be withdrawn immediately.

The subject may have been withdrawn from the study at any time at the discretion of the dermatologist investigator for medical reasons and/or due to non-adherence to the treatment scheme and other duties stipulated in the study protocol. The reasons were to be fully documented on the CRF.

An erythema score of 2 or more to a study product (see Table 3.1 in Appendix I for interpretation of scores) observed at the first or second reading of the induction phase would have indicated the subject was most likely pre-sensitized and application of the product in question would have been discontinued. If this reaction was observed in subsequent readings, this would have necessitated a change in patch location to an adjacent site, and potentially patch conditions, for the remaining applications in the induction phase. In the case of an allergic reaction, the product would not be applied and the decision to reapply would be discussed with the sponsor.

Withdrawals

The following medical and other reasons justified a premature termination (by subject or dermatologist investigator) of any of the study products:

- withdrawal of informed consent,
- serious adverse events,
- allergic reactions to the investigational products,
- subject's request,
- occurrence of one of the safety criteria for non-inclusion after treatment had been instituted,
- the patches became dislodged or were misplaced such that continuous contact with the skin had been interrupted,
- subject was lost to follow-up, and/or
- dermatologist investigator's judgment.

If a subject withdrew from the study, all efforts were made to complete a final evaluation, if possible. Subjects discontinued for having experienced an adverse event (AE) were followed until the AE was resolved, a reasonable explanation was provided for the event, or the subject was referred to his/her own primary medical doctor (PMD). The specific AE in question was recorded on the appropriate CRF.

3.5 INVESTIGATIONAL PRODUCT (IP)

3.5.1 Investigational Product Specifications

IP Category	:	[redacted]
Formula No.	:	
Batch No.	:	
Description	:	
Amount Applied	:	20 μL
Patch Type	:	Occlusive
Evaporation	:	No

[redacted]

Dilution : No
Special Instructions : No

3.5.2 Description of Patch Conditions

Products evaluated under occlusive patch conditions are applied under a Finn Chamber. This chamber, formed of an 8 mm aluminum cup affixed to Scanpor tape, provides an isolation chamber in which the investigational product is placed. An amount of investigational product sufficient to fill the chamber (usually 20 µL or mg) is placed within the Finn Chamber such that it does not extend onto the adhesive tape surfaces. Liquid investigational product is soaked into a small filter disk placed within the Finn Chamber. For gels and ointments, an amount sufficient to fill the chamber is applied. The chamber is maintained in place by a hypoallergenic adhesive strip (Micropore) and serves to limit the investigational product to the designated skin contact site. Liquids are applied to the patch using an Eppendorf single channel adjustable pipette set at the appropriate amount to be applied to the patch, usually 20 µL. Creams, semi-solids, and solids are weighed by applying product to a patch that has been pre-weighed on a pre-calibrated weight balance. The product and patch are then weighed on the pre-calibrated weight balance to determine the appropriate amount of product, usually 20 mg. The weighed patch is used as a visual guide to prepare patches.

The patches were affixed with Micropore to the test sites on either the left or right side of the infrascapular area of the subject's back. The choice of left or right side was made by the clinical staff based on a visual inspection of skin clarity. A blank patch served as a negative control.

[redacted]

3.5.4 Treatment Compliance

All patches were applied by clinical study staff and removed by the subjects. Whereas bathing was allowed (low tub bath/frontal showers), the patched area was not to be soaked and was to be kept as dry as possible, per the instructions given to each subject (see Section 3.3.1). A dermatologist investigator-trained, experienced evaluator assessed study compliance. Records of patch applications and visit schedule compliance were recorded on the subjects' CRFs.

3.6 SAFETY EVALUATIONS

3.6.1 Local Tolerability Assessments

Assessment of the patch sites was performed 9 times during the induction phase, 2 times following challenge and, if applicable, 3 times following rechallenge. The examination of the treated sites was carried out under an artificial type D65 North daylight illuminator. The scores outlined in Table 3.1,

[redacted]

Appendix I were used to express the response observed at the time of examination. Allergy was evaluated according to the International Contact Dermatitis Research Group [6].

3.6.2 Adverse Events

An adverse event is defined as an occurrence of a new symptom(s) of a medical nature during use of the investigational product whether or not considered related to the investigational product, eg, headache, influenza, broken bones, fever, nausea. A serious adverse event is defined as death, a life threatening adverse experience, inpatient hospitalization, a persistent or significant disability/incapability, or a congenital anomaly/birth defect. Serious adverse events were to be reported to the sponsor within 24 hours of the investigative personnel's knowledge of the event. All Aes, whether observed by the clinical staff or by the subject, and whether or not thought to be study-related, were to be recorded on an Adverse Event form. Assessment of severity and causality will be based on definitions found on the AE form. Pregnancy, although not itself an adverse event, was also to be reported on an adverse event form.

Expected Adverse Events

Any observed response that was denoted using the irritation criteria summarized in Table 3.1 was not considered an AE. Likewise, any tape-related irritation was not noted as an AE.

3.7 QUALITY CONTROL

The Quality Control Unit of the Dermatological Safety Department conducted a 100% review of all study-related documents. The protocol was reviewed prior to the start of the study, the medical screening forms and informed consent documents were reviewed in-process of the study, and the regulatory binder was reviewed post-study.

