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

Status: Draft Report for Panel Review
Release Date: February 11, 2022
Panel Meeting Date: March 06-07, 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.; Daniel C. Liebler, Ph.D.; Ronald C. Shank, Ph.D.; Thomas J. Slaga, Ph.D.; and Paul W. Snyder, D.V.M., Ph.D. The Cosmetic Ingredient Review (CIR) Executive Director is Bart Heldreth, Ph.D. This report was prepared by Wilbur Johnson, former Senior Scientific Analyst/Writer, and Regina Tucker, Scientific Analyst/Writer, CIR.

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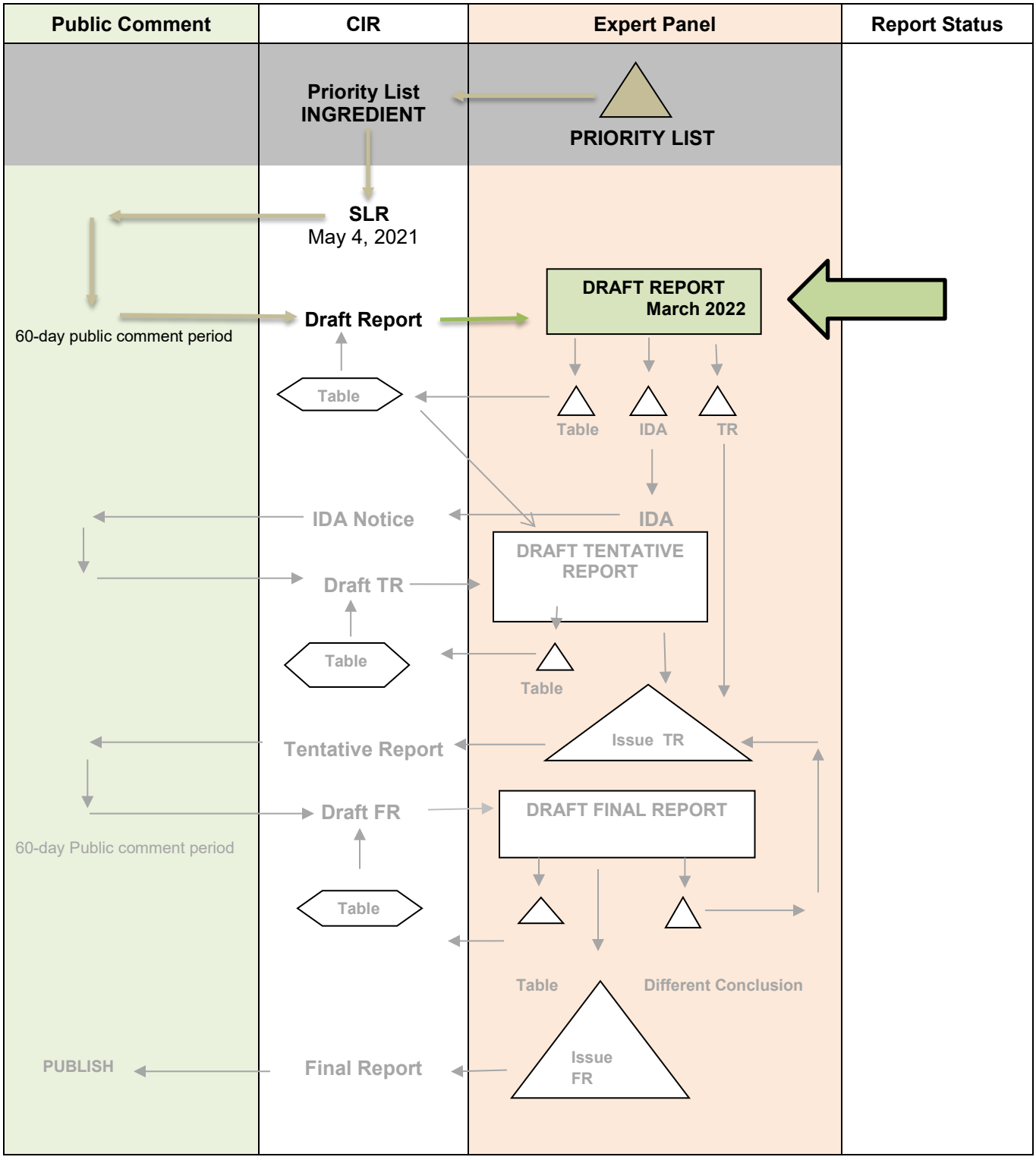
SAFETY ASSESSMENT FLOW CHART

INGREDIENT/FAMILY *Rosa centifolia*-derived ingredients

MEETING March 2022



Cosmetic Ingredient Review

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Memorandum

To: Expert Panel for Cosmetic Ingredient Safety Members and Liaisons

From: Regina Tucker
Scientific Analyst/Writer, CIR

Date: February 11, 2022

Subject: Safety Assessment of *Rosa centifolia*-derived ingredients as Used in Cosmetics

Enclosed is a draft report of the Safety Assessment of *Rosa centifolia*-derived ingredients (report_*RosaCentifolia_032022*) as used in cosmetics. A Scientific Literature Review (SLR) on 12 *Rosa centifolia*-derived ingredients was issued on May 4, 2021. Comments were received on the SLR (*PCPCcomments_RosaCentifolia_032022*), and a comments response checklist is included (response-PCPCcomments_RosaCentifolia_032022).

The following unpublished data have been added to the draft report that is included for the Panel's review:

- Unpublished irritation and sensitization data submitted by the Research Institute for Fragrance Materials (RIFM) *(RIFMdata_RosaCentifolia_032022)*
- Manufacturing, safety, and specification data on Rosa Centifolia Flower Extract, Flower Juice, and Flower Water . (*data1_RosaCentifolia_032022)*
- Chemical characterization and method of manufacture data specific to Rosa Centifolia Flower Extract and Rosa Centifolia Flower Water as used in a cosmetic formulation. *(data2_RosaCentifolia_032022)*
- Use concentration data *(data3_RosaCentifolia_032022)*
- Human maximization and skin irritation test on a face mask containing 0.8% Rosa Centifolia Flower *(data4_RosaCentifolia_032022)*
- Additional summary information for the above HRIPT *(data5RosaCentifolia_032022)*

Also included in this package for your review are the report history (*history_RosaCentifolia_032022*), flow chart (*flow_RosaCentifolia_032022*), literature search strategy (*strategy_RosaCentifolia_032022*), ingredient data profile (*dataprofile_RosaCentifolia_032022*), and 2022 FDA VCRP data (*VCRP_RosaCentifolia_032022*).

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, or unsafe 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.

Personal Care Products Council
Committed to Safety, Quality & Innovation

Memorandum

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

FROM: Alexandra Kowcz, MS, MBA
Industry Liaison to the CIR Expert Panel

DATE: June 1, 2021

SUBJECT: Scientific Literature Review: Safety Assessment of *Rosa centifolia*-Derived Ingredients as Used in Cosmetics (release date May 4, 2021)

The Personal Care Products Council has no suppliers listed for Rosa Centifolia Flower Oil.

The Personal Care Products Council respectfully submits the following comments on the scientific literature review, Safety Assessment of *Rosa centifolia*-Derived Ingredients as Used in Cosmetics.

Key Issues
Since Phenethyl Alcohol is considered one of the main volatile components of *Rosa centifolia*, the Introduction should note that Phenethyl Alcohol has been reviewed by CIR and the conclusion should be stated.

The Introduction should note the RIFM monograph published in 1974 (reference 10).

Although the complex mixtures derived from *Rosa centifolia* may not be regulated in Europe, it would be helpful if the Cosmetic Use section noted that two of the main volatile components, Citronellol and Geraniol are included in Annex III as fragrance allergens. These ingredients must be on the label if they exceed 0.001% in leave-on and 0.01% in rinse-off products.

Additional Considerations
Acute, Oral, *Rosa centifolia* flower extract – As the method is stated as OECD TG 425 limit test, please delete "method not stated).

Anti-mutagenicity – Did the authors (reference 26) provide any discussion as to why the activity differed among the three cultivars?

Carcinogenicity – Please provide a reference for the study that looked at the effect on triacylglycerol synthesis. If the results of this study are not going to be stated, maybe the study should be deleted from the CIR report.

Sensitization – Please provide the reference for the human maximization study.

Summary – Please revise: “there were no toxicologically relevant findings were observed”

Draft Report Comment Responses

Rosa centifolia derived ingredients – March 2022 – Regina Tucker	
Comment Submitter: Personal Care Products Council **Date of Submission: June 1, 2021**	
Comment	**Response/Action**
(1) Introduction: Since Phenethyl Alcohol is considered one of the main volatile components of Rosa centifolia, the Introduction should note that Phenethyl Alcohol has been reviewed by CIR and the conclusion should be stated.	Response: The report text has been revised to include this comment.
(2) The Introduction should note the RIFM monograph published in 1974 (reference 10).	Response: The report text has been revised to include this comment.
(3) Although the complex mixtures derived from Rosa centifolia may not be regulated in Europe, it would be helpful if the Cosmetic Use section noted that two of the main volatile components, Citronellol and Geraniol are included in Annex III as fragrance allergens. These ingredients must be on the label if they exceed 0.001% in leave-on and 0.01% in rinse-off products	Response: The report text has been revised to include this comment.
(4) Acute, Oral, Rosa centifolia flower extract – As the method is stated as OECD TG 425 limit test, please delete "method not stated)	Response: Edit made.
(5) Anti-mutagenicity – Did the authors (reference 26) provide any discussion as to why the activity differed among the three cultivars?	Response: The analysis of antimutagenicity indicated that the blue-colored anthocyanin(s) (whose concentration was maximum in the passion cultivar) was the major contributing bioactive constituent.
(6) Carcinogenicity – Please provide a reference for the study that looked at the effect on triacylglycerol synthesis. If the results of this study are not going to be stated, maybe the study should be deleted from the CIR report.	Response: Should have been deleted from SLR that was announced. Now deleted.
(7) Sensitization – Please provide the reference for the human maximization study.	Response: The reference is at the end of the first sentence (as in SLR that was announced).
(8) Summary – Please revise: "there were no toxicologically relevant findings were observed".	Response: When compared to the saline control group, no toxicologically relevant findings were observed after dosing with Rosa Centifolia Flower Extract.

CIR History of:

Rosa centifolia-derived Ingredients

May 2021

A Scientific Literature Review (SLR) on Rose centifolia-derived ingredients was issued on May 4, 2021.

January 2022

Updated (2022) VCRP data were received and incorporated.

Draft Report, Teams/Panel: March 7-8, 2022

Comments on the SLR and the following unpublished data, received from the Council, have been added to the draft report that is included for the Panel's review:

- Use concentration data
- Human maximization test on a face mask containing 0.8% Rosa Centifolia Flower
- Human skin irritation test on a face mask containing 0.8% Rosa Centifolia Flower

- Method of manufacture, specifications, and safety data sheet on Rosa Centifolia Flower Extract
- Specifications and safety data sheet on Rosa Centifolia Flower Juice
- Method of manufacture, specifications, and safety data sheet on Rosa Centifolia Flower Water

- Method of manufacture and composition data on Rosa Centifolia Flower Extract and Rosa Centifolia Flower Water
- HRIPT on 20% Rosa Centifolia Flower Extract
- Additional details for the HRIPT on 20% Rosa Centifolia Flower Extract
- Unpublished data received from the Research Institute for Fragrance Materials (RIFM) which includes the following:
  UV absorption data on Rosa Centifolia Flower Oil
  Maximization tests on Rosa Centifolia Flower Oil (test concentrations not stated)
  Phototoxicity tests on Rosa Centifolia Flower Oil (1% to 33%).

Rosa centifolia-derived Ingredients Data Profile* –March 7-8, 2022 – Wilbur Jonhnson/Regina Tucker																															
						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 Silico	In Vivo	Dermal	Oral	In Vitro	Animal	Human	In Vitro	Animal	Human	Phototoxicity	In Vitro	Animal	Case Report	Other Clinical Reports
Rosa Centifolia Bud Extract		X																												
Rosa Centifolia Callus Culture Extract																														
Rosa Centifolia Extract			X																										X	
Rosa Centifolia Flower	14	X																				X			X					
Rosa Centifolia Flower Extract	174	X	X	X	X				X			X													X					X
Rosa Centifolia Flower Juice	1	X	X	X	X																									
Rosa Centifolia Flower Oil	25	X	X					X	X												X	X			X	X				
Rosa Centifolia Flower Powder	5	X	X																											
Rosa Centifolia Flower Water	99	X	X	X	X																									
Rosa Centifolia Flower Wax	10	X	X																											
Rosa Centifolia Leaf Cell Extract																														
Rosa Centifolia Stem Extract																														

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

Rosa centifolia-derived Ingredients

Ingredient	CAS #	InfoBase	PubMed	TOXNET	FDA*	EU	ECHA	IUCLID	SIDS	HPVIS	NICNAS	NTIS	NTP	WHO	FAO	ECE-TOC	Web
Rosa Centifolia Bud Extract		Yes	0/0			No	No	No	No	No	No	No	No	No	No	No	Yes
Rosa Centifolia Callus Culture Extract		Yes	0/0		Yes*	No	No	No	No	No	No	No	No	No	No	No	Yes
Rosa Centifolia Extract		Yes	6/6		Yes*	No	No	No	No	No	No	No	No	No	No	No	Yes**
Rosa Centifolia Flower		Yes	4/4			No	No	No	No	No	No	No	No	No	No	No	No
Rosa Centifolia Flower Extract	84604-12-6	Yes	1/1		Yes*	No	No	No	No	No	No	No	No	No	No	No	Yes
Rosa Centifolia Flower Juice		Yes	0/0			No	No	No	No	No	No	No	No	No	No	No	Yes
Rosa Centifolia Flower Oil		Yes	1		Yes	No	No	No	No	No	No	No	No	No	No	No	Yes
Rosa Centifolia Flower Powder		Yes	0/0			No	No	No	No	No	No	No	No	No	No	No	Yes
Rosa Centifolia Flower Water		Yes	1/1			No	No	No	No	No	No	No	No	No	No	No	Yes
Rosa Centifolia Flower Wax		Yes	0/0			No	No	No	No	No	No	No	No	No	No	No	Yes
Rosa Centifolia Leaf Cell Extract		Yes	0/0		Yes*	No	No	No	No	No	No	No	No	No	No	No	Yes
Rosa Centifolia Stem Extract		Yes	0/0		Yes*	No	No	No	No	No	No	No	No	No	No	No	Yes
Rosa centifolia (genus and species, not an ingredient)			/22		Yes*	No	No	No	No	No	No	No	No	No	No	No	Yes

*Rose Absolute (can also be Rosa centifolia): Essential oil, oleoresins (solvent-free), and natural extractants (including distillates) GRAS for use in foods for human consumption (21 CFR 182.20). Same derivatives GRAS for use in foods, drugs, and related products for animal consumption (21 CFR 582.20) – Need to determine if any of other ingredients covered by 12 CFR 182.20 and 21 CFR 582.20.

**Search Rosa Centifolia Extract – Cosmetic Analysis

Dr. Duke's has composition data on Rosa centifolia

No IFRA standard in Standards Library

Rosa Centifolia Flower Extract has fragrance function also listed

Qualifiers
Absorption
Acute
Allergy
Allergic
Allergenic
Cancer
Carcinogen
Chronic
Development
Developmental
Excretion
Genotoxic
Irritation
Metabolism
Mutagen
Mutagenic
Penetration
Percutaneous
Pharmacokinetic
Repeated dose
Reproduction
Reproductive
Sensitization
Skin
Subchronic
Teratogen
Teratogenic
Toxic
Toxicity
Toxicokinetic
Toxicology
Tumor

LINKS

InfoBase (self-reminder that this info has been accessed; not a public website) - http://www.personalcarecouncil.org/science-safety/line-infobase
ScfFinder (usually a combined search for all ingredients in report; list # of this/# useful) - https://scifinder.cas.org/scifinder
PubMed (usually a combined search for all ingredients in report; list # of this/# useful) - http://www.ncbi.nlm.nih.gov/pubmed
Toxnet databases (usually a combined search for all ingredients in report; list # of this/# useful) – https://toxnet.nlm.nih.gov/ (includes Toxline; HSDB; ChemIDPlus; DAR; IRIS; CCRIS; CPDB; GENE-TOX)

FDA databases – http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm (CFR); then,
list of all databases: http://www.fda.gov/ForIndustry/FDABasicsforIndustry/ucm234631.htm; then,
http://www.accessdata.fda.gov/scripts/fcn/fcnnavigation.cfm?rpt=eafuslisting&displayall=true (EAFUS);
http://www.fda.gov/food/ingredientspackaginglabeling/gras/default.htm (GRAS);
http://www.fda.gov/food/ingredientspackaginglabeling/gras/scogs/ucm2006852.htm (SCOGS database);
http://www.accessdata.fda.gov/scripts/fdcc/?set=IndirectAdditives (indirect food additives list);
http://www.fda.gov/Drugs/InformationOnDrugs/default.htm (drug approvals and database);
http://www.fda.gov/downloads/AboutFDA/CentersOffices/CDER/UCM135688.pdf (OTC ingredient list);
http://www.accessdata.fda.gov/scripts/cder/iig/ (inactive ingredients approved for drugs)

EU (European Union); check CosIng (cosmetic ingredient database) for restrictions and SCCS (Scientific Committee for Consumer Safety) opinions - http://ec.europa.eu/growth/tools-databases/cosing/
ECHA (European Chemicals Agency – REACH dossiers) – http://echa.europa.eu/information-on-chemicals;jsessionid=A978100B4E4CC39C78C93A851EB3E3C7.live1
IUCLID (International Uniform Chemical Information Database) - https://iuclid6.echa.europa.eu/search
OECD SIDS documents (Organisation for Economic Co-operation and Development Screening Info Data Sets)- http://webnet.oecd.org/hpv/ui/Search.aspx
HPVIS (EPA High-Production Volume Info Systems) - https://ofmext.epa.gov/hpvis/HPVISlogon
NICNAS (Australian National Industrial Chemical Notification and Assessment Scheme)- Chemical information | Australian Industrial Chemicals Introduction Scheme (AICIS)
NTIS (National Technical Information Service) - http://www.ntis.gov/
NTP (National Toxicology Program) - http://ntp.niehs.nih.gov/
WHO (World Health Organization) technical reports - http://www.who.int/biologicals/technical_report_series/en/
FAO (Food and Agriculture Organization of the United Nations) - http://www.fao.org/food/food-safety-quality/scientific-advice/jecfa/jecfa-additives/en/ (FAO);
FEMA (Flavor & Extract Manufacturers Association) - Flavor Extract Manufacturers Association (FEMA) (femaflavor.org) Web – perform general search; may find technical data sheets, published reports, etc
ECETOC (European Center for Ecotoxicology and Toxicology Database) - http://www.ecetoc.org/

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

Fragrance Websites, if applicable

IFRA (International Fragrance Association) – http://www.ifraorg.org/
RIFM (the Research Institute for Fragrance Materials) should be contacted

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

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ABBREVIATIONS

CFR	Code of Federal Regulations
CIR	Cosmetic Ingredient Review
Council	Personal Care Products Council
FCA	Freund's Complete Adjuvant
FDA	Food and Drug Administration
GRAS	generally recognized as safe
LA	Luria agar
LD_{50}	lethal dose, 50%
8-MOP	8-methoxypsoralen
Panel	Expert Panel for Cosmetic Ingredient Safety
Rif^R	rifampicin-resistant
Rif^S	rifampicin-sensitive
*rpo*B	RNA polymerase B
RIFM	Research Institute for Fragrance Materials
s.c.	subcutaneous
US	United States
VCRP	Voluntary Cosmetic Registration Program
wINCI	web-based *International Cosmetic Ingredient Dictionary and Handbook*

INTRODUCTION

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

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

According to the web-based *International Cosmetic Ingredient Dictionary and Handbook* (wINCI; *Dictionary*), most *Rosa centifolia*-derived ingredients are reported to function as skin conditioning agents in cosmetic products (See Table 1).[1] Other functions associated with ingredients in this group include abrasives, antioxidants, fragrance ingredients, and skin protectants.

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

This safety assessment includes relevant published and unpublished data that are available for each endpoint that is evaluated. Published data are identified by conducting an exhaustive search of the world's literature. A list of the search engines and websites that are used and the sources that are typically explored, as well as the endpoints that the Panel typically evaluates, is provided on the 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 may be provided by the cosmetics industry, as well as by other interested parties.

The Panel does not typically review ingredients that function only as fragrance ingredients, because, as fragrances, the evaluation of the safety of these ingredients is the purview of the Research Institute for Fragrance Materials (RIFM). Rosa Centifolia Flower Oil is reported to function only as a fragrance ingredient in cosmetics, according to the wINCI *Dictionary* (see Table 1). The safety of this ingredient is not currently being reviewed by RIFM. However, a published RIFM monograph was available for "Rose Oil Moroccan,"[4] and unpublished studies were provided by RIFM to the CIR on Rosa Centifolia Flower Oil.[5-15] The unpublished studies were ascribed, typically, to an "absolute" or a "concrete;" these names are provided with the data.

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

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

CHEMISTRY

Definition and Plant Identification

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

Cabbage rose is a common name for *Rosa centifolia*.[16] *Rosa centifolia* L. (Rosaceae), a perennial plant that is commonly known as hundred-leaved rose or shatapatri or taruni, is available throughout India.[17] It is a complex hybrid that is bred from *Rosa gallica* L., *Rosa moschata* Herm., *Rosa canina* L., and *Rosa damascene* Mill.

According to another source, *Rosa centifolia* grows as a plant, shrub, bush, or thicket.[18] This plant is of Asiatic origin, and the countries where it is extensively cultivated for extractive purposes include: Bulgaria, Turkey, Morocco, France, and Italy. The parts used are the flowers, buds, leaves, and fruit (hips).

Chemical Properties

Rosa Centifolia Extract is a light-brown, viscous liquid, and Rosa Centifolia Flower Wax is a solid that is insoluble in water.[18,19] According to another source, either Rosa Centifolia Bud Extract, Rosa Centifolia Callus Culture Extract, or Rosa

Centifolia Flower Extract may be a solid or liquid, depending upon the components of the extract.[20-22] Also, the water solubility of either extract is related to components of the extract and the solvent that is used for extraction. Rosa Centifolia Flower Oil is miscible with chloroform.[23] UV absorption data indicate an absorption peak at 320 nm (shoulder) for Rosa Centifolia Flower Oil (rose absolute French).[5] A flash point of ≥ 100ºC has been reported for a Rosa Centifolia Flower Extract trade name mixture.[24] Chemical properties data on *Rosa centifolia*-derived ingredients are presented in Table 2.

Method of Manufacture

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

Rosa Centifolia Extract

A *Rosa centifolia* extract is prepared by extraction with volatile solvents, which are subsequently removed (usually under vacuum).[18] The removal of solvents is followed by redissolution in alcohol, chilling, filtration, and removal of the alcohol.

Rosa Centifolia Flower Extract

According to one method of manufacture of Rosa Centifolia Flower Extract, a fraction of the petals of rose of Marocco (*Rosa centifolia*) is extracted by a mixture of propylene glycol + water.[25] This process is followed by filtration, yielding a Rosa Centifolia Flower Extract trade name mixture. Another source indicates that this trade name mixture (hydroglycolic extract) is prepared from the petals of rose (*Rosa centifolia*) by controlled extraction using propylene glycol and water.[26]

The production method for another Rosa Centifolia Flower Extract trade name mixture has also been described.[27] Dried raw material is extracted with hot water, and this step is followed by filtration and then concentration. The concentrated filtrate is dissolved in 1,3-butylene glycol (50 vol%) solution. The resulting solution is subjected to sedimentation and filtration, and the production sequence ends with adjustment, and packaging.

Rosa Centifolia Flower Juice

According to one method of manufacture of Rosa Centifolia Flower Juice, petals of *Rosa centifolia* are rehydrated and then pressed.[28] This process is followed by stabilization with vegetal glycerin and then filtration, yielding a Rosa Centifolia Flower Juice trade name mixture. According to another source, in the method of manufacture of this trade name mixture, the *Rosa centifolia* petals are cold pressed without using any solvents.[29]

Rosa Centifolia Flower Oil

Steam distillation of the flowers of *Rosa centifolia* is the method of production of *Rosa centifolia* flower oil.[4,23]

Rosa Centifolia Flower Powder

Rosa Centifolia Flower Powder is obtained from the dried, ground flowers of *Rosa centifolia*.[1]

Rosa Centifolia Flower Water

Steam distillation of the flowers of *Rosa centifolia* is the method of production of Rosa Centifolia Flower Water (aqueous solution).[1] According to another source, the distillation of *Rosa centifolia* (rose) yields the following 3 products: rose water, rose oil, and rose waste biomass.[30,31] The method of manufacture of a Rosa Centifolia Flower Water trade name material involves the steam distillation of *Rosa centifolia* petals, and this process is followed by filtration.[32]

The production method for a Rosa Centifolia Flower Water trade name mixture has also been described.[27] Dried raw material is subjected to steam distillation, yielding a water-soluble fraction. Ethanol (15 vol%) is then added to this fraction, and the production sequence ends with filtration and packaging.

Rosa centifolia flower wax

The extraction process that is used to produce rose absolutes (aromatic oils) from *Rosa centifolia* also yields an intermediary product that contains resins, waxes, and other lipids.[33] After the volatile oils have been removed, the waxy components can be used to produce floral wax.

Composition/Impurities

The main volatile constituents of *Rosa centifolia* have been identified as citronellol, geraniol, and phenethyl alcohol.[18] Composition data relating to the whole plant, essential oil, and flower and leaf parts of *Rosa centifolia* are presented in Table 3.[16,18,34,35]

Composition data on *Rosa centifolia* hydrosol were also found in the published literature.[36] Hydrosols are products of the hydrodistillation of aromatic herbs and plants and are basically saturated solutions of essential oils (volatile fraction) in water. Rose hydrosols (e.g., *Rosa centifolia*) contain 103 ± 4.1 mg/l of total volatile compounds. The major volatile compounds in

Rosa centifolia hydrosol have been identified as: phenethyl alcohol (42 ± 2 mg/l), citronellol (22 ± 1 mg/l), geraniol (14 ± 1 mg/l).

Rosa Centifolia Flower Extract

A Rosa Centifolia Flower Extract trade mixture consists of 2.8% to 3.8% dry extract.[26] The total aerobic microbial count is ≤ 100 colony forming units (CFU)/g. According to another source, the same Rosa Centifolia Flower Extract trade mixture contains propylene glycol, water, and Rosa Centifolia Flower Extract.[24] Additional data on composition indicate that another Rosa Centifolia Flower Extract trade name mixture contains flavonoid and tannin.[27]

Rosa Centifolia Flower Juice

One Rosa Centifolia Flower Juice trade name mixture contains glycerin, Rosa Centifolia Flower Juice, and potassium (sorbate (0.2%).[37] Additional data on this Rosa Centifolia Flower Juice trade name mixture indicate that the total aerobic microbial count is ≤ 100 CFU/g.[29]

Rosa Centifolia Flower Water

A Rosa Centifolia Flower Water trade name material (aqueous extract of *Rosa centifolia* petals) contains the preservative, phenoxyethanol (1.5%), and the total aerobic mesophilic microorganisms count is ≤ 100 CFU/g.[38] According to another source, this Rosa Centifolia Flower Water tradename material contains 98.5% Rosa Centifolia Flower Water and 1.5% phenoxyethanol.[39] Composition data on another Rosa Centifolia Flower Water trade name material indicate that it contains β-phenylethyl alcohol and geraniol.[27]

USE

Cosmetic

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

According to 2022 VCRP data, Rosa Centifolia Flower Extract has the greatest frequency of use; it is reported to be used in 174 cosmetic products, 150 of which are leave-on formulations (Table 4).[40] The results of a concentration of use survey conducted by the Council in 2021 indicate that Rosa Centifolia Flower Water has the highest concentration of use; it is used at maximum use concentrations up to 0.096%.[41] According to both VCRP and Council survey data, 5 of the 12 *Rosa centifolia*-derived ingredients reviewed in this safety assessment are not currently in use in cosmetic products. These ingredients are listed in Table 5.[40]

Cosmetic products containing *Rosa centifolia*-derived ingredients may incidentally come in contact with the eyes (e.g., Rosa Centifolia Flower Extract is used in mascaras at up to 0.02%). [40] *Rosa centifolia*-derived ingredients are also being used in cosmetic products that may be incidentally ingested (e.g., Rosa Centifolia Flower Extract is used at up to 0.002% in lipstick formulations).

Some of these ingredients are reported to be used in cosmetic products that could possibly be inhaled; for example, Rosa Centifolia Flower Extract is reported to be used at up to 0.025% in spray fragrance preparations and at up to 0.0001% in face powders.[40,41] In practice, 95% to 99% of the droplets/particles released from cosmetic sprays have aerodynamic equivalent diameters > 10 μm, with propellant sprays yielding a greater fraction of droplets/particles < 10 μm, compared with pump sprays.[42-45] Therefore, most droplets/particles incidentally inhaled from cosmetic sprays would be deposited in the nasopharyngeal and bronchial regions and would not be respirable (i.e., they would not enter the lungs) to any appreciable amount.[42,43] 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 .[46-48]

The *Rosa centifolia*-derived ingredients are not restricted from use in any way under the rules governing cosmetic products in the European Union.[49] However, it should be noted that 2 of the main volatile components of *Rosa centifolia*, citronellol and geraniol, are included in Annex III of the Cosmetics Regulation European Commission (EC) No. 1223/2009 (list of substances which cosmetic products must not contain except subject to the restrictions laid down) as fragrance allergens. These ingredients must be on the label if they exceed 0.001% in leave-on and 0.01% in rinse-off products.

Non-Cosmetic

According to the US FDA, essential oils, oleoresins (solvent-free), and natural extractives (including distillates) of rose absolute (*Rosa alba* L., *Rosa centifolia* L., *Rosa damascena* Mill., *Rosa gallica* L., and vars. of these spp.), rose buds, and rose

flowers are generally recognized as safe (GRAS) for use in foods for human consumption (21 CFR 182.20). The FDA has also determined that these are GRAS for use in foods, drugs, and related products for animal consumption (21 CFR 582.20).

Rosa centifolia is famous among oil-producing species of roses, amounting to 4.25 tons per year around the globe.[50] Additionally, it is used in the traditional systems of medicine for the management of inflammatory conditions, including arthritis, cough, asthma, bronchitis, wounds, and ulcers.[17,51] Specifically, therapeutic uses (as astringent) of the dried petals of rose flower (e.g., from *Rosa centifolia*) include treatment of mild inflammations of the oral and pharyngeal mucosa (dosage = 1 to 2 g of drug per cup (200 ml) of water, for tea).[52]

TOXICOKINETIC STUDIES

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

TOXICOLOGICAL STUDIES

Acute Toxicity Studies

Dermal

Rosa Centifolia Flower Oil

An acute dermal LD_{50} of > 2.5 g/kg for Rosa Centifolia Flower Oil was reported in a study involving rabbits (number and strain not stated).[4] Details relating to the test protocol and study results are not included.