4 DATA MANAGEMENT

[redacted]

4.2 DATABASE MANAGEMENT AND QUALITY CONTROL

Data were double-keyed and validated using ClinPlus (DZS Software Solutions), which directly generated SAS® data sets. After resolution of double-key discrepancies and a combination of manual

and automated data review procedures, the final data sets were subject to a quality control (QC) audit. SAS® programs for data analysis and presentation were applied to secure validated data sets.

5 INTERPRETATION OF THE RESULTS

5.1 SAMPLE SIZE

With a sample size of 100, in the absence of any sensitization reactions, a 95% upper confidence bound on the population rate of sensitization would be 3.5% [7].

5.2 POPULATIONS

All subjects who were treated were evaluable for adverse events. The evaluation of sensitization was based on all subjects who completed the challenge phase of the study.

5.3 CRITERIA OF EVALUATION OF SKIN COMPATIBILITY

Skin compatibility was evaluated from the skin reactions observed (number, intensity, frequency) and compared with that established for the chosen investigational product as a reference with the untreated control site. The analysis of skin compatibility include all subjects in the test, however many times they were evaluated during the induction phase.

5.4 DERMAL SENSITIZATION POTENTIAL

The determination of dermal sensitization potential was based on specific scoring criteria derived from observations in the challenge phase of the study, and confirmed in the re-challenge phase, if necessary.

The recurrence of a cutaneous response at re-challenge equivalent to or more severe than that observed at challenge was considered indicative of a sensitization reaction. The observation of such a response in even a single subject suggested that the study product may have the potential to cause hypersensitivity.

For all subjects who entered re-challenge, a narrative description of reactions in the challenge and re-challenge phases was to be provided together with the opinion of the dermatologist investigator as to whether such reactions were felt to be indicative of contact allergic response.

6 RESULTS

Summary data tables are provided in Appendix I of this report. Supportive listings are provided in Appendix II.

6.1 SUBJECTS EVALUATED

6.1.1 Subject Disposition

Subject disposition is shown in Table 1 and summarized in Text Table 6-1; these data are supported by Data Listing 1.

[redacted]

Text Table 6-1 Subject Disposition

Number of subjects enrolled	114
Number of subjects treated	114
Number of subjects discontinued	13
Lost to follow-up	5
Voluntary withdrawal	7
Adverse event	1
Number of subjects completed	101

Source: Appendix I, Table 1

6.1.2 Protocol Deviations

There was 1 protocol deviation: 12 subjects (10.5%) were between the ages of 60 and 65, a deviation from the protocol-specified not more than 10% within this age range. This deviation did not affect the validity of the study.

6.1.3 Baseline Demographic and Background Characteristics

All subjects met the inclusion and non-inclusion criteria. Demographic information is summarized in Table 2, these data are supported by Data Listing 2. The study population comprised 26 (23%) males and 88 (77%) females, of whom 77 (67%) were Caucasian, 35 (31%) were Hispanic, 1 (1%) was Asian and 1 (1%) was Other. Subject ages ranged from 19 to 65 years; the mean was 46 years.

6.2 SAFETY RESULTS

6.2.1 Induction and Challenge Responses

One hundred one subjects completed the induction phase and were included in determining the presence of significant irritation. One hundred one subjects completed the challenge phase of the study and were included in the sensitization analysis. There was no requirement for a re-challenge phase to be conducted. A summary of the repeated insult patch test responses during the induction and challenge phases of the study is provided in Table 3, Appendix I, a by-subject listing of the sensitization response data is provided in Data Listing 3, Appendix II.

6.2.2 Overall Experience of Adverse Events

There was 1 non-product-related serious adverse event (SAE) reported. See Data Listing 4, Appendix II for details.

7 CONCLUSIONS

Under the conditions employed in this study, there was no evidence of sensitization or significant irritation to [redacted]

[redacted]

8 REFERENCES

1. ICH Topic E6 " Note for guidance on Good Clinical Practices (CPMP/ICH/135/95)" – ICH Harmonized tripartite Guideline for Good Clinical Practices having reached Step 5 of the ICH Process at the ICH Steering Committee meeting on 1 May 1996.
2. Jordan, WP. 24-, 48-, and 48/48-hour Patch Tests. *Contact Dermatitis* 1980. 6: 151-152.
3. Marzulli F. N.; Maibach H. I. Contact Allergy: Predictive Test in Man. *Contact Dermatitis* 1976. 2:1-17
4. Lanman, BM, EB Elvers, and CJ Howard. "The Role of Human Patch Testing in a Product Development Program." Joint Conference on Cosmetic Goods Association, Washington DC, April 21-23, 1968.
5. Declaration of Helsinki adopted by the 18th World Medical Assembly, Helsinki, Finland, June 1964, and amended by the 29th World Medical Assembly, Tokyo, Japan, October 1975; 35th World Medical Assembly, Venice, Italy, October 1983; 41st World Medical Assembly, Hong Kong, September, 1989; 48th General Assembly, Somerset West, Republic of South Africa, October 1996; 52th General Assembly, Edinburgh, 2000; AMM General Assembly, Washington, 2002 and the AMM General Assembly, Tokyo, 2004.
6. CDRG = The International Contact Dermatitis Research Group, Fregert S. Manual of Contact Dermatitis, 2nd Edition
7. Mood AM, Graybill FA, Boes DC. Introduction to the Theory of Statistics. 3rd ed. New York: McGraw-Hill Higher Ed; 1974:Chapter 7.

[redacted]

[redacted]

APPENDIX I

SUMMARY TABLES

[redacted]

[redacted]

Table 1: Summary of Subject Enrollment and Disposition

	N (%)
Subjects enrolled	114
Subjects completed induction phase	101 (88.6)
Subjects completed all phases	101 (88.6)
Total subjects discontinued	13 (11.4)
Lost to follow-up	5 (4.4)
Voluntary withdrawal	7 (6.1)
Adverse events	1 (0.9)

Note: All percentages are relative to total subjects enrolled.

See data listing 1 for further detail.

[redacted]

[redacted]

[redacted]

Table 2: Summary of Subject Demographics
All Enrolled Subjects

Age	
N (%) 18 to 44	43 (37.7)
N (%) 45 to 59	59 (51.8)
N (%) 60 to 65	12 (10.5)
Mean (SD)	46.8 (10.5)
Median	47.9
Range	19.0 to 65.6
Gender	
N (%) Male	26 (22.8)
N (%) Female	88 (77.2)
Race	
Asian	1 (0.9)
Caucasian	77 (67.5)
Hispanic	35 (30.7)
Other	1 (0.9)

See data listing 2 for further detail.

[redacted]

[redacted]

[redacted]

Table 3: Summary of Dermatologic Response Grades
Number of Subjects by Product

[redacted]

	Induction Reading										Challenge Phase 48hr		Challenge Phase 96hr	
Response (EAM)	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**Make Up**	**L**	**R**	**L**	**R**
00	107	104	103	103	102	102	101	100	101	0	101	100	101	101
10	0	0	0	0	0	0	1	1	0	0	0	1	0	0
Total evaluable	107	104	103	103	102	102	102	101	101	0	101	101	101	101
Number absent	0	0	0	0	0	0	0	0	0		0	0	0	0
Number discontinued	7	10	11	11	12	12	12	13	13		13	13	13	13

Maximum Elicited Response During Induction
All Subjects Completing Induction (N=101)

Response	n(%) Subjects
00	100 (99.0%)
10	1 (1.0%)

See Table 3.1 for key to symbols and scores

[redacted]

[redacted]

[redacted]

Table 3.1: Key To Symbols and Scores

Score or Symbol	Response or Description of Reaction
	Erythema Results (E)
0	No visible erythema
+/-	Doubtful erythema
1	Mild erythema (faint pink)
2	Moderate erythema (well defined)
3	Severe erythema
4	Caustic erythema - erosive aspect and/or necrotic aspect
	Allergic Results (A)
0	No reaction
1	Weak positive reaction: erythema, infiltration, possibly papules
2	Strong positive reaction: erythema, vesicles, papules, infiltration
3	Extreme positive reaction: intense erythema, infiltration, vesicles may coalesce to form a blister
	Additional Comments (M)
E	- Edema from 0 to 3
P	- Papules
V	- Vesicles
B	- Bullae
S	- Spreading of reaction beyond the patch area
Pe	- Petichiae
SV	- Soap effect
F	- Fissuring
D	- Desquamation
Dr	- Dryness
C	- Skin coloration - hyperpigmentation
H	- Hypopigmentation
Fr	- Follicular reaction
NA	- Not applied
T	Tape reaction
*	Additional free comments (First new site reading)
N9G	No ninth grading
Cr	Exudation and/or surface encrustation
X	Succeeding patch not applied and succeeding grade (in brackets) denotes a residual reaction
--	Subject absent

[redacted]

APPENDIX II

DATA LISTINGS

[redacted]

[redacted]

Data Listing 1: Subject Enrollment and Disposition

	Study Dates						
Subject No.	Screened	1st Applic	Chall Applic	Ended	Last Reading #	Completion Status	Days in Study
001	11/03/08	11/03/08	12/08/08	12/12/08	C2	C	40
002	11/03/08	11/03/08	12/08/08	12/12/08	C2	C	40
003	11/03/08	11/03/08	12/08/08	12/12/08	C2	C	40
004	11/03/08	11/03/08	12/08/08	12/12/08	C2	C	40
005	11/03/08	11/03/08	12/08/08	12/12/08	C2	C	40
006	11/03/08	11/03/08	12/08/08	12/12/08	C2	C	40
007	11/03/08	11/03/08	12/08/08	12/12/08	C2	C	40
008	11/03/08	11/03/08	12/08/08	12/12/08	C2	C	40
009	11/03/08	11/03/08	12/08/08	12/12/08	C2	C	40
010	11/03/08	11/03/08	12/08/08	12/12/08	C2	C	40
011	11/03/08	11/03/08	12/08/08	12/12/08	C2	C	40
012	11/03/08	11/03/08	12/08/08	12/12/08	C2	C	40
013	11/03/08	11/03/08	12/08/08	12/12/08	C2	C	40
014	11/03/08	11/03/08	--	11/05/08	I0	L	3
015	11/03/08	11/03/08	12/08/08	12/12/08	C2	C	40
016	11/03/08	11/03/08	12/08/08	12/12/08	C2	C	40
017	11/03/08	11/03/08	12/08/08	12/12/08	C2	C	40
018	11/03/08	11/03/08	--	11/07/08	I1	S	5
019	11/03/08	11/03/08	12/08/08	12/12/08	C2	C	40
020	11/03/08	11/03/08	12/08/08	12/12/08	C2	C	40
021	11/03/08	11/03/08	12/08/08	12/12/08	C2	C	40
022	11/03/08	11/03/08	12/08/08	12/12/08	C2	C	40
023	11/03/08	11/03/08	12/08/08	12/12/08	C2	C	40
024	11/03/08	11/03/08	12/08/08	12/12/08	C2	C	40
025	11/03/08	11/03/08	12/08/08	12/12/08	C2	C	40
026	11/03/08	11/03/08	12/08/08	12/12/08	C2	C	40
027	11/03/08	11/03/08	12/08/08	12/12/08	C2	C	40
028	11/03/08	11/03/08	12/08/08	12/12/08	C2	C	40
029	11/03/08	11/03/08	12/08/08	12/12/08	C2	C	40
030	11/03/08	11/03/08	12/08/08	12/12/08	C2	C	40
031	11/03/08	11/03/08	12/08/08	12/12/08	C2	C	40
032	11/03/08	11/03/08	12/08/08	12/12/08	C2	C	40
033	11/03/08	11/03/08	12/08/08	12/12/08	C2	C	40
034	11/03/08	11/03/08	12/08/08	12/12/08	C2	C	40
035	11/03/08	11/03/08	12/08/08	12/12/08	C2	C	40
036	11/03/08	11/03/08	12/08/08	12/12/08	C2	C	40
037	11/03/08	11/03/08	12/08/08	12/12/08	C2	C	40