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

Oral

Rosa Centifolia Flower Extract

The acute oral toxicity of a *Rosa centifolia* flower extract (ethanol extract) was evaluated according to Organization for Economic Cooperation and Development (OECD) Test Guideline (TG) 425.[17] A limit test on a *Rosa centifolia* flower extract (ethanol extract; dose = 2 g/kg body weight; route of administration not stated) was performed using 5 male Wistar albino rats. Dosing was followed by a 14-d observation period. None of the animals died during the observation period, and the LD_{50} was established at > 2 g/kg body weight.

Rosa Centifolia Flower Oil

The acute oral toxicity of Rosa Centifolia Flower Oil (rose absolute French) was evaluated using 10 rats (strain not stated).[6] The test substance was administered (protocol not included) as a single oral dose of 5 g/kg. Dosing was followed by a 14-day observation period. Three of 10 animals died on day 2 of the observation period; piloerection and lethargy were observed. An LD_{50} of > 5 g/kg was reported.

Short-Term Toxicity Studies

Oral

Rosa Centifolia Flower Extract

The short-term oral toxicity of *Rosa centifolia* flower extract (ethanol extract) was evaluated according to OECD TG 407.[17] Two groups of 8 male Wistar rats were used. *Rosa centifolia* flower extract was administered orally (route of administration not stated; dose of 640 mg/kg) to one of the groups once daily for 28 d. The control group was dosed orally with normal saline (1 ml/kg). After day 28, the animals were killed, and the heart and liver were examined histologically. Repeated dosing resulted in a statistically significant decrease in hepatic transaminases and an increase in white blood cells. However, it was noted that these changes were within the physiological limits for the rat and not toxicologically relevant. When compared to the control group, no other physiological, biochemical, or histopathological changes were observed in the animals dosed with *Rosa centifolia* flower extract.

Subchronic Toxicity Studies

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

Chronic Toxicity Studies

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

DEVELOPMENTAL AND REPRODUCTIVE TOXICITY STUDIES

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

GENOTOXICITY STUDIES

Genotoxicity studies of *Rosa centifolia*-derived ingredients reviewed in this safety assessment were not found in the published literature, an unpublished data were not submitted.

ANTI-MUTAGENICITY STUDIES

Rosa Centifolia Flower Extract

The anti-mutagenicity of aqueous extracts of petals from different cultivars ("passion," "pink noblesse," and "sphinx") of *Rosa centifolia* was studied using the *Escherichia coli* RNA polymerase B (*rpo*B)-based Rif ^{S}→Rif ^{R} (rifampicin sensitive to resistant) forward mutation assay against ethyl methanesulfonate-induced mutagenesis.[53] *E. coli* MG1655 cells were used. The cell suspension was mixed with *Rosa centifolia* flower extract (aqueous extract) and ethyl methanesulfonate (133 mM) and the mixture was incubated. Later, the culture was serially diluted and spread-plated on Luria agar (LA)-rifampicin (100 μg/ml) plates for scoring Rif ^{R} mutants and LA plates for enumerating viable cells. Mutation frequency was calculated as ratio of total number of Rif ^{R} mutants per ml to the total number of viable cells in same culture volume. Spontaneous mutation frequency was determined by incubating the cell suspension in the absence of mutagen. The Rif ^{R} mutation frequency in *E. coli* cells exposed to ethyl methanesulfonate was approximately $1500/10^{8}$ cells, whereas the spontaneous mutation frequency was approximately $1/10^{8}$ cells. Aqueous extracts of rose petals of the 3 cultivars, "passion," "pink noblesse," and "sphinx" (1.5 mg/ml), resulted in reduction in the mutation frequency by 55%, 19%, and 4%, respectively. Thus, the "passion," cultivar was the most antimutagenic among the rose cultivars that were evaluated. The analysis of antimutagenicity indicated that the blue-colored anthocyanin(s) (whose concentration was maximum in the passion cultivar) was the major contributing bioactive constituent.

CARCINOGENICITY STUDIES

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

OTHER RELEVANT STUDIES

Anti-Inflammatory Activity

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

Rosa Centifolia Flower Extract

The anti-inflammatory activity of a *Rosa centifolia* flower extract (ethanol extract; doses of 32, 64, and 128 mg/kg) was evaluated using the carrageenan-induced paw edema and Freund's complete adjuvant (FCA)-induced arthritis model.[17] The study involved the following 5 groups of 6 male Wistar albino rats, dosed by gavage: group 1 (2 ml/kg of 1% gum acacia suspension; vehicle control), group 2 (3 mg/kg of indomethacin), group 3 (32 mg/kg of *Rosa centifolia* flower extract), group 4 (64 mg/kg of *Rosa centifolia* flower extract), and group 5 (128 mg/kg of *Rosa centifolia* flower extract). At 30 min post-administration, paw inflammation was induced by subcutaneous (s.c.) administration of 0.1 ml of 1% λ-carrageenan in saline into the subplantar surface of the left hind paw. Paw volume was measured at 1 h, 3 h, and 6 h after s.c. λ-carrageenan injection. The *Rosa centifolia* flower extract (64 and 128 mg/kg) statistically significantly ($p < 0.01$) inhibited carrageenan-induced paw edema at 1 h, 3 h, and 6 h post-carrageenan challenge and demonstrated statistically significant ($p < 0.01$) antiarthritic activity on days 3, 7, 14, and 21 after complete FCA immunization. Treatment with the *Rosa centifolia* flower extract (128 mg/kg) also caused a statistically significant decrease in circulating pro-inflammatory cytokine levels when compared to the control.

DERMAL IRRITATION AND SENSITIZATION STUDIES

The dermal irritation and sensitization studies summarized below are presented in Table 6.

Undiluted Rosa Centifolia Flower Oil was classified as moderately irritating to the skin when applied for 24 h to intact or abraded skin of rabbits (number and strain not stated) using occlusive patches.[4] In a study involving hairless mice (number and

strain not stated), undiluted Rosa Centifolia Flower Oil was applied to the back for an unspecified duration; skin irritation was not observed.[4] In clinical studies, a face mask containing 0.8% Rosa Centifolia Flower (undiluted) was not irritating in a 24-h occlusive patch test involving 20 subjects.[54] Rosa Centifolia Flower Oil (2% in petrolatum) was not irritating in a 48-h closed patch test (number of subjects not stated).[4]

A face mask containing Rosa Centifolia Flower was not a sensitizer in a maximization study using sodium lauryl sulfate (SLS) pretreatment,[55] and a Rosa Centifolia Flower Extract trade name mixture (20% in solution) was not a sensitizer in a human repeated insult patch test (HRIPT) involving 55 subjects.[27,56] Multiple maximization studies with SLS pretreatment were performed with Rosa Centifolia Flower Oil. In most studies, the test substance (tested at 2% in one study;[4] concentration tested not stated in most)[7-10]was not an irritant or a sensitizer. However, in one maximization study, Rosa Centifolia Flower Oil (absolute rose French) produced sensitization in 17 of 25 subjects,[11] and in another, it induced contact sensitization (mild reaction) in 1 of 25 subjects.[7]

Photosensitization/Phototoxicity

Animal

Rosa Centifolia Flower Oil

The phototoxicity of Rosa Centifolia Flower Oil (rose centifolia concrete) was evaluated using groups of 6 male hairless mice (*Skh:hairless-1*).[9] Dilution assays were performed using fluorescent blacklight lamps. Details relating to light exposure were not included. Test groups were treated with a saturated solution of the test substance (33% in benzene), and up to 6 serial binary dilutions. (1% to 16.7%). Results for the test substance were compared to 8-methoxypsoralen (8-MOP). Reference groups were treated with 0.01% 8-MOP in methanol, and 3 binary dilutions (0.00125% to 0.005%). Rosa Centifolia Flower Oil (rose centifolia concrete) was strongly phototoxic, but only at the highest concentration tested (33% in benzene), with a phototoxic index of 0.75. All responses were abolished as a result of binary dilution. At the highest concentration, the animals exhibited prolonged (to 96 h) erythema and moderately prolonged edema. For 8-MOP, unexpected activity at a concentration of 0.0025% was reported. Furthermore, the appearance of a weak and very delayed (but ambiguous) response in 1 of 6 mice treated with 0.00125% 8-MOP. Two marginal responses to this concentration were observed upon examination at 120 h.

Six groups of male hairless mice (*Skh:hairless-1*) were tested in a phototoxicity study of Rosa Centifolia Flower Oil (rose Bulgare concrete).[10] Dilution assays were performed using fluorescent blacklight lamps. Details relating to light exposure were not included. Test groups were treated with the test substance (saturated solution in benzene), at up to 6 serial dilutions (1% to 33%). Reference groups were treated with 0.01% 8-MOP (in methanol) and 3 serial binary dilutions (0.0012% to 0.005%). Rosa Centifolia Flower Oil (rose Bulgare concrete) was irritating at high concentrations (16% and 33%), and the phototoxic response (not strongly dose-related) was apparently superimposed on the irritant background. This was further described as an unusual response with the appearance of a phototoxic reaction. In most cases, the reaction was localized to the light-exposed area, but had the appearance of multiple petechiae, rather than the confluent edema or erythema normally observed. The reaction was first observed prior to irradiation. When the mask was removed after irradiation, the petechiae were confined to the irradiated area. Because the petechiae were observed prior to irradiation, it was suspected that localization was related to occlusion rather than light exposure. Evidence of a typical phototoxic response remained in some animals, but no clear dose response was apparent. Thus, the phototoxic index was indeterminate because of the absence of a clear phototoxic threshold. The authors concluded that the test substance was mildly phototoxic (at 16% and 33% concentrations), but that some other reaction unrelated to light exposure was of greater significance. Phototoxicity was not observed at lower concentrations. 8-MOP concentrations of 0.01% and 0.005%, but not lower concentrations, were phototoxic.

OCULAR IRRITATION STUDIES

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

CLINICAL STUDIES

Case Report

Rosa Centifolia Extract

A non-atopic female patient with a history of polymorphic light eruption presented with a 2-wk history of a rash after use of a rose absolute eau de parfum and a non-scented body lotion containing *Rosa centifolia*.[57] Erythema, papules, and edematous plaques were observed on the neck (only perfume application site), upper chest, arms, shoulders, abdomen, and upper thighs. Patch testing (protocol not stated) was performed using van der Bend chambers, and *Rosa centifolia* (5% in alcohol) and the body lotion induced the following positive reactions: + (on day 2), ++ (on day 4), and + (on day 7). Testing with the eau de parfum did not cause a positive reaction on day 2, but did cause positive reactions on days 4 (+ reaction) and 7 (+ reaction).

Other Clinical Reports

Rosa Centifolia Flower Extract

A clinical evaluation (double-blind study) of a shampoo for seborrheic dermatitis was performed using 3 groups of up to 25 patients with this scalp condition.[58] The composition of the shampoo was as follows: 0.01% *Rosa centifolia* flower extract, 0.005% epigallocatechin gallate, 0.3% zinc pyrithione, and 0.45% climbazole. The study was classified as double-blind, and one group of 24 was treated with the *Rosa centifolia* flower extract shampoo. The other 2 groups were treated with a 2% ketoconazole shampoo (25 patients) and a 1% zinc pyrithione shampoo (23 patients), respectively. All patients in each group were instructed to massage their scalps for at least 5 min with the assigned shampoo. This was followed by rinsing with water 3 times per wk for 4 wk. A clinical severity score was determined at 2 and 4 wk after shampoo use. Irritation was assessed using a questionnaire, and photographs were taken using a folliscope. In all groups, the clinical severity score improved statistically significantly ($p < 0.05$) relative to baseline at wks 2 and 4. However, the changes in the clinical severity score at weeks 2 and 4 did not differ statistically significantly between the 3 groups ($p = 0.39$ and $p = 0.63$, respectively). The changes in clinical severity subscores (i.e., for erythema, dandruff, and lesion extent) at weeks 2 and 4 did not differ statistically significantly between the 3 groups. Irritation did not differ statistically significantly between the 3 groups ($p = 0.63$). Of the 11 patients who complained of irritation, 9 reported pruritus and 4 reported erythema. These reactions were identified as mild, and the distribution of reactions among the groups was not stated.

Rosa centifolia

A randomized, placebo-controlled aromatherapy trial was performed.[59] In the experimental group of 25 female subjects, treatment involved massage into abdominal skin (for 15 min after topical application) of a botanical mixture consisting of *Lavandula officinalis* (lavender, 2 drops), *Salvia sclarea* (clary sage, 1 drop), and *Rosa centifolia* (rose, 1 drop) in 5 ml of almond oil. The subjects reported no treatment-related side effects.

SUMMARY

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

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

According to 2022 VCRP data, Rosa Centifolia Flower Extract has the greatest frequency of use; it is reported to be used in 174 cosmetic products (150 leave-on, 23 rinse-off, and 1 diluted for bath use). The results of a concentration of use survey conducted by the Council in 2021 indicate that Rosa Centifolia Flower Water is has the highest concentration of use; it is used at maximum use concentrations up to 0.096%.

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

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

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

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

The short-term (28-d) oral toxicity of Rosa Centifolia Flower Extract (ethanol extract) was evaluated using groups of 8 male Wistar rats. When compared to the saline control group, no toxicologically relevant findings were observed after dosing with Rosa Centifolia Flower Extract.

The anti-mutagenicity of aqueous extracts of petals from different cultivars ("passion," "pink noblesse," and "sphinx") of *Rosa centifolia* was studied using the *E. coli rpo* B-based $Rif^S \rightarrow Rif^R$ forward mutation assay against ethyl methanesulfonate-induced mutagenesis. The cell suspension was mixed with *Rosa centifolia* flower extract (aqueous extract) and ethyl methanesulfonate (133 mM). Aqueous extracts of rose petals of the 3 cultivars, "passion," "pink noblesse," and "sphinx" (1.5 mg/ml), resulted in reduction in the ethyl methanesulfonate mutation frequency by 55%, 19%, and 4%, respectively.

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

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

A face mask containing Rosa Centifolia Flower was not a sensitizer in a maximization study using SLS pretreatment, and a Rosa Centifolia Flower Extract trade name mixture (20% in solution) was not a sensitizer in an HRIPT involving 55 subjects.[27,56] Multiple maximization studies with SLS pretreatment were performed with Rosa Centifolia Flower Oil. In most studies, the test substance (tested at 2% in one study; concentration tested not stated in most) was not an irritant or a sensitizer. However, in one maximization study, Rosa Centifolia Flower Oil (absolute rose French) produced sensitization in 17 of 25 subjects, and in another, it induced contact sensitization (mild reaction) in 1 of 25 subjects.

Rosa Centifolia Flower Oil (rose centifolia concrete) was strongly phototoxic at the highest concentration tested (33% in benzene) in a study using groups of 6 male hairless mice (*Skh:hairless-1*); the phototoxic index was 0.75. In another phototoxicity study, Rosa Centifolia Flower Oil (rose Bulgare concrete) was mildly phototoxic at 16% and 33%, and the phototoxic response (not strongly dose-related) was apparently superimposed on the irritant background. In most cases, the reaction was localized to the light-exposed area, but had the appearance of multiple petechiae, rather than the confluent edema or erythema normally observed. The reaction was first observed prior to irradiation.

A non-atopic female patient presented with a rash after use of a non-scented body lotion containing *Rosa centifolia.* Patch testing with *Rosa centifolia* (5% in alcohol) and the body lotion induced the following positive reactions: + (on day 2), ++ (on day 4), and + (on day 7).