Key:
Last Reading # (I=Induction Phase, C=Challenge Phase)
Completion Status (C=Completed, L=Lost to follow-up, S=Voluntary withdrawal, V=Protocol violation, AE=Adverse event, O=Other)

[redacted]

[redacted]

[redacted]

Data Listing 1: Subject Enrollment and Disposition

	Study Dates						
Subject No.	Screened	1st Applic	Chall Applic	Ended	Last Reading #	Completion Status	Days in Study
038	11/03/08	11/03/08	12/08/08	12/12/08	C2	C	40
039	11/03/08	11/03/08	--	11/21/08	I7	L	19
040	11/03/08	11/03/08	12/08/08	12/12/08	C2	C	40
041	11/03/08	11/03/08	--	11/07/08	I1	L	5
042	11/03/08	11/03/08	12/08/08	12/12/08	C2	C	40
043	11/03/08	11/03/08	12/08/08	12/12/08	C2	C	40
044	11/03/08	11/03/08	12/08/08	12/12/08	C2	C	40
045	11/03/08	11/03/08	12/08/08	12/12/08	C2	C	40
046	11/03/08	11/03/08	12/08/08	12/12/08	C2	C	40
047	11/03/08	11/03/08	12/08/08	12/12/08	C2	C	40
048	11/03/08	11/03/08	12/08/08	12/12/08	C2	C	40
049	11/03/08	11/03/08	12/08/08	12/12/08	C2	C	40
050	11/03/08	11/03/08	12/08/08	12/12/08	C2	C	40
051	11/03/08	11/03/08	12/08/08	12/12/08	C2	C	40
052	11/03/08	11/03/08	--	11/10/08	I2	S	8
053	11/03/08	11/03/08	12/08/08	12/12/08	C2	C	40
054	11/03/08	11/03/08	12/08/08	12/12/08	C2	C	40
055	11/03/08	11/03/08	12/08/08	12/12/08	C2	C	40
056	11/03/08	11/03/08	--	11/05/08	I0	AE	3
057	11/03/08	11/03/08	12/08/08	12/12/08	C2	C	40
058	11/03/08	11/03/08	12/08/08	12/12/08	C2	C	40
059	11/03/08	11/03/08	12/08/08	12/12/08	C2	C	40
060	11/03/08	11/03/08	--	11/05/08	I0	S	3
061	11/03/08	11/03/08	12/08/08	12/12/08	C2	C	40
062	11/03/08	11/03/08	12/08/08	12/12/08	C2	C	40
063	11/03/08	11/03/08	12/08/08	12/12/08	C2	C	40
064	11/03/08	11/03/08	--	11/05/08	I0	S	3
065	11/03/08	11/03/08	12/08/08	12/12/08	C2	C	40
066	11/03/08	11/03/08	12/08/08	12/12/08	C2	C	40
067	11/03/08	11/03/08	--	11/07/08	I1	L	5
068	11/03/08	11/03/08	12/08/08	12/12/08	C2	C	40
069	11/03/08	11/03/08	12/08/08	12/12/08	C2	C	40
070	11/03/08	11/03/08	12/08/08	12/12/08	C2	C	40
071	11/03/08	11/03/08	12/08/08	12/12/08	C2	C	40
072	11/03/08	11/03/08	12/08/08	12/12/08	C2	C	40
073	11/03/08	11/03/08	12/08/08	12/12/08	C2	C	40
074	11/03/08	11/03/08	12/08/08	12/12/08	C2	C	40

Key:
Last Reading # (I=Induction Phase, C=Challenge Phase)
Completion Status (C=Completed, L=Lost to follow-up, S=Voluntary withdrawal, V=Protocol violation, AE=Adverse event, O=Other)

[redacted]

[redacted]

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Data Listing 1: Subject Enrollment and Disposition