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

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

DISCUSSION

To be developed.

CONCLUSION

To be determined.

TABLES

Table 1. Definitions and functions of the ingredients in this safety assessment.[1]

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

Table 2. Chemical properties

Property	Value/Results	Reference
Rosa Centifolia Bud Extract		
Form	Solid or liquid; appearance is related to components of the extract	20
Solubility	Solubility is related to components of extract and solvent used for extraction	20
Rosa Centifolia Callus Culture Extract		
Form	Solid or liquid; appearance is related to components of the extract	21
Solubility	Solubility is related to components of extract and solvent used for extraction	21
Rosa Centifolia Extract		
Form	Yellowish to light-brown viscous liquid	18
Rosa Centifolia Flower Extract		
Form	Solid or liquid; appearance is related to components of the extract	22
Solubility	Solubility is related to components of extract and solvent used for extraction	22
Rosa Centifolia Flower Extract (trade mixture)		
Form (at 20°C)	translucent solution with possibly a slight precipitate (brown orange color)	26
Density (at 20°C)	1.053 – 1.065	26
Refractive index (at 20°C)	1.412 – 1.423	26
Solubility	Miscible in water and alcohol (50% v/v); immiscible in mineral oils and vegetable oils	26
Flash point	≥ 100°C	24
Rosa Centifolia Flower Juice (trade mixture)		
Form (20°C)	liquid to opalescent liquid with an orange to brown color	29
Density (at 20°C)	1.130 – 1.150	29
Refractive index (at 20°C)	1.390 – 1.410	29
Solubility	Miscible in water and alcohol (50% v/v); immiscible in mineral oils and vegetable oils	29
Rosa Centifolia Flower Oil		
Form	Colorless or yellow liquid	23
Solubility	Miscible with chloroform	23
Specific gravity (at 30º C/15º C)	Between 0.848 and 0.863	23
Refractive index (at 30º C)	Between 1.457 and 1.463	23
Rosa Centifolia Flower Oil (rose absolute French)		
UV absorption peak (nm)	320 (shoulder)	5
Rosa Centifolia Flower Water (trade name material)		
Form (at 20°C)	Colorless, transparent liquid.	38
Density (at 20°C)	0.999 – 1.002	38
Refractive index (at 20°C)	1.332 – 1.339	38
Solubility	Miscible in water and alcohol (50% v/v) and immiscible in mineral oils and vegetable oils; soluble in propylene glycol	38,39
Rosa Centifolia Flower Wax		
Form	Solid	19
Solubility	Insoluble in water	19

Table 3. Chemical composition of *Rosa centifolia*

Constituents	Concentration
Essential Oil	
α-pinene	not stated.[16]
β-phenethyl alcohol	0.09%.[35]
β-pinene	not stated.[16]
cis-rose oxide	0.07%.[35]
citral	not stated.[16]
citronellol	1200 ppm.[16]
citronellol	9.22%.[35]
n-eicosane C_{20}	0.55%.[35]
eugenol	0.74%.[35]
farnesol	3.48%.[35]
geranic acid	not stated.[16]
geraniol	17.60%.[35]
geraniol aldehyde	not stated.[16]
n-heneicosane C_{21}	6.31%.[35]
n-heptacosane C_{27}	1.79%.[35]
n-heptadecane	1.07%.[35]
limonene	0.05%.[35]
linalool	1.03%.[35]
methyl eugenol	0.56%.[35]
myrcene	not stated.[16]
nerol	4.36%.[35]
n-nonadecane C_{19}	8.10%.[35]
nonadecene $C_{19:1}$	2.28%.[35]
n-pentacosane C_{25}	2.86%.[35]
trans-rose oxide	0.04%.[35]
n-tricosane C_{23}	5.90%.[35]
Flower	
cyanin	not stated.[16]
EO (undefined)	2000 ppm.[16]
eusupinin A	not stated.[34]
gallic acid	not stated.[16]
malic acid	not stated.[16]
methionine sulfoxide	not stated.[16]
pectin	not stated.[16]
quercitrin	not stated.[16]
resin	not stated.[16]
rugosin A	not stated.[34]
rugosin B	not stated.[34]
rugosin D	not stated.[34]
saponin	13,000 ppm.[16]
shisonin-A	not stated.[16]
sugar	not stated.[16]
tannins	100,000 to 240,000 ppm.[16]
tartaric acid	not stated.[16]
tellimagrandin I	not stated.[34]
wax	not stated.[16]
Leaf	
saponin (in leaf)	85,000 ppm[16]
Whole plant (main volatile constituents)	
citronellol	not stated[18]
geraniol	not stated[18]
phenethyl alcohol	not stated[18]
Whole plant (constituent levels potentially present)	
citral	< 8 ppm.[38]
citronellol	< 250 ppm.[29]
citronellol	< 100 ppm.[38]
eugenol	< 6 ppm.[38]
geraniol	< 250 ppm.[29]
geraniol	< 150 ppm.[38]
farnesol	< 4 ppm.[38]

Table 4. Frequency (2022) and concentration (2021) of use according to duration and type of exposure.[40,41]

	# of Uses	Max Conc of Use (%)	# of Uses	Max Conc of Use (%)	# of Uses	Max Conc of Use (%)
	Rosa Centifolia Flower		Rosa Centifolia Flower Extract		Rosa Centifolia Flower Juice	
Totals*	**14**	**NR**	**174**	**0.0001-0.025**	**1**	**NR**
Duration of Use						
Leave-On	*6*	*NR*	*150*	*0.0001-0.025*	*1*	*NR*
Rinse-Off	*2*	*NR*	*23*	*0.0001-0.002*	*NR*	*NR*
Diluted for (Bath) Use	*6*	*NR*	*1*	*0.0001-0.002*	*NR*	*NR*
Exposure Type						
Eye Area	NR	NR	5	0.0005-0.02	NR	NR
Incidental Ingestion	NR	NR	7	0.002	NR	NR
Incidental Inhalation-Spray	4[a]; 2[b]	NR	5; 50[a]; 71[b]	0.0005-0.025; 0.01[b]	1[a]	NR
Incidental Inhalation-Powder	4[a]	NR	50[a]; 1[c]	0.0001; 0.00013-0.002[c]	1[a]	NR
Dermal Contact	13	NR	158	0.0001-0.025	1	NR
Deodorant (underarm)	NR	NR	NR	NR	NR	NR
Hair - Non-Coloring	NR	NR	9	0.001-0.002	NR	NR
Hair-Coloring	NR	NR	NR	NR	NR	NR
Nail	NR	NR	NR	NR	NR	NR
Mucous Membrane	7	NR	11	0.0001-0.002	NR	NR
Baby Products	NR	NR	1	NR	NR	NR

	Rosa Centifolia Flower Oil		Rosa Centifolia Flower Powder		Rosa Centifolia Flower Water	
Totals*	**25**	**0.001-0.002**	**5**	**NR**	**99**	**0.0000096-0.096**
Duration of Use						
Leave-On	*17*	*0.001-0.002*	*3*	*NR*	78	*0.000096-0.096*
Rinse Off	*6*	*NR*	*1*	*NR*	21	*0.0000096-0.023*
Diluted for (Bath) Use	*2*	*NR*	*1*	*NR*	NR	*0.0048*
Exposure Type						
Eye Area	NR	NR	NR	NR	10	NR
Incidental Ingestion	1	0.001	NR	NR	3	NR
Incidental Inhalation-Spray	4[a]; 8[b]	NR	2[a];1[b]	NR	1; 30[a]; 33[b]	0.00096; 0.00096[b]
Incidental Inhalation-Powder	4[a]	0.001-0.002[c]	2[a]	NR	30[a]	0.096[c]
Dermal Contact	20	0.001-0.002	5	NR	93	0.0000096-0.096
Deodorant (underarm)	NR	NR	NR	NR	NR	NR
Hair - Non-Coloring	3	NR	NR	NR	2	0.00096-0.023
Hair-Coloring	NR	NR	NR	NR	NR	0.0096
Nail	NR	NR	NR	NR	NR	NR
Mucous Membrane	5	0.001	1	NR	10	0.0048
Baby Products	NR	NR	NR	NR	NR	NR

	Rosa Centifolia Flower Wax	
Totals*	**10**	**NR**
Duration of Use		
Leave-On	*9*	*NR*
Rinse Off	*1*	*NR*
Diluted for (Bath) Use	*NR*	*NR*
Exposure Type		
Eye Area	1	NR
Incidental Ingestion	3	NR
Incidental Inhalation-Spray	3[a]; 1[b]	NR
Incidental Inhalation-Powder	3[a]	NR
Dermal Contact	6	NR
Deodorant (underarm)	NR	NR
Hair - Non-Coloring	NR	NR
Hair-Coloring	NR	NR
Nail	NR	NR
Mucous Membrane	4	NR
Baby Products	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]Not specified that these products are sprays or powders, but it is possible the use can be as a spray or powder, therefore the information is captured in both categories
[b]It is possible that these products may be sprays, but it is not specified whether the reported uses are sprays
[c]It is possible that these products may be powders, but it is not specified whether the reported uses are powders
NR = Not Reported

Table 5. *Rosa centifolia*-derived ingredients with no reported uses.[40]

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

Table 6. Dermal irritation and sensitization studies

Test Article	Concentration/Dose	Test Population	Procedure	Results	Reference
			ANIMAL		
Irritation					
Rosa Centifolia Flower Oil	Undiluted	Rabbits (number and strain not stated)	Applied for 24 h to intact or abraded skin using occlusive patches. Additional study details not included	Test substance classified as moderately irritating to the skin	[4]
Rosa Centifolia Flower Oil	Undiluted	Hairless mice (number and strain not stated)	Applied to the back for an unspecified duration. Additional study details not included	No evidence of skin irritation	[4]
			HUMAN		
Irritation					
Face mask containing 0.8% Rosa Centifolia Flower	Undiluted	20 subjects	Product applied, under occlusive patch, for 24 h. Irritation scores determined at time of patch removal	No evidence of skin irritation	[54]
Rosa Centifolia Flower Oil	2% in petrolatum	number of subjects not stated	48-h closed patch test	No evidence of skin irritation	[4]
Sensitization					
Face mask containing 0.8% Rosa Centifolia Flower	tested neat	25 subjects (20 females, 5 males)	Product (0.05 ml) applied, under occlusive dressing (15 mm cotton cloth secured with occlusive tape), to SLS (0.25%) pretreated site on upper outer arm or back. Procedure involved five 48-h induction periods, followed by 7-10 d non-treatment period. Test substance, 0.05 ml under a single challenge patch (secured with occlusive tape), applied for 48 h to new skin site on opposite outer arm or opposite side of back. Challenge site evaluated for reactions at time of patch removal and 24 h later	No adverse or unexpected reactions during induction phase. No evidence of contact allergy at time of challenge patch removal or 24 later. Concluded that product does not possess a detectable contact-sensitizing potential and, hence, is not likely to cause contact sensitivity reactions under normal use conditions	[54]
Rosa Centifolia Flower Extract trade name mixture	20% in solution	55 subjects (45 females, 10 males)	HRIPT (modified Shelanski method). Total of 9 induction patches (occlusive patches) applied over 3-wk period. Induction phase followed by 10- to 21-day non-treatment period. Occlusive challenge patch applied to new site on lower back.	No dermal reactions observed during induction or challenge phase. Test substance did not induce delayed contact sensitization	[27,56]
Rosa Centifolia Flower Oil	2% in petrolatum	24 subjects	Maximization test. Protocol details not included	No evidence of skin sensitization	[4]
Rosa Centifolia Flower Oil (absolute rose French)	Concentration not stated	25 subjects	Maximization test. Test substance applied, under occlusion, to volar forearm of each subject for 5 alternate-day 48-h periods. Application sites pretreated for 24 h with 5% aqueous SLS under occlusion. Challenge sites evaluated at time of patch removal and 24 h later. Additional protocol details not included	Sixteen cases of sensitization (all 2+ reactions, very strong sensitization) and 1 case of sensitization (1+ reaction, mild sensitization)	[11]
Rosa Centifolia Flower Oil (concrete rose Bulgare)	Concentration not stated	28 subjects	Maximization test. Test substance applied, under occlusion, to volar aspect of forearm for 5 alternate-day 48-h periods. Test site pretreated for 24 h with 5% aqueous SLS (under occlusion). After 10- to 14-day non-treatment period, challenge phase. Single challenge application preceded by 30-min application of SLS (under occlusion). Another challenge application (different site, no pretreatment) also made	Moderate degree of irritation observed at SLS-treated site. No other significant or allergic reactions observed.	[8]

Table 6. Dermal irritation and sensitization studies

Test Article	Concentration/Dose	Test Population	Procedure	Results	Reference
Rosa Centifolia Flower Oil (concrete rose maroc)	Concentration not stated	25 subjects	Modified maximization test procedure. Test substance applied, under occlusion, to volar aspect of forearm for 5 alternate 48-h periods. Initial patch test site pretreated for 24 h with 5% aqueous SLS (under occlusion). After 10- to 14-day non-treatment period, test substance (under occlusive challenge patch) applied for 48 h to new test site. Challenge applications preceded by 30-min application of 5% aqueous SLS (under occlusion). Additional challenge site not pretreated with SLS.	Approximately 1/3 of subjects tested developed irritation at SLS-treated site. No other significant irritation or allergic reactions observed. Test substance produced no reactions that were considered significantly irritating or allergic in nature	[12]
Rosa Centifolia Flower Oil (concrete rose turque)	Concentration not stated	22 subjects	Modified maximization test procedure. The test substance applied, under occlusion, to volar aspect of forearm for 5 alternate 48-h periods. Initial patch test site pretreated for 24 h with 5% aqueous SLS (under occlusion). After 10- to 14-day non-treatment period, test substance, under occlusive challenge patch, applied for 48 h to new test site. Challenge applications preceded by 30-min application of 5% aqueous SLS (under occlusion). Additional challenge site not pretreated with SLS.	Test substance produced no reactions that were considered significantly irritating or allergic in nature	[13]
Rosa Centifolia Flower Oil (rose centifolia concrete)	Concentration not stated	33 subjects	Modified maximization test procedure. Test substance applied, under occlusion, to volar aspect of forearm for 5 alternate 48-h periods. Initial patch test site pretreated for 24 h with 5% aqueous SLS (under occlusion). After 10- to 14-day non-treatment period, test substance, under occlusive challenge patch, applied for 48 h to new test site. Challenge applications preceded by 30-min application of 5% aqueous SLS (under occlusion). Additional challenge site not pretreated with SLS.	Sweat retention response observed in 1 subject. Test substance produced no reactions that were considered significantly irritating or allergic in nature	[14]
Rosa Centifolia Flower Oil (rose de Mai absolute)	Concentration not stated	24 subjects	Modified maximization test procedure. Test substance applied, under occlusion, to volar aspect of forearm for 5 alternate 48-h periods. Initial test site pretreated for 24 h with 5% aqueous SLS (under occlusion). After 10- to 14-day non-treatment period, test substance, under occlusive challenge patch, applied for 48 h to new test site. Challenge applications preceded by 30-min application of 2% aqueous SLS (under occlusion). Additional challenge site not pretreated with SLS.	A 3+ reaction observed in 1 subject after initial patch application. Retesting of subject did not yield positive reaction. Test substance did not induce skin sensitization	[15]
Rosa Centifolia Flower Oil (rose absolute French)	Concentration not stated	25 subjects	Maximization test. Test substance applied, under occlusion, to volar forearm for 5 alternate-day 48-h periods. Patch test sites pretreated for 24 h with 5% aqueous SLS (under occlusion). After 10-day non-treatment period, test substance, under occlusive challenge patch, applied for 48 h to new test site. Challenge applications preceded by 1-h application of 10% aqueous SLS (under occlusion). Challenge sites evaluated at time of patch removal and 24 h later.	Test substance induced contact sensitization (mild reaction) in 1 subject. Statement to the effect that test substance unlikely to present danger of contact sensitization during normal, intended use	[7]

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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: June 2, 2021

SUBJECT: *Rosa centifolia*-Derived Ingredients

CEP-Solabia Group. 2015. Manufacturing process Glycolysat® of Rose UP (Rosa Centifolia Flower Extract).

CEP-Solabia Group. 2015. Specifications data sheet Glycolysat® of Rose UP (Rosa Centifolia Flower Extract).

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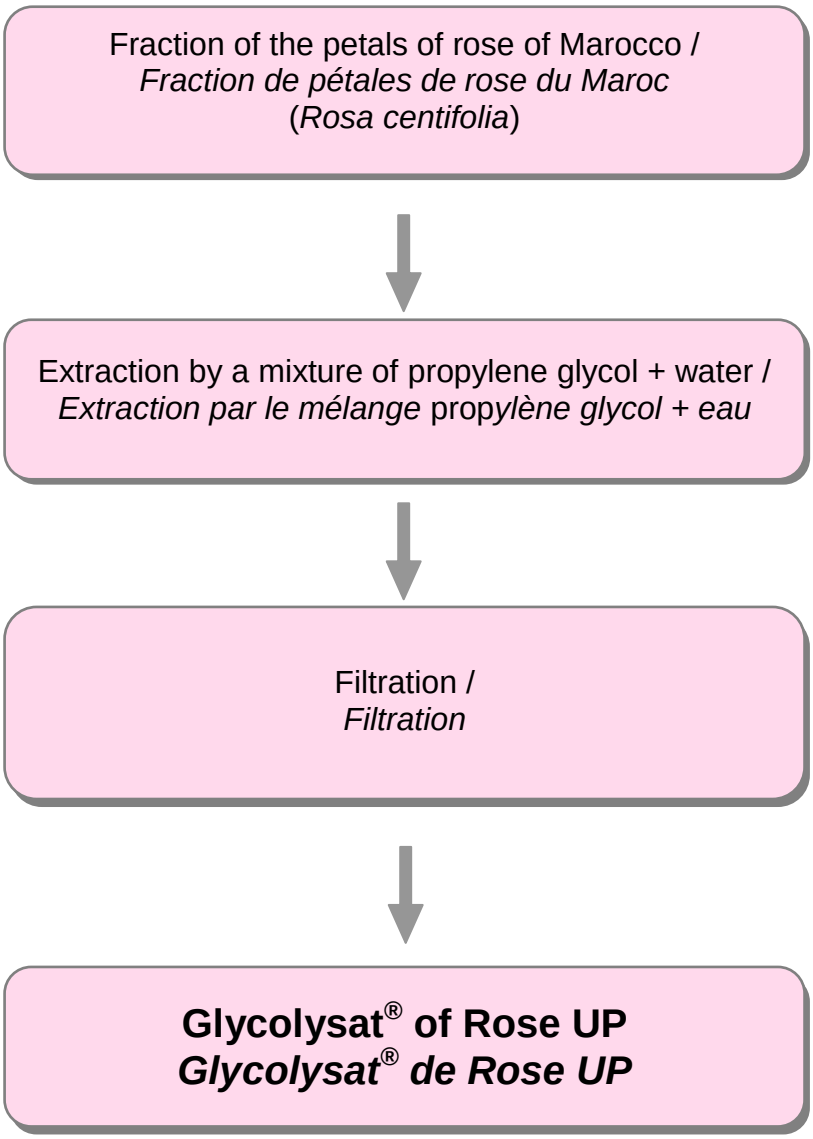
MANUFACTURING PROCESS
PROCEDE DE FABRICATION

Glycolysat® of Rose UP
Glycolysat® de Rose UP

Ref. FG521



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SPECIFICATIONS DATA SHEET

Glycolysat® of Rose UP

Ref. FG521

DEFINITION

Glycolysat® of Rose UP is a hydroglycolic extract prepared from the petals of rose (*Rosa centifolia*). 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*	FG521KC - can of 5 Kg FG521KE - can of 20 Kg

ORGANOLEPTIC CHARACTERISTICS

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

ANALYTICAL CHARACTERISTICS

• **pH**	4.2 – 5.2
• **Refractive index at 20°C**	1.412 – 1.423
• **Density at 20°C**	1.053 – 1.065
• **Dry extract**	2.8% – 3.8%

MICROBIOLOGICAL CHARACTERISTICS

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

Glycolysat® of Rose 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 / Rosa centifolia extract	
• **CTFA**	Propylene glycol (and) Water (and) Rosa centifolia flower extract	
• **CAS**	Propylene glycol	57-55-6
	Aqua	7732-18-5
	Rosa centifolia extract	84604-12-6
• **EINECS**	Propylene glycol	200-338-0
	Aqua	231-791-2
	Rosa centifolia extract	283-289-8

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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 Rose UP

Ref. FG521

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

- **Commercial name** — Glycolysat® of Rose UP
- **Recommended used** — Cosmetic
- **Supplier** — CEP – SOLABIA Group
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  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 / Rosa centifolia extract ; unpreserved
- **CAS**

Propylene glycol	57-55-6
Aqua	7732-18-5
Rosa centifolia extract	84604-12-6

- **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 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 orange
- **Odor** — characteristic
- **pH** (state on delivery) — 4.2 – 5.2
- **Flash point** — $\geq$ 100°C
- **Explosion characteristics** — not available
- **Density at 20°C** — 1.053 – 1.065
- **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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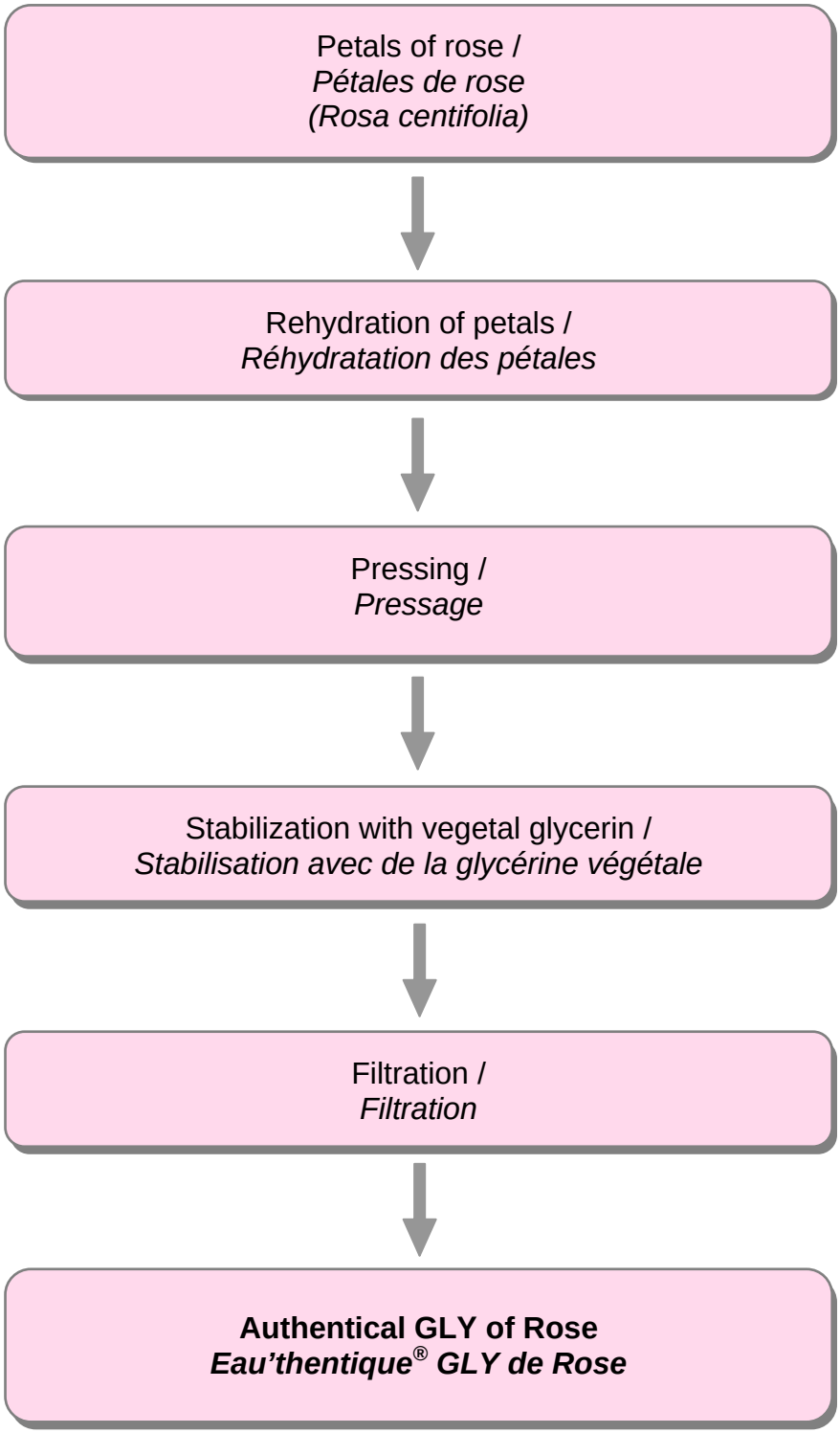
MANUFACTURING PROCESS
PROCEDE DE FABRICATION

Authentical GLY of Rose
Eau'thentique® GLY de Rose

Ref. FJ506



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SPECIFICATIONS DATA SHEET

Authentical GLY of Rose

Ref. FJ506

DEFINITION

Authentical GLY of Rose is a vegetal juice 100% pure plant, stabilized with glycerin, obtained from the selected petals of cabbage rose *(Rosa centifolia),* cold pressed without using any solvents.

PRESENTATION

• **Sample**	plastic opaque flask - 125 mL
• **Code / Packaging** *to be mentioned with your order*	FJ506KC - can 5 kg FJ506KE - can 20 kg

ORGANOLEPTIC CHARACTERISTICS

• **Appearance**	limpid to opalescent liquid
• **Color**	orange to brown
• **Odor**	characteristic of rose

ANALYTICAL CHARACTERISTICS *(Values subject to modification according to the next productions)*

• **pH**	4.0 – 6.0
• **Density**	1.130 – 1.150
• **Refractive index**	1.390 – 1.410

MICROBIOLOGICAL CHARACTERISTICS

• **Total aerobic mesophilic micro-organisms** *according USP*	≤ 100 C.F.U./g

Authentical GLY of Rose

Additional Analysis

- **Allergenic substances study**: a bibliographical study on *Rosa centifolia* revealed the presence in the plant of geraniol (< 250 ppm) and citronellol (< 250 ppm). The other allergenic substances as listed in the 7th amendment of the European Cosmetic Directive have not been found in the plant bibliography.

Solubilities (10% diluted)

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

Storage and use

Shelf life	3 years in closed original packaging
Preservative system	0.2% potassium sorbate
Storage conditions	store at room temperature, away from light
Use conditions	mix before use if necessary

Legislative Information

INCI	Glycerin / Rosa centifolia flower juice	
CTFA	Glycerin (and) Rosa centifolia flower juice	
CAS	Glycerin	56-81-5
	Rosa centifolia flower juice	999999-99-4
EINECS	Glycerin	200-289-5
	Rosa centifolia flower juice	310-127-6
Other regulation status	authorized in Japan	

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SAFETY DATA SHEET

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

Authentical GLY of Rose

Ref. FJ506

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

- **Commercial name** — Authentical GLY of Rose
- **Recommended used** — Cosmetic
- **Supplier** — CEP – SOLABIA Group
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  info.fds@solabia.fr

II. IDENTIFICATION OF THE DANGERS

- **Human health hazards** MODIFICATION — Might be harmful in case of accidental ingestion.
  Might cause a slight temporary irritation to eyes
- **Environment hazards** — none currently known under normal conditions of use
- **Physico-chemical hazards** — none currently known under normal conditions of use

III. COMPOSITION / INFORMATION ON THE INGREDIENTS

- **Designation** — Glycerin / Rosa centifolia flower juice ;
  preserved with 0.2% potassium sorbate
- **CAS**
  Glycerin 56-81-5
  Rosa centifolia flower juice 999999-99-4
- **Hazardous components** — none

IV. FIRST AIDS PROCEDURE MODIFICATION

- **Inhalation** — Not concerned
- **Ingestion** — Do not induce vomiting. Consult a doctor
- **Skin contact** — Wash skin with plenty of water and soap
- **Eye contact** — Rinse 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 MODIFICATION

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

VII. MANIPULATION AND STORAGE MODIFICATION

- **Manipulation** — wear protective clothing, goggles and gloves
- **Storage conditions** — store at room temperature, protected from light and moisture
- **Recommended packaging materials** — no restriction currently known

VIII. CONTROL OF EXPOSURE / INDIVIDUAL PROTECTION

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

IX. PHYSICAL AND CHEMICAL CHARACTERISTICS

• **Physical state at 20°C**	limpid to opalescent liquid	
• **Color**	orange to brown	
• **Odor**	characteristic	
• **pH** (state on delivery)	4.0 – 6.0	
• **Flash point**	not available	
• **Explosion characteristics**	not available	
• **Density at 20°C**	1.130 – 1.150	
• **Solubility**	water	soluble
	alcohol 50% v/v	soluble
	mineral / vegetal oils	non miscible

X. STABILITY AND REACTIVITY MODIFICATION

- **Stability** — stable in storing conditions mentioned on § VII
- **Conditions to avoid** — none currently known
- **Materials to avoid** — strong oxidizing agents, alkali, halogens
- **Hazardous decomposition products** — production of acrolein at high temperature > 280°C

XI. TOXICOLOGICAL INFORMATION

- **Acute toxicity** — no available data
- **Local effects** — no available data

XII. ECOLOGICAL INFORMATION MODIFICATION

- **Ecotoxicity** — biodegradable product (biodegradability ≈ 99.8%)

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

- Not classified as hazardous - 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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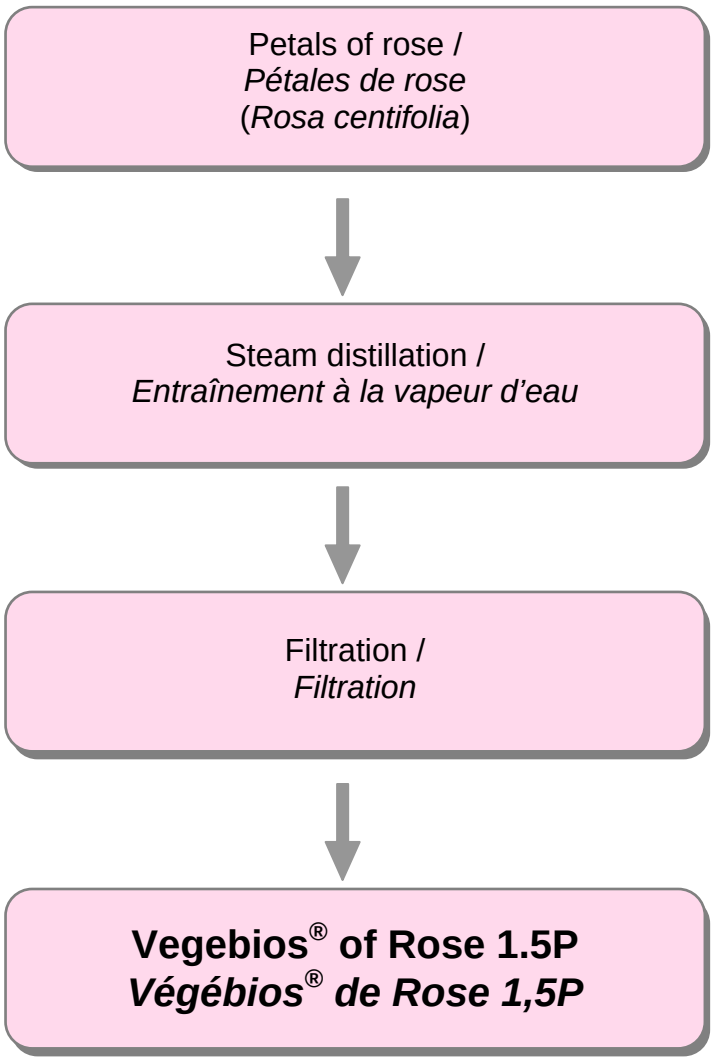
MANUFACTURING PROCESS
PROCEDE DE FABRICATION

Vegebios® of Rose 1.5P
Végébios® de Rose 1,5P

Ref. FV541



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SPECIFICATIONS DATA SHEET

Vegebios® of Rose 1.5P

Ref. FV541

DEFINITION

Vegebios® of Rose 1.5P is an aqueous extract obtained by steam distillation of rose petals (*Rosa centifolia*).