	Study Dates						
Subject No.	Screened	1st Applic	Chall Applic	Ended	Last Reading #	Completion Status	Days in Study
075	11/03/08	11/03/08	12/08/08	12/12/08	C2	C	40
076	11/03/08	11/03/08	--	11/05/08	I0	L	3
077	11/03/08	11/03/08	--	11/14/08	I4	S	12
078	11/03/08	11/03/08	12/08/08	12/12/08	C2	C	40
079	11/03/08	11/03/08	12/08/08	12/12/08	C2	C	40
080	11/03/08	11/03/08	12/08/08	12/12/08	C2	C	40
081	11/03/08	11/03/08	12/08/08	12/12/08	C2	C	40
082	11/03/08	11/03/08	12/08/08	12/12/08	C2	C	40
083	11/03/08	11/03/08	12/08/08	12/12/08	C2	C	40
084	11/03/08	11/03/08	12/08/08	12/12/08	C2	C	40
085	11/03/08	11/03/08	12/08/08	12/12/08	C2	C	40
086	11/03/08	11/03/08	12/08/08	12/12/08	C2	C	40
087	11/03/08	11/03/08	12/08/08	12/12/08	C2	C	40
088	11/03/08	11/03/08	12/08/08	12/12/08	C2	C	40
089	11/03/08	11/03/08	12/08/08	12/12/08	C2	C	40
090	11/03/08	11/03/08	12/08/08	12/12/08	C2	C	40
091	11/03/08	11/03/08	12/08/08	12/12/08	C2	C	40
092	11/03/08	11/03/08	12/08/08	12/12/08	C2	C	40
093	11/03/08	11/03/08	12/08/08	12/12/08	C2	C	40
094	11/03/08	11/03/08	12/08/08	12/12/08	C2	C	40
095	11/03/08	11/03/08	12/08/08	12/12/08	C2	C	40
096	11/03/08	11/03/08	12/08/08	12/12/08	C2	C	40
097	11/03/08	11/03/08	12/08/08	12/12/08	C2	C	40
098	11/03/08	11/03/08	12/08/08	12/12/08	C2	C	40
099	11/03/08	11/03/08	12/08/08	12/12/08	C2	C	40
100	11/03/08	11/03/08	12/08/08	12/12/08	C2	C	40
101	11/03/08	11/03/08	12/08/08	12/12/08	C2	C	40
102	11/03/08	11/03/08	12/08/08	12/12/08	C2	C	40
103	11/03/08	11/03/08	12/08/08	12/12/08	C2	C	40
104	11/03/08	11/03/08	12/08/08	12/12/08	C2	C	40
105	11/03/08	11/03/08	12/08/08	12/12/08	C2	C	40
106	11/03/08	11/03/08	12/08/08	12/12/08	C2	C	40
107	11/03/08	11/03/08	--	11/05/08	I0	S	3
108	11/03/08	11/03/08	12/08/08	12/12/08	C2	C	40
109	11/03/08	11/03/08	--	11/05/08	I0	S	3
110	11/03/08	11/03/08	12/08/08	12/12/08	C2	C	40
111	11/03/08	11/03/08	12/08/08	12/12/08	C2	C	40
112	11/03/08	11/03/08	12/08/08	12/12/08	C2	C	40
113	11/03/08	11/03/08	12/08/08	12/12/08	C2	C	40
114	11/03/08	11/03/08	12/08/08	12/12/08	C2	C	40

Key:
Last Reading # (I=Induction Phase, C=Challenge Phase)
Completion Status (C=Completed, L=Lost to follow-up, S=Voluntary withdrawal, V=Protocol violation, AE=Adverse event, O=Other)

[redacted]

[redacted]

[redacted]

Data Listing 3: Dermatologic Response Grades
By Product and Subject

[redacted]

Subject No.	Induction Reading 1 EAM	2 EAM	3 EAM	4 EAM	5 EAM	6 EAM	7 EAM	8 EAM	9 EAM	MU	Challenge Phase 48-hour L	48-hour R	96-hour L	96-hour R	120-hour(*) L	120-hour(*) R
001	00	00	00	00	00	00	00	00	00		00	00	00	00		
002	00	00	00	00	00	00	00	00	00		00	00	00	00		
003	00	00	00	00	00	00	00	00	00		00	00	00	00		
004	00	00	00	00	00	00	00	00	00		00	00	00	00		
005	00	00	00	00	00	00	00	00	00		00	00	00	00		
006	00	00	00	00	00	00	00	00	00		00	00	00	00		
007	00	00	00	00	00	00	00	00	00		00	00	00	00		
008	00	00	00	00	00	00	00	00	00		00	00	00	00		
009	00	00	00	00	00	00	00	00	00		00	00	00	00		
010	00	00	00	00	00	00	00	00	00		00	00	00	00		
011	00	00	00	00	00	00	00	00	00		00	00	00	00		
012	00	00	00	00	00	00	00	00	00		00	10	00	00		
013	00	00	00	00	00	00	00	00	00		00	00	00	00		
014	--	--	--	--	--	--	--	--	--		--	--	--	--		
015	00	00	00	00	00	00	00	00	00		00	00	00	00		
016	00	00	00	00	00	00	00	00	00		00	00	00	00		
017	00	00	00	00	00	00	00	00	00		00	00	00	00		
018	00	--	--	--	--	--	--	--	--		--	--	--	--		
019	00	00	00	00	00	00	00	00	00		00	00	00	00		
020	00	00	00	00	00	00	00	00	00		00	00	00	00		
021	00	00	00	00	00	00	00	00	00		00	00	00	00		
022	00	00	00	00	00	00	00	00	00		00	00	00	00		
023	00	00	00	00	00	00	00	00	00		00	00	00	00		
024	00	00	00	00	00	00	00	00	00		00	00	00	00		
025	00	00	00	00	00	00	10	10	00		00	00	00	00		
026	00	00	00	00	00	00	00	00	00		00	00	00	00		
027	00	00	00	00	00	00	00	00	00		00	00	00	00		

(*) when required
E = Erythema results A = Allergic results M = Additional comments MU = Make-up visit
See Table 3.1 for Key to Symbols and Scores

[redacted]

[redacted]

Data Listing 3: Dermatologic Response Grades
By Product and Subject

[redacted]

Subject No.	Induction Reading 1 EAM	2 EAM	3 EAM	4 EAM	5 EAM	6 EAM	7 EAM	8 EAM	9 EAM	MU	Challenge Phase 48-hour L	48-hour R	96-hour L	96-hour R	120-hour(*) L	120-hour(*) R
028	00	00	00	00	00	00	00	00	00		00	00	00	00		
029	00	00	00	00	00	00	00	00	00		00	00	00	00		
030	00	00	00	00	00	00	00	00	00		00	00	00	00		
031	00	00	00	00	00	00	00	00	00		00	00	00	00		
032	00	00	00	00	00	00	00	00	00		00	00	00	00		
033	00	00	00	00	00	00	00	00	00		00	00	00	00		
034	00	00	00	00	00	00	00	00	00		00	00	00	00		
035	00	00	00	00	00	00	00	00	00		00	00	00	00		
036	00	00	00	00	00	00	00	00	00		00	00	00	00		
037	00	00	00	00	00	00	00	00	00		00	00	00	00		
038	00	00	00	00	00	00	00	00	00		00	00	00	00		
039	00	00	00	00	00	00	00	--	--		--	--	--	--		
040	00	00	00	00	00	00	00	00	00		00	00	00	00		
041	00	--	--	--	--	--	--	--	--		--	--	--	--		
042	00	00	00	00	00	00	00	00	00		00	00	00	00		
043	00	00	00	00	00	00	00	00	00		00	00	00	00		
044	00	00	00	00	00	00	00	00	00		00	00	00	00		
045	00	00	00	00	00	00	00	00	00		00	00	00	00		
046	00	00	00	00	00	00	00	00	00		00	00	00	00		
047	00	00	00	00	00	00	00	00	00		00	00	00	00		
048	00	00	00	00	00	00	00	00	00		00	00	00	00		
049	00	00	00	00	00	00	00	00	00		00	00	00	00		
050	00	00	00	00	00	00	00	00	00		00	00	00	00		
051	00	00	00	00	00	00	00	00	00		00	00	00	00		
052	00	00	--	--	--	--	--	--	--		--	--	--	--		
053	00	00	00	00	00	00	00	00	00		00	00	00	00		
054	00	00	00	00	00	00	00	00	00		00	00	00	00		

(*) when required
E = Erythema results A = Allergic results M = Additional comments MU = Make-up visit
See Table 3.1 for Key to Symbols and Scores

[redacted]

[redacted]

[redacted]

Data Listing 3: Dermatologic Response Grades
By Product and Subject

[redacted]

Subject No.	Induction Reading 1 EAM	2 EAM	3 EAM	4 EAM	5 EAM	6 EAM	7 EAM	8 EAM	9 EAM	MU	Challenge Phase 48-hour L	48-hour R	96-hour L	96-hour R	120-hour(*) L	120-hour(*) R
055	00	00	00	00	00	00	00	00	00		00	00	00	00		
056	--	--	--	--	--	--	--	--	--		--	--	--	--		
057	00	00	00	00	00	00	00	00	00		00	00	00	00		
058	00	00	00	00	00	00	00	00	00		00	00	00	00		
059	00	00	00	00	00	00	00	00	00		00	00	00	00		
060	--	--	--	--	--	--	--	--	--		--	--	--	--		
061	00	00	00	00	00	00	00	00	00		00	00	00	00		
062	00	00	00	00	00	00	00	00	00		00	00	00	00		
063	00	00	00	00	00	00	00	00	00		00	00	00	00		
064	--	--	--	--	--	--	--	--	--		--	--	--	--		
065	00	00	00	00	00	00	00	00	00		00	00	00	00		
066	00	00	00	00	00	00	00	00	00		00	00	00	00		
067	00	--	--	--	--	--	--	--	--		--	--	--	--		
068	00	00	00	00	00	00	00	00	00		00	00	00	00		
069	00	00	00	00	00	00	00	00	00		00	00	00	00		
070	00	00	00	00	00	00	00	00	00		00	00	00	00		
071	00	00	00	00	00	00	00	00	00		00	00	00	00		
072	00	00	00	00	00	00	00	00	00		00	00	00	00		
073	00	00	00	00	00	00	00	00	00		00	00	00	00		
074	00	00	00	00	00	00	00	00	00		00	00	00	00		
075	00	00	00	00	00	00	00	00	00		00	00	00	00		
076	--	--	--	--	--	--	--	--	--		--	--	--	--		
077	00	00	00	00	--	--	--	--	--		--	--	--	--		
078	00	00	00	00	00	00	00	00	00		00	00	00	00		
079	00	00	00	00	00	00	00	00	00		00	00	00	00		
080	00	00	00	00	00	00	00	00	00		00	00	00	00		
081	00	00	00	00	00	00	00	00	00		00	00	00	00		