PRESENTATION

• **Sample**	plastic flask - 125 mL
• **Code / Packaging** *to be mentioned with your order*	FV541KC – can 5 kg FV541KE – can 20 kg

ORGANOLEPTIC CHARACTERISTICS

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

ANALYTICAL CHARACTERISTICS

• **pH** MODIFICATION	4.0 - 7.2
• **Refractive index at 20°C**	1.332 – 1.339
• **Density at 20°C**	0.999 – 1.002

MICROBIOLOGICAL CHARACTERISTICS

• **Total aerobic mesophilic micro-organisms** *according USP*	≤ 100 C.F.U./g

Vegebios® of Rose 1.5P

Additional Analysis

- **Allergenic substances study**: a bibliographical study on realized *Rosa centifolia* revealed the potential presence of citral (< 8 ppm), citronellol (< 100 ppm), eugenol (< 6 ppm), geraniol (< 150 ppm) and farnesol (< 4 ppm) in the plant. The other allergenic substances listed in the 7th amendment of the European Cosmetic Directive are not mentioned in the bibliography of the petals of rose.

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**	Rosa centifolia water
• **CTFA**	Rosa centifolia flower water
• **CAS**	84604-12-6
• **EINECS**	283-289-8

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Vegebios® of Rose 1.5P

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) - Annex II

Date of issue: 01/06/2015 Revision date: : Version: 1.0

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

1.1. Product identifier

Product form : Mixture

Trade name : Vegebios® of Rose 1.5P

Name : Rosa centifolia water; Preserved with 1.5% phenoxyethanol

Product code : FV541

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

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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]
Rosa centifolia water	(CAS No) 84604-12-6 (EC no) 283-289-8	98,5	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

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	: 4,0 - 7,2 (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: 4,0 - 7,2 (in the state of delivery)

Serious eye damage/irritation : Not classified
No data available
pH: 4,0 - 7,2 (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

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: June 16, 2021

SUBJECT: Rosa Centifolia Flower Extract and Rosa Centifolia Flower Water

Anonymous. 2021. Rosa Centifolia Flower Extract as Rose Extract BG and Rosa Centifolia Flower Water as Rose Water D.

June 2021

Rosa Centifolia Flower Extract as Rose Extract BG
Rosa Centifolia Flower Water as Rose Water D

chemical characterization and method of manufacture data, specific to use in cosmetic formulations;

Trade name	The chemical characterization
Rose Extract BG	<Composition> Flavonoid and tannin
Rose Water D	<Composition> β-phenylethyl alcohol and geraniol

Trade name	The method of manufacture
Rose Extract BG	Dried raw material⇒extract with hot water⇒filtrate ⇒concentration⇒dissolve in 50vol% 1,3-butylene glycolic solution ⇒sedimentation⇒filtrate⇒adjustment⇒packaging
Rose Water D	Dried raw material⇒steam distillation⇒obtain the water-soluble fraction⇒add ethanol (15vol%)⇒filtrate⇒packaging

skin irritation and sensitization data at maximum reported use concentrations

Trade name	Test Item	Concentration of test solution	Result	Method
Rose Extract BG	Human skin sensitization test (Repeated Insult Patch Test)	20%	Mild material, Not induce delayed contact sensitization	Modified Shelanski Method 55 subjects
Rose Water D	No data			

Testing facility: Clinical Research Laboratories, Inc.

Concentration of Use by FDA Product Category – *Rosa centifolia* -Derived Ingredients*

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

Ingredient	Product Category	Maximum Concentration of Use
Rosa Centifolia Flower Extract	Bubble baths	0.0001%
Rosa Centifolia Flower Extract	Other bath preparations	0.002%
Rosa Centifolia Flower Extract	Eye lotions	0.0005%
Rosa Centifolia Flower Extract	Mascaras	0.02%
Rosa Centifolia Flower Extract	Colognes and toilet waters	0.0005-0.025%
Rosa Centifolia Flower Extract	Other fragrance preparations Spray	0.025%
Rosa Centifolia Flower Extract	Hair conditioners	0.001%
Rosa Centifolia Flower Extract	Shampoos (noncoloring)	0.001-0.002%
Rosa Centifolia Flower Extract	Face powders	0.0001%
Rosa Centifolia Flower Extract	Foundations	0.0001%
Rosa Centifolia Flower Extract	Lipstick	0.002%
Rosa Centifolia Flower Extract	Bath soaps and detergents	0.0001-0.001%
Rosa Centifolia Flower Extract	Other personal cleanliness products	0.0001%
Rosa Centifolia Flower Extract	Skin cleansing (cold creams, cleansing lotions, liquids, and pads)	0.002%
Rosa Centifolia Flower Extract	Face and neck products Not spray	0.00013-0.002%
Rosa Centifolia Flower Extract	Body and hand products Not spray	0.001-0.002%
Rosa Centifolia Flower Extract	Moisturizing products Not spray	0.001%
Rosa Centifolia Flower Extract	Skin fresheners	0.01%
Rosa Centifolia Flower Extract	Other skin care preparations	0.01%
Rosa Centifolia Flower Oil	Lipstick	0.001%
Rosa Centifolia Flower Oil	Face and neck products Not spray	0.002%
Rosa Centifolia Flower Oil	Body and hand products Not spray	0.001%
Rosa Centifolia Flower Oil	Moisturizing products Not spray	0.002%
Rosa Centifolia Flower Oil	Other skin care preparations	0.001%
Rosa Centifolia Flower Water	Bath oils, tablets, and salts	0.0048%
Rosa Centifolia Flower Water	Hair conditioners	0.023%
Rosa Centifolia Flower Water	Hair sprays Aerosol	0.00096%

Rosa Centifolia Flower Water	Shampoos (noncoloring)	0.0096%
Rosa Centifolia Flower Water	Tonics, dressings, and other hair grooming aids	0.00096%
Rosa Centifolia Flower Water	Hair dyes and colors	0.0096%
Rosa Centifolia Flower Water	Skin cleansing (cold creams, cleansing lotions, liquids, and pads)	0.0000096%
Rosa Centifolia Flower Water	Face and neck products Not spray	0.096%
Rosa Centifolia Flower Water	Body and hand products Not spray	0.096%
Rosa Centifolia Flower Water	Moisturizing products Not spray	0.096%
Rosa Centifolia Flower Water	Night products Not spray	0.000096%
Rosa Centifolia Flower Water	Other skin care preparations	0.02%

*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 2021
Table prepared: June 23, 2021

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: May 11, 2021

SUBJECT: Rosa Centifolia Flower

Anonymous. 2011. An evaluation of the contact sensitization potential of a topical coded products in human skin by means of the maximization assay (face mask contains 0.8% Rosa Centifolia Flower).

Anonymous. 2011. Clinical evaluation report: Human patch test (test material contains 0.8% Rosa Centifolia Flower).

Di[redacted]

FINAL REPORT dated July 27, 2011

[redacted] Protocol: #7302

Sample: Face Mask coded [redacted]

[redacted]

Title: An Evaluation of the Contact-Sensitization Potential of a Topical Coded Product in Human Skin by means of the Maximization Assay

product contains 0.8% Rosa Centifolia Flower

Sponsor: [redacted]

[redacted] Submission Form dated June 1, 2011

Principal Investigator: [redacted] (Board Certified Dermatologist)

Testing Facility: [redacted]

[redacted] **M.D.**
Principal Investigator

July 27, 2011
Date

[redacted]

FINAL REPORT

STUDY TITLE:

An assessment of the contact-sensitizing potential of a coded topically-applied test agent using a Human Maximization Assay.

[redacted] PROTOCOL:

[redacted] Protocol #**7302**

GUIDELINES FOR THE CONDUCT OF THE STUDY:

All procedures were conducted in compliance with the regulations of the Food and Drug Administration (FDA) (21 CFR 50, 56, 312) ICH-GCP Consolidated Guidelines, May 9, 1997 Federal Register) and in accordance with [redacted]'s Standard Operating Procedures (SOP's).

STUDY OBJECTIVE:

The objective of this study was to assess the skin sensitizing potential of any preparation designed for topical use by means of the Maximization Test (see references #1 and #2).

DESIGN RATIONALE:

A repeat insult patch test wherein the test product was applied under an occlusive dressing to an SLS (sodium lauryl sulfate) pre-treated site on the upper outer arm or back repeatedly to the same designated area for five 48-hour induction periods followed 7-10 days later by a single challenge to a naïve skin site on the opposite outer arm or the opposite side of the back.

STUDY SPONSOR:

[redacted]

SPONSOR STUDY:

[redacted] Submission Form dated June 1, 2011

TESTING FACILITY:

[redacted]

PRINCIPAL INVESTIGATOR:

[redacted], M.D. (Board Certified Dermatologist)

Medical Director, [redacted]

[redacted]

[redacted] ADMINISTRATIVE STRUCTURE:

[redacted] (Panel Recruitment/Initial Screening)

[redacted] (Technician /Patch Applications/Removals/Recognize/Report AE's)

[redacted] (Evaluator)

[redacted] (Quality Assurance)

INFORMED CONSENT:

Prior to acceptance into the study, each subject was informed by the Investigator or his designee of the nature and purpose of the study, possible side-effects and any other relevant information. The study procedures and possible risks and discomfort were explained to each panelist during the interview using popular understandable language and terms, and the panelists were encouraged to ask questions regarding the study. Each interviewed panelist who qualified was then asked to read and sign the consent form prior to enrollment. Copies of all consent forms are on file at [redacted].

CONDUCTION DATES:

This study was conducted between June 6, 2011 through July 8, 2011.

TEST MATERIAL:

The test product, supplied by the sponsor, was labeled Face Mask and coded [redacted]. One jar was supplied. The test product was tested as supplied viz. neat.

TEST PRODUCT ACCOUNTABILITY:

The test sample was received in good condition by our Quality Assurance Department. The test material was checked for (1) amount (2) product number or code (3) material container etc. The material was individually listed on a special sheet (drug/test product log form) signed by the receiver, the laboratory supervisor and the investigator (physician). The test sample was stored under ambient conditions in an inaccessible location under the supervision of the investigator.

DISPOSITION OF REMAINING CLINICAL SUPPLIES:

All remaining test material(s) will be disposed of in accordance with applicable governmental regulations following completion of the study and submission of the final written report to the Sponsor.

PANEL COMPOSITION:

Healthy, adult volunteers over the age of 18 years were recruited for this study. Panelists had no blemishes, excess hair or other marks on their upper outer arms or back that would obscure grading of the test site. Both male and female panelists were eligible. None of the subjects had a medical or dermatological illness and none were sensitive to sunscreens or to topical preparations and/or cosmetics. A completed subject was a subject who satisfied the admission criteria and who completed the scheduled study procedures.

Inclusion Criteria:

1. Healthy adult male and female volunteers between the ages of 18 and 65 years.
2. All subjects who were willing to follow the study requirements and voluntarily gave their informed consent.

Exclusion Criteria:

1. Subjects with any significant internal diseases e.g., cardiac, pulmonary, renal, hepatic, etc.
2. History of allergy or hypersensitivity to cosmetics, toiletries or other dermatological products
3. History of recurrent dermatological diseases, e.g., psoriasis, atopic eczema, chronic urticaria
4. Pregnancy or mothers who are breastfeeding or planning a pregnancy
5. Scars, moles or other blemishes over the upper arm(s) or back which can interfere with the study
6. Subjects receiving systemic or topical drugs or medications which can interfere with delayed immunologic responses e.g., corticosteroids, non-steroidal anti-inflammatories, retinoids, immunosuppressants
7. Other conditions considered by the investigator as sound reasons for disqualification from enrollment into the study

SUBJECT ASSIGNMENT:

Volunteer subjects were screened and selected as described above and assigned a study number. The initials of each subject accepted into the study were recorded sequentially as they were enrolled.

RECORDING OF DATA:

The case report forms (CRF's) for this study were provided by the Investigator. All case report forms were completed in actual time, during each subject's visit. Copies of the CRF's will be retained by the investigator along with the original signed informed consent forms.

HANDLING OF STUDY DOCUMENTS:

All study related documents, case report forms (CRF's), original informed subject consent forms and any data generated were kept under secure lock in the technician's office for the duration of the study.

STUDY PROCEDURES:

Method and Procedures[1,2]

Patches were applied to the upper outer arm or back of each subject. The entire test was composed of three distinct phases: (1) an Induction phase and (2) a Rest Phase and (3) a Challenge phase.

(1) **Induction Phase**:

Approximately 0.05ml of aqueous SLS (0.25%) was applied to a designated site under a 15mm disc of Webril cotton cloth and the patch was fastened to the skin with occlusive tape for a period of 24 hours. After 24 hours, the SLS patch was removed and 0.05ml of the test material was applied to the same site before the site was again covered with occlusive tape (induction patch). The induction patch was left in place for 48 hours (or for 72 hours when placed over a weekend) following which it was removed and the site again examined for irritation. If no irritation was present, a 0.25% aqueous SLS patch was again reapplied to the same site for 24 hours, followed by reapplication of a fresh induction patch with the test material to the same site. This sequence viz. 24 hour SLS pre-treatment followed by 48 hours of test material application was continued for a total of 5 induction exposures.

If irritation developed at any time-point during the induction phase as previously outlined, the 24-hour SLS pre-treatment patch was eliminated and only the test material was reapplied to the same site after a 24-hour rest period during which no patch was applied.

The aim during this phase of the study was to maintain at least a minimal degree of irritation in order to enhance penetration through the corneum barrier.

(2) **Rest Period**:

No exposure to the test material was made during this rest period, which lasted for 10-14 days after the last induction patch.

(3) **Challenge Phase**:

After a 10-14 day rest period, the subjects were challenged with a single application of the test material to a new skin site on the opposite upper outer arm or opposite side of the back in order to determine if sensitization had developed.

Pre-treatment with SLS was performed prior to challenge. Approximately 0.05ml of a 5.0% aqueous solution was applied to a fresh skin site under a 15mm disc of Webril cotton and covered with occlusive tape. The SLS patch was left in place for one hour. It was then removed and 0.05ml of the test material was applied to the same site, as outlined above. The challenge patch was then covered by occlusive tape and left in place for 48 hours. After that period, the patch was removed and the site graded, and again 24 hours later for any reactions.