(*) when required
E = Erythema results A = Allergic results M = Additional comments MU = Make-up visit
See Table 3.1 for Key to Symbols and Scores

[redacted]

[redacted]

[redacted]

Data Listing 3: Dermatologic Response Grades
By Product and Subject

[redacted]

Subject No.	Induction Reading 1 EAM	2 EAM	3 EAM	4 EAM	5 EAM	6 EAM	7 EAM	8 EAM	9 EAM	MU	Challenge Phase 48-hour L	48-hour R	96-hour L	96-hour R	120-hour(*) L	120-hour(*) R
082	00	00	00	00	00	00	00	00	00		00	00	00	00		
083	00	00	00	00	00	00	00	00	00		00	00	00	00		
084	00	00	00	00	00	00	00	00	00		00	00	00	00		
085	00	00	00	00	00	00	00	00	00		00	00	00	00		
086	00	00	00	00	00	00	00	00	00		00	00	00	00		
087	00	00	00	00	00	00	00	00	00		00	00	00	00		
088	00	00	00	00	00	00	00	00	00		00	00	00	00		
089	00	00	00	00	00	00	00	00	00		00	00	00	00		
090	00	00	00	00	00	00	00	00	00		00	00	00	00		
091	00	00	00	00	00	00	00	00	00		00	00	00	00		
092	00	00	00	00	00	00	00	00	00		00	00	00	00		
093	00	00	00	00	00	00	00	00	00		00	00	00	00		
094	00	00	00	00	00	00	00	00	00		00	00	00	00		
095	00	00	00	00	00	00	00	00	00		00	00	00	00		
096	00	00	00	00	00	00	00	00	00		00	00	00	00		
097	00	00	00	00	00	00	00	00	00		00	00	00	00		
098	00	00	00	00	00	00	00	00	00		00	00	00	00		
099	00	00	00	00	00	00	00	00	00		00	00	00	00		
100	00	00	00	00	00	00	00	00	00		00	00	00	00		
101	00	00	00	00	00	00	00	00	00		00	00	00	00		
102	00	00	00	00	00	00	00	00	00		00	00	00	00		
103	00	00	00	00	00	00	00	00	00		00	00	00	00		
104	00	00	00	00	00	00	00	00	00		00	00	00	00		
105	00	00	00	00	00	00	00	00	00		00	00	00	00		
106	00	00	00	00	00	00	00	00	00		00	00	00	00		
107	--	--	--	--	--	--	--	--	--		--	--	--	--		
108	00	00	00	00	00	00	00	00	00		00	00	00	00		

(*) when required
E = Erythema results A = Allergic results M = Additional comments MU = Make-up visit
See Table 3.1 for Key to Symbols and Scores

[redacted]

[redacted]

Data Listing 3: Dermatologic Response Grades
By Product and Subject

[redacted]

Subject No.	Induction Reading 1 EAM	2 EAM	3 EAM	4 EAM	5 EAM	6 EAM	7 EAM	8 EAM	9 EAM	MU	Challenge Phase 48-hour L	48-hour R	96-hour L	96-hour R	120-hour(*) L	120-hour(*) R
109	--	--	--	--	--	--	--	--	--		--	--	--	--		
110	00	00	00	00	00	00	00	00	00		00	00	00	00		
111	00	00	00	00	00	00	00	00	00		00	00	00	00		
112	00	00	00	00	00	00	00	00	00		00	00	00	00		
113	00	00	00	00	00	00	00	00	00		00	00	00	00		
114	00	00	00	00	00	00	00	00	00		00	00	00	00		

(*) when required
E = Erythema results A = Allergic results M = Additional comments MU = Make-up visit
See Table 3.1 for Key to Symbols and Scores

[redacted]

[redacted]

[redacted]

Data Listing 4: Adverse Events

Subject No. 056

Adverse Event: PREGNANCY	Date of Onset: 11/06	Date of Resolution:
Severity: N/A	Frequency: Single episode	Outcome: Persisted
Relation to Study Product: Unrelated	Duration: N/A	Action Taken/Study Product: Discontinued
Serious? YES		Action Taken/Treatment?: NO

[redacted]

[redacted]

2022 VCRP Data – *Malva sylvestris* (Mallow) derived-Ingredients

Ingredient Family Total Uses: 287

INGREDIENT_NAME	CATEGORY_CODE & DESCRIPTION	CPIS_COUNT
Malva Sylvestris (Mallow) Extract Total Uses: 198		
Malva Sylvestris (Mallow) Extract	02A - Bath Oils, Tablets, and Salts	4
Malva Sylvestris (Mallow) Extract	03A - Eyebrow Pencil	4
Malva Sylvestris (Mallow) Extract	03D - Eye Lotion	3
Malva Sylvestris (Mallow) Extract	03G - Other Eye Makeup Preparations	6
Malva Sylvestris (Mallow) Extract	05F - Shampoos (non-coloring)	1
Malva Sylvestris (Mallow) Extract	07B - Face Powders	2
Malva Sylvestris (Mallow) Extract	07C - Foundations	1
Malva Sylvestris (Mallow) Extract	07E - Lipstick	52
Malva Sylvestris (Mallow) Extract	07F - Makeup Bases	1
Malva Sylvestris (Mallow) Extract	07H - Makeup Fixatives	1
Malva Sylvestris (Mallow) Extract	07I - Other Makeup Preparations	6
Malva Sylvestris (Mallow) Extract	10E - Other Personal Cleanliness Products	2
Malva Sylvestris (Mallow) Extract	12A - Cleansing	3
Malva Sylvestris (Mallow) Extract	12C - Face and Neck (exc shave)	33
Malva Sylvestris (Mallow) Extract	12D - Body and Hand (exc shave)	2
Malva Sylvestris (Mallow) Extract	12F - Moisturizing	33
Malva Sylvestris (Mallow) Extract	12G - Night	6
Malva Sylvestris (Mallow) Extract	12H - Paste Masks (mud packs)	4
Malva Sylvestris (Mallow) Extract	12I - Skin Fresheners	1
Malva Sylvestris (Mallow) Extract	12J - Other Skin Care Preps	33
Malva Sylvestris (Mallow) Flower Total Uses: 1		
Malva Sylvestris (Mallow) Flowers	02A - Bath Oils, Tablets, and Salts	1
Malva Sylvestris (Mallow) Flower Extract Total Uses: 72		
Malva Sylvestris (Mallow) Flower Extract	01A - Baby Shampoos	1
Malva Sylvestris (Mallow) Flower Extract	01B - Baby Lotions, Oils, Powders, and Creams	1
Malva Sylvestris (Mallow) Flower Extract	02B - Bubble Baths	1
Malva Sylvestris (Mallow) Flower Extract	03G - Other Eye Makeup Preparations	2
Malva Sylvestris (Mallow) Flower Extract	05A - Hair Conditioner	2
Malva Sylvestris (Mallow) Flower Extract	05F - Shampoos (non-coloring)	8
Malva Sylvestris (Mallow) Flower Extract	05G - Tonics, Dressings, and Other Hair Grooming Aids	4
Malva Sylvestris (Mallow) Flower Extract	05H - Wave Sets	1
Malva Sylvestris (Mallow) Flower Extract	05I - Other Hair Preparations	3
Malva Sylvestris (Mallow) Flower Extract	07A - Blushers (all types)	1

Malva Sylvestris (Mallow) Flower Extract	07B - Face Powders	5
Malva Sylvestris (Mallow) Flower Extract	07C - Foundations	2
Malva Sylvestris (Mallow) Flower Extract	10A - Bath Soaps and Detergents	1
Malva Sylvestris (Mallow) Flower Extract	10B - Deodorants (underarm)	1
Malva Sylvestris (Mallow) Flower Extract	12A - Cleansing	12
Malva Sylvestris (Mallow) Flower Extract	11C - Mens Talcum	1
Malva Sylvestris (Mallow) Flower Extract	12C - Face and Neck (exc shave)	8
Malva Sylvestris (Mallow) Flower Extract	12D - Body and Hand (exc shave)	5
Malva Sylvestris (Mallow) Flower Extract	12F - Moisturizing	6
Malva Sylvestris (Mallow) Flower Extract	12G - Night	1
Malva Sylvestris (Mallow) Flower Extract	12H - Paste Masks (mud packs)	3
Malva Sylvestris (Mallow) Flower Extract	12I - Skin Fresheners	1
Malva Sylvestris (Mallow) Flower Extract	12J - Other Skin Care Preps	2

Malva Sylvestris (Mallow) Flower/Leaf Extract
Total Uses: 4

Malva Sylvestris (Mallow) Flower/Leaf Extract	03D - Eye Lotion	1
Malva Sylvestris (Mallow) Flower/Leaf Extract	05G - Tonics, Dressings, and Other Hair Grooming Aids	1
Malva Sylvestris (Mallow) Flower/Leaf Extract	12C - Face and Neck (exc shave)	2

Malva Sylvestris (Mallow) Flower/Leaf/Stem Extract
Total Uses: 5

Malva Sylvestris (Mallow) Flower/Leaf/Stem Extract	05A - Hair Conditioner	1
Malva Sylvestris (Mallow) Flower/Leaf/Stem Extract	07A - Blushers (all types)	1
Malva Sylvestris (Mallow) Flower/Leaf/Stem Extract	12F - Moisturizing	2
Malva Sylvestris (Mallow) Flower/Leaf/Stem Extract	12I - Skin Fresheners	1

Malva Sylvestris (Mallow) Leaf Extract
Total Uses: 4

Malva Sylvestris (Mallow) Leaf Extract	10B - Deodorants (underarm)	1
Malva Sylvestris (Mallow) Leaf Extract	12C - Face and Neck (exc shave)	1
Malva Sylvestris (Mallow) Leaf Extract	12D - Body and Hand (exc shave)	1
Malva Sylvestris (Mallow) Leaf Extract	12J - Other Skin Care Preps	1

Malva Sylvestris (Mallow) Leaf Powder
Total Uses: 1

Malva Sylvestris (Mallow) Leaf Powder	06D - Hair Shampoos (coloring)	1

Malva Sylvestris (Mallow) Oil
Total Uses: 2

Malva Sylvestris (Mallow) Oil	10A - Bath Soaps and Detergents	2