SCORING SCALE:

0 = not sensitized

1 = mild sensitization (viz. erythema and a little edema)

2 = moderate sensitization (erythema with infiltration, raised, spreading beyond the borders of the patch, with or without vesiculation)

3 = strong sensitization (large vesiculo-bullous reaction).

Based on these findings the number of subjects with positive responses were tabulated for the test material. The test system shown below was used to classify the allergenic potential of the test substance.

SENSITIZATION RATES:	**GRADES:**	**CLASSIFICATION**:
0 - 2/25	1	Weak
3 - 7/25	2	Mild
8 - 13/25	3	Moderate
14 - 20/25	4	Strong
21 - 25/25	5	Extreme

ADVERSE EXPERIENCES:

No adverse experiences or unanticipated reactions were encountered or reported by any of the panelists.

RESULTS:

A total of twenty-six (26) healthy, adult, male and female volunteers who satisfied the inclusion criteria were enrolled into this study. There were 21 females and 5 males. Their ages ranged from 21 to 65 years. One subject #11 (initials L-A, a female) failed to maintain the scheduled study visits and was lost to follow-up. She was subsequently dropped from the study for lack of compliance. The remaining 25 volunteers completed this investigation, as outlined in the standard protocol. The demographic data are shown in Table 1. No adverse or unexpected reactions were seen in any of the panelists during the induction phase.

The results of the challenge are shown in the enclosed table (Table 2). No instances of contact allergy were recorded at either 48 or 72 hours after the application of the challenge patches.

CONCLUSION:

Under the conditions of this test, the test sample labeled Face Mask and coded [redacted] does not possess a detectable contact-sensitizing potential and hence is not likely to cause contact sensitivity reactions under normal use conditions.

References:

(1) Kligman, A.M.: The Maximization Test. J.I.D., Vol. 47, No. 5, pp. 393-409, 1966.

(2) Kligman, A.M. and Epstein W.: Updating the Maximization Test for Identifying Contact Allergens. Contact Dermatitis. Vol. 1, 231-239, 1975.

TABLE 1

DEMOGRAPHIC DATA

Subject Number:	Subject Initials:	Age:	Sex:	Race:
01	M-D	56	F	A
02	C-W	47	F	B
03	W-W	54	M	C
04	P-P	42	F	C
05	E-S	45	F	C
06	N-H	54	F	B
07	T-R	48	M	C
08	L-M	42	F	C
09	S-D	50	F	C
10	R-R	65	F	B
11	L-A	42	F	C
12	J-A	60	F	C
13	P-S	57	M	C
14	M-D	21	M	C
15	B-D	50	F	C
16	M-B	41	M	C
17	S-C	30	F	C
18	A-W	48	F	C
19	A-C	35	F	C
20	L-P	56	F	C
21	D-H	38	F	C
22	C-R	54	F	C
23	D-S	49	F	C
24	P-D	56	F	C
25	R-S	54	F	C
26	R-C	56	F	C

A = Asian
B = Black
C = Caucasian

TABLE 2

MAXIMIZATION TESTING RESULTS

Sample: Face Mask coded [redacted] (tested as supplied)

Subject Number:	48-Hour Grading	72-Hour Grading
01	0	0
02	0	0
03	0	0
04	0	0
05	0	0
06	0	0
07	0	0
08	0	0
09	0	0
10	0	0
11	-	-
12	0	0
13	0	0
14	0	0
15	0	0
16	0	0
17	0	0
18	0	0
19	0	0
20	0	0
21	0	0
22	0	0
23	0	0
24	0	0
25	0	0
26	0	0

Challenge Readings:

48-Hour Reading – July 7, 2011
72-Hour Reading – July 8, 2011

[redacted] [redacted]

CLINICAL EVALUATION REPORT: HUMAN PATCH TEST

This test follows the procedure described in SOP, HPT.1 **TO:** [redacted]

PRODUCT PROFILE NO: [redacted] DATE: June 1, 2011 LAB REF.: [redacted]-2300-11

1. TEST MATERIAL: Naturals Rose Petal Face Mask F#[redacted] contains 0.8% Rosa Centifolia Flower

2. CONTROL MATERIAL: PS Goji Berry Face Mask F#[redacted]

3. TEST PROCEDURE:

Single-Insult (24hr.) __X__ Occlusive (Blenderm) Patch __X__ Semi-Occlusive Patch_____.

4. CONCENTRATION:

Full-Strength __X__ Aqueous _____ Solution _____ Dispersion_____ Aqueous Paste_____.
Other:_____.

_____Volatiles were allowed to evaporate prior to occlusion on the patch.
_____Patch was hydrated just prior to application to skin.

5. TEST RESULTS:

TEST MATERIAL	*SUBJECTS*	*IRRITATION SCORE**									
		0	±	1	1+	2	2+	3	3+	4	PII
Naturals Rose Petal Face Mask F#[redacted]	20	20	0	0	0	0	0	0	0	0	0.00
PS Goji Berry Face Mask F#[redacted]	20	20	0	0	0	0	0	0	0	0	0.00

___ Skin staining noted. Erythematous response was read "through" the Stain.

6. CONCLUSIONS:

A. There were no significant differences in irritancy observed between the Test Material (s) and the Reference Control (s). __X__.

B. _____.
_____.
_____.
_____.

Study Conducted By: [redacted]. Approved By: [redacted]

* SCORE
0 = No evidence of any effect.
± (Barely Perceptible) = minimal faint uniform or spotty erythema
1 (Mild) = Pink uniform erythema covering most of the contact site.
2 (Moderate) = Pink-red erythema visibly uniform in entire contact area.
3 (Marked) = Bright red erythema with accompanying edema petechiae or papules.
4 (Severe) = Deep red erythema with vesiculation or weeping with or without edema.

+, 1+, 2+ and 3+ = Intermediate scores contributing 0.5, 1.5, 2.5 and 3.5 respectively, to the P.I.I.
P.I.I. - Primary Irritation Index - a value depicting the average skin response of the test panel as a whole. It is calculated by choosing the higher of the two Irritation Scores per panelist, adding them all together and dividing by the total number of test subjects.

CC:

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: August 4, 2021

SUBJECT: Rosa Centifolia Flower Extract

Anonymous. 2021. Additional Summary Information for HRIPT on Rosa Centifolia Flower Extract as Rose Extract BG with Individual Data (original study summary provided to CIR June 16, 2021, with memo 4)

August 2021

Additional Summary Information for HRIPT on Rosa Centifolia Flower Extract as Rose Extract BG with Individual Data (original summary provided to CIR June 16, 2021, with memo 4)

Fifty-six subjects were selected for the study: 1 subject discontinued study participation for reasons unrelated to the test material. Fifty-five subjects, age 20-70 (10 males, 45 females) completed the study.

Occlusive patches were used (9 induction patches over a 3-week period; after a 10-21 day rest period a challenge patch was applied for 24 hours to a new site on the lower back).

No dermal reactions were observed during either the induction or challenge phases of the study.

CLINICAL
RESEARCH
LABORATORIES

Table I - Summary of Dermal Scores

Test Material:	ROSE EXTRACT BG, Lot No. 80340707

Subject Number	Induction Scores									Challenge Scores		
	1	2	3	4	5	6	7	8	9	24 Hour	48 Hour	72 Hour
1	0	0	0	0	0	0	0	0	0	0	0	0
2	0	0	0	0	0	0	0	0	0	0	0	0
3	0	0	0	0	0	0	0	0	0	0	0	0
4	0	0	0	0	0	0	0	0	0	0	0	0
5	0	0	0	0	0	0	0	0	0	0	0	0
6	0	0	0	0	0	0	0	0	0	0	0	0
7	0	0	0	0	0	0	0	0	0	X	0	0*
8	0	0	0	0	0	0	0	0	0	0	0	0
9	0	0	0	0	0	0	0	0	X	0	0	0
10	0	0	0	0	0	0	0	0	0	0	0	0
11	0	0	0	0	0	0	0	0	0	0	0	0
12	0	0	0	0	0	0	0	0	0	0	0	0
13	0	0	0	0	0	0	0	0	0	0	0	0
14	0	0	0	0	0	0	0	0	0	0	X	0*
15	0	0	0	0	0	0	0	0	0	0	0	0
16	0	0	0	0	0	0	0	0	0	0	0	0
17	0	0	0	0	0	0	0	0	0	0	0	0
18	0	0	0	0	0	0	0	0	0	0	0	0
19	0	0	0	0	0	0	0	0	0	0	0	0
20	0	0	0	0	0	0	0	0	0	0	0	0
21	0	0	0	0	0	0	0	0	0	0	0	0
22	0	0	0	0	0	0	0	0	0	0	0	0
23	0	0	0	0	0	0	0	0	0	0	0	0
24	0	0	0	0	0	0	0	0	0	0	0	0
25	0	0	0	0	0	0	0	0	0	0	0	0
26	0	0	0	0	0	0	0	0	0	0	0	0
27	0	0	0	0	0	0	0	0	0	0	0	0
28	0	0	0	0	0	0	0	0	0	0	0	0

*No reaction was observed at the 96 hour evaluation.

CLINICAL RESEARCH LABORATORIES

Table I - Summary of Dermal Scores (continued)

Test Material:	ROSE EXTRACT BG, Lot No. 80340707

Subject Number	Induction Scores									Challenge Scores		
	1	2	3	4	5	6	7	8	9	24 Hour	48 Hour	72 Hour
29	0	0	0	0	0	0	0	0	0	0	0	0
30	0	0	0	0	0	0	0	0	0	0	0	0
31	Discontinued											
32	0	0	0	0	0	0	0	0	0	0	0	0
33	0	0	0	0	0	0	0	0	0	0	0	0
34	0	0	0	0	0	0	0	0	0	0	0	0
35	0	0	0	0	0	0	0	0	0	0	0	0
36	0	0	0	0	0	0	0	0	0	0	0	0
37	0	0	0	0	0	0	0	0	0	0	0	0
38	0	0	0	0	0	0	0	0	0	0	0	0
39	0	0	0	0	0	0	0	0	0	0	0	0
40	0	0	0	0	0	0	0	0	0	0	0	0
41	0	0	0	0	0	0	0	0	0	X	0	0*
42	0	0	0	0	0	0	0	0	0	0	0	0
43	0	0	0	0	0	0	0	0	0	0	0	0
44	0	0	0	0	0	0	0	0	0	0	0	0
45	0	0	0	0	0	0	0	0	0	0	0	0
46	0	0	0	0	0	0	0	0	X	0	0	0
47	0	0	0	0	0	0	0	0	0	0	0	0
48	0	0	0	0	0	0	0	0	0	0	0	0
49	0	0	0	0	0	0	0	0	0	0	0	0
50	0	0	0	0	0	0	0	0	0	0	0	0
51	0	0	0	0	0	0	0	0	0	0	0	0
52	0	0	0	0	0	0	0	0	0	0	0	0
53	0	0	0	0	0	0	0	0	0	0	0	0
54	0	0	0	0	0	0	0	0	0	0	0	0
55	0	0	0	0	0	0	0	0	0	0	0	0
56	0	0	0	0	0	0	0	0	0	0	0	0

*No reaction was observed at the 96 hour evaluation.

2036
07/18

TEMPLE UNIVERSITY
HEALTH SCIENCES CENTER
SCHOOL OF MEDICINE
PHILADELPHIA, PENNSYLVANIA 19140

SKIN AND CANCER HOSPITAL
FREDERICK URBACH, M.D.
PROFESSOR AND CHAIRMAN

AREA CODE 215-221-3924

July 18, 1973

Dr. Donald L. Opdyke, President
Research Institute for Fragrance Materials, Inc.
P.O. Box 1152, 375 Sylvan Avenue
Englewood Cliffs, New Jersey 07632

Dear Don:

The eighth and ninth reports on phototoxicity studies performed on fourteen compounds sent to us recently are enclosed for your information.

The technique was identical to that reported in our previous reports. A table is attached and the results in essence are as follows:

> Thirteen of the fourteen compounds showed no phototoxicity. Compound No. [redacted] had a slight irritant effect and slight phototoxicity response.

Enclosed are the absorption spectra of the compounds tested.

With my best personal regards,

Sincerely,

Frederick Urbach, M.D.

Enclosures

CC: Dr. P. Donald Forbes

/0

TABLE OF BIOLOGIC RESPONSES

RESEARCH REPORT FM-8

	COMPOUND	IRRITATING EFFECT	SKIN STAINING	PHOTOTOXICITY RESPONSE	ABSORPTION PEAK(S) (nm)
1.	[redacted]	--	--	--	270
2.		--	--	--	<250
3.		--	--	--	280
4.		--	--	--	270(shoulder)
5.		--	--	--	235
6.		+	--	+	320
7.		--	+	--	300(shoulder)
8.	Rose Absolute French 72-220	--	--	--	320(shoulder)

QTest
Biological Testing

Federated Medical Resources Building
Beaver Dam Road
Honey Brook, Pennsylvania 19344
(215) 273-2919

September 8, 1980

Donald L. Opdyke, Ph.D.
Research Institute for Fragrance Materials, Inc.
375 Sylvan Avenue
Englewood Cliffs, New Jersey 07632

Dear Dr. Opdyke:

Enclosed is our report #QFM-6 covering dilution assays on five additional materials. As you will note, phototoxicity of [redacted] samples was confirmed; this was sometimes of questionable practical significance because of strong contact irritancy, particularly in the case of [redacted]. Similarly the apparent phototoxicity of Rose Bulgare occurred only at irritating concentrations; irritation in this case had an unusual appearance and distribution. The sample of [redacted] was not phototoxic.

A single material indicated as possibly phototoxic has yet to be tested by dilution assay. Rather than set up a specific test we will incorporate it in available space of other ongoing tests in the near future.

If we can be of further service please let us know.

Yours very truly,

Ronald E. Davies

Ronald E. Davies, Ph.D.

RED:jcd
enclosure

REPORT

#QFM-6

(Our Experiments #Q80-007 & Q80-010)

Title: Dilution Assays of Fragrance Materials

Material Tested: Five Fragrance Materials: [redacted]; Rose Bulgare Concrete 80-24; [redacted]

Investigator: P.D. Forbes
R.E. Davies

Date: Sept 8, 1980

Q-TEST
Federated Medical Resources Building
Beaver Dam Road
Honey Brook, Pennsylvania 19344

Abstract

Dilution assays were carried out on five materials previously reported to produce phototoxic or other light-related responses. Three samples of [redacted] and [redacted] were confirmed as phototoxic. This was associated with non-specific (non-light related) irritancy at high concentrations, but evidence for specifically light-associated damage was unambiguous in at least one dilution of each of the first two. In the case of J[redacted] phototoxicity was seen against a background of irritancy at all levels of positive response. The Phototoxic Indices calculated for these samples were 2.0, 2.5 and 2.0 respectively.

Rose Bulgare Concrete 80-24, like the Jasmins, was irritating at high concentrations, with a phototoxic response, not strongly dose-related, apparently superimposed on the irritant background. Phototoxic Index was indeterminate, however, because of the absence of a clear phototoxic threshold.

[redacted] had previously been described as producing an atypical, mild, apparently light-associated response limited to localized flaking. The dilution assay confirmed the presence of flaking at high concentrations, but the effect was not restricted to the light exposed area. It thus appears that this material produces a low level of contact irritancy but that there is no indication of a specifically phototoxic effect.

Introduction

Materials which have been observed to exhibit phototoxic activity in screening, development or safety tests are compared by serial dilution to dilutions of the reference standard material, 0.01% 8-methoxypsoralen in methanol. Threshold dilutions of reference and standard are considered to be of equal potency.

Methods

Unless special circumstances indicate the need for a different light source, dilution assays are conducted using fluorescent blacklight lamps. Test groups are treated with the level of test material previously shown to be effective, and up to seven serial binary dilutions. Reference groups are treated with 0.01% 8-MOP in methanol, and three serial binary dilutions. Each group consists of six male hairless mice (Skh:hairless-1) 8 ± 1 weeks of age. All other details are identical to specifications in protocol PS-1.

Of the five materials tested only [redacted] was a liquid and thus suitable for direct application; subsequent dilutions were made in methanol. All other compounds were made up as approximately saturated solutions in benzene, with subsequent dilutions in benzene. The two materials (Rose Bulgare Concrete and [redacted]) tested in Experiment Q80-007 were prepared in six concentrations, based on their strong activity in the screening study. Since activity disappeared rapidly on dilution in this and some previous dilution assays, materials tested in Experiment Q80-010 were prepared in only four dilutions; in each case this provided an adequate testing range.

Results and Discussion

Results are summarized in Tables 1 and 2. The three samples of [redacted] were all irritating, producing a background of generalized edema and erythema against which phototoxic responses were often difficult to detect. Least irritating was the [redacted], and at a 10% concentration this compound was unambiguously phototoxic. Similarly [redacted] was strongly irritating at a 25% concentration, but at 12.5% phototoxicity was clearly detectable.

The most severely irritating of these compounds was [redacted], which produced generalized edema in most animals even at a 6.2% concentration; against this background the localized phototoxic response was often obscured, but was detectable often enough to confirm phototoxic activity. The three materials were approximately comparable in Phototoxic Indices, which ranged from 2.0 to 2.5. The potential hazard would presumably be low in the case of the Egypte samples because of limitations imposed by the irritancy.

Rose Bulgare Concrete 80-24 produced an unusual response which had the appearance of a phototoxic reaction. It was localized in most cases to the light exposed area, but had the appearance of multiple petechiae rather than the confluent edema or erythema normally observed. Moreover the response was first seen prior to irradiation. When the mask was removed after irradiation the petechiae were confined to the irradiated area, but because of their prior presence it must be suspected that localization was related to occlusion rather than light exposure. There remained evidence of typical phototoxic response in some animals, but no clear dose response

Results and Discussion (continued)

was apparent and no Phototoxic Index could be calculated. It is concluded that the material was mildly phototoxic, but that some other reaction unrelated to light exposure was of greater significance.

[redacted] was not phototoxic. The localized flaking previously described as an atypical light-associated reaction was again observed, but was not confined to the irradiated area. The response thus appears to be attributable to minimal irritancy rather than photo-toxicity.

Table 1

Experiment Q80-007. Dilution Assay

Group	Test material and concentration	Animals Affected		Interpretation
		Contact Irritancy	Irradiated Area Discernible	
	Rose Bulgare Concrete 80-24			
A	33% in benzene*	6/6**	2/6	Weekly phototoxic
B	16%	6/6	3/6	Weekly phototoxic
C	8.2%	0/6	0/6	Not phototoxic
D	4.1%	0/6	0/6	Not phototoxic
E	2.0%	0/6	0/6	Not phototoxic
F	1.0%	0/6	0/6	Not phototoxic
	[redacted]			
G	25% in benzene***	6/6	4/6	Phototoxic
H	12.5%	6/6	2/6	Weekly phototoxic
I	6.2%	4/6	1/6	Weekly phototoxic
J	3.1%	1/6	0/6	Not phototoxic
K	1.6%	0/6	0/6	Not phototoxic
L	0.8%	0/6	0/6	Not phototoxic
	8-Methoxypsoralen			
M	0.01% in methanol	0/5****	5/5	Phototoxic
N	0.005%	0/6	6/6	Phototoxic
O	0.0025%	0/6	0/6	Not phototoxic
P	0.0012%	0/6	0/6	Not phototoxic

* 648 mg in 1.3 ml benzene
** Abnormal confined reaction. See discussion
*** 650 mg in 1.9 ml benzene
**** One animal died after treatment. No evident pathology.

Table 2

Experiment Q80-010. Dilution Assay

Group	Test material and concentration	Animals Affected		Interpretation
		Contact Irritancy	Irradiated Area Discernible	
	[redacted]			
A	100%	6/6	0/6	Not phototoxic
B		6/6	1/6	Questionable
C		0/6	0/6	Not phototoxic
D		0/5*	0/5	Not phototoxic
	[redacted]			
E	25% in benzene**	6/6	2/6	Phototoxic
F	12.5%	0/6	6/6	Phototoxic
G	6.2%	0/6	1/6	Weekly phototoxic
H	3.1%	0/6	0/6	Not phototoxic
	8-Methoxypsoralen			
I	0.01% in methanol	0/6	6/6	Phototoxic
J	0.005%	0/6	6/6	Phototoxic
K	0.0025%	0/6	6/6	Phototoxic
L	0.0012%	0/6	2/6	Weekly phototoxic
	[redacted]			
M	20% in Benzene***	3/6	6/6	Phototoxic
N	10%	0/6	4/6	Phototoxic
O	5%	0/6	0/6	Not phototoxic
P	2.5%	0/6	0/6	Not phototoxic

* One animal found dead after 1 day. No obvious pathology
** 1 gm in 3 ml benzene
*** 1 gm in 4 ml benzene

SYNOPSIS

OBJECTIVE: To determine the sensitizing potential of:

Group II - 1975
NAK-2-5R(0) Rose de Mai Absolute

SUBJECTS: Thirty healthy inmate volunteers were screened and twenty-four completed the experiment.

METHOD: The materials were pretested on all subjects in order to determine whether sodium lauryl sulfate (SLS) pretreatment was required. A patch of each material was applied to normal sites on the backs for 48 hours under occlusion. No evidence of irritation was observed and all subjects were pretested with 5% SLS.

MAXIMIZATION TEST: (Modified after JID 47:393-409, 1966). The materials were applied under occlusion to the same sites on the volar aspects of the forearms of all subjects for five alternate day 48 hour periods. Patch sites were pre-treated for 24 hours with 5% aqueous SLS under occlusion for the initial patch only. Following a 10-14 day rest period, challenge patches of all materials were applied under occlusion to fresh sites for 48 hours. Challenge applications were preceded by 30 minute applications of 2% aqueous SLS under occlusion on the left side of the back whereas the test materials were applied without SLS treatment on the right side. Additonal SLS controls were placed on the left and petrolatum on the right and labeled site 5. Questionable reactions were biopsied and retests applied one week later at new sites.

RESULTS: Data sheets with final tabulations are enclosed. Subject #28 reacted to all the medications giving 3+ reactions at sites 1 .

Retesting of subject #28 was carried out sequentially, first at sites 1 and upon retesting these sites were completely negative.

CONCLUSION:

preparations NAK-2-5R(0) gave no evidence of sensitization in the twenty-four subjects tested.

Respectfully submitted,

William L. Epstein, M.D.
April 16, 1975

SYNOPSIS

OBJECTIVE: To determine the sensitizing potential of:

GROUP XV - 1980
80-2-24 CONCRETE ROSE BULGARE

SUBJECTS: Thirty-six healthy inmate volunteers were screened and twenty-eight completed the study. During the screening two subjects, numbers 10 and 21, failed because they gave 3 and 4+ reactions at site 4 (80-4-45) presumably due to prior sensitization.

METHOD: The materials were pretested on all subjects in order to determine whether sodium lauryl sulfate (SLS) pretreatment was required. A patch of each material was applied to normal sites on the backs for 48 hours under occlusion. No significant evidence or irritation was observed and all subjects were pretreated with 5% SLS.

MAXIMIZATION PROCEDURE: (Modified after JID 47:393-409, 1966). The materials were applied under occlusion to the same site on the volar aspects of the forearms of all subjects for five alternate-day 48 hour periods. Patch sites were pretreated for 24 hours with 5% aqueous SLS under occlusion for the initial patch only. Following a ten to fourteen day rest period challenge patches of all materials were applied under occlusion to fresh sites for 48 hours. Challenge applications were preceded by 30 minute applications of 5% aqueous SLS under occlusion without SLS treatment on the right side. Additional SLS controls were placed on the left and petrolatum on the right and labeled site 5. The questionable reactions were followed daily and retests applied at new sites two weeks later.

RESULTS: Data sheets with final tabulations are enclosed. In this study there was a moderate degree of irritation at the SLS treated site.

No other significant irritant or allergic reactions were seen.

CONCLUSIONS:

Preparations 80-2-24 produced no reactions or were considered significantly irritant or allergic in the twenty-eight subjects tested.

Respectfully Submitted,

William L. Epstein, M.D.

August 1, 1980

SYNOPSIS

OBJECTIVE: To determine the sensitizing potential of:

Group XVIII-1980
80-2-26 CONCRETE ROSE MAROC

SUBJECTS: Twenty-eight healthy male and female volunteers were screened and twenty-five completed the study.

METHOD: The materials were pretested on all subjects in order to determine whether sodium lauryl sulfate (SLS) pretreatment was required. A patch of each material was applied to normal sites on the backs for 48 hours under occlusion. No significant evidence of irritation was observed and all subjects were pretreated with 5% SLS.

MAXIMIZATION PROCEDURE: (Modified after JID 47:393-409, 1966). The materials were applied under occlusion to the same site on the volar aspects of the forearms of all subjects for five alternate 48 hour periods. Patch sites were pretreated for 24 hours with 5% aqueous SLS under occlusion for the initial patch only. Following a ten to fourteen day rest period, challenge patches of all materials were applied under occlusion to fresh sites for 48 hours. Challenge applications were preceded by 30-minute applications of 5% aqueous SLS under occlusion without SLS treatment on the right side. Additional SLS controls were placed on the left and petrolatum on the right and labeled site 5.

RESULTS: Data sheets with final tabulations are enclosed. In this study approximately one third of the subjects developed some irritation at the SLS treated site. No other significant irritant or allergic reactions were observed.

CONCLUSIONS: Preparations 80-2-26,
produced no reactions that were considered significantly irritant or allergic in the twenty-five subjects tested.

Respectfully submitted,

William L. Epstein, M.D.

WLE/vah

August 26, 1980

SYNOPSIS

OBJECTIVE: To determine the sensitizing potential of:

Group XX-1980
80-2-27 CONCRETE ROSE TURQUE

SUBJECTS: Twenty-six healthy male and female volunteers were screened, and twenty-two completed the study.

METHOD: The materials were pretested on all subjects in order to determine whether sodium lauryl sulfate (SLS) pretreatment was required. A patch of each material was applied to normal sites on the backs for 48 hours under occlusion. No significant evidence of irritation was observed and all subjects were pretreated with 5% SLS.

MAXIMIZATION PROCEDURE: (Modified after JID 47:393-409, 1966). The materials were applied under occlusion to the same site on the volar aspects of the forearms of all subjects for five alternate 48 hour periods. Patch sites were pretreated for 24 hours with 5% aqueous SLS under occlusion for the initial patch only. Following a ten to fourteen day rest period, challenge patches of all materials were applied under occlusion to fresh sites for 48 hours. Challenge applications were preceded by 30-minute applications of 5% aqueous SLS under occlusion without SLS treatment on the right side. Additional SLS controls were placed on the left and petrolatum on the right and labeled site 5.

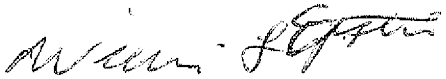
RESULTS: Data sheets with final tabulations are enclosed.

No other significant irritant or allergic reactions were seen.

CONCLUSIONS:

Preparations 80-2-27,
produced no reactions that were considered significantly irritant or allergic in the twenty-two subjects tested.

Respectfully submitted,



William L. Epstein, M.D.

WLE/vah

August 26, 1980

SYNOPSIS

OBJECTIVE: To determine the sensitizing potential of:

GROUP XXVI - 1980
80-2-25 Rose Centifolia Concrete

SUBJECTS: Forty-one healthy inmate volunteers were screened and thirty-three completed the study.

METHOD: The materials were pretested on all subjects in order to determine whether sodium laural sulfate (SLS) pretreatment was required. A patch of each material was applied to normal sites on the backs for 48 hours under occlusion. No significant evidence or irritation was observed and all subjects were pretreated with 5% SLS.

MAXIMIZATION PROCEDURE: (Modified after JID 47:393-409, 1966). The materials were applied under occlusion to the same site on the volar aspects of the forearms of all subjects for five alternate-day 48 hour periods. Patch sites were pretreated for 24 hours with 5% aqueous SLS under occlusion for the initial patch only. Following a ten to fourteen day rest period challenge patches of all materials were applied under occlusion to fresh sites for 48 hours. Challenge applications were preceded by 30 minute applications of 5% aqueous SLS under occlusion without SLS treatment on the right side. Additional SLS controls were placed on the left and petrolatum on the right and labeled site 6. The questionable reactions were followed daily and retests applied at new sites one week later.

RESULTS: Data sheets with final tabulations are enclosed.

In one subject, #32, a sweat retention response was observed at site 1. No other significant reactions were noted.

CONCLUSIONS:

Preparations 80-2-25, produced no reactions that were considered significantly irritant or allergic in the thirty-three subjects tested.

Respectfully submitted,

William L. Epstein

William L. Epstein, M.D.
November 7, 1980

SYNOPSIS

OBJECTIVE: To determine the sensitizing potential of:

GROUP XXVI - 1980
80-2-25 Rose Centifolia Concrete

SUBJECTS: Forty-one healthy inmate volunteers were screened and thirty-three completed the study.

METHOD: The materials were pretested on all subjects in order to determine whether sodium laural sulfate (SLS) pretreatment was required. A patch of each material was applied to normal sites on the backs for 48 hours under occlusion. No significant evidence or irritation was observed and all subjects were pretreated with 5% SLS.

MAXIMIZATION PROCEDURE: (Modified after JID 47:393-409, 1966). The materials were applied under occlusion to the same site on the volar aspects of the forearms of all subjects for five alternate-day 48 hour periods. Patch sites were pretreated for 24 hours with 5% aqueous SLS under occlusion for the initial patch only. Following a ten to fourteen day rest period challenge patches of all materials were applied under occlusion to fresh sites for 48 hours. Challenge applications were preceded by 30 minute applications of 5% aqueous SLS under occlusion without SLS treatment on the right side. Additional SLS controls were placed on the left and petrolatum on the right and labeled site 6. The questionable reactions were followed daily and retests applied at new sites one week later.

RESULTS: Data sheets with final tabulations are enclosed.

In one subject, #32, a sweat retention response was observed at site 1. No other significant reactions were noted.

CONCLUSIONS:

Preparations 80-2-25, produced no reactions that were considered significantly irritant or allergic in the thirty-three subjects tested.

Respectfully submitted,

William L. Epstein

William L. Epstein, M.D.
November 7, 1980

S Y N O P S I S

OBJECTIVE:

To determine the contact-sensitization potential of

RIFM 72-2-220 ROSE ABSOLUTE FRENCH

SUBJECTS:

Twenty-five healthy male inmate volunteers completed the experiment.

METHOD:

Pre-testing - The materials were pre-tested on five subjects in order to determine whether sodium lauryl sulfate pre-treatment was required. A patch of each material was applied to normal sites on the backs for 48 hours under occlusion. No subject had any irritation from these materials and it was decided to use SLS pre-treatment in the test.

Maximization Test (J.I.D., Vol. 47, No. 5; 1966; 393-409) - The materials were applied under occlusion to the same sites on the volar forearms of all subjects for five alternate-day 48-hour periods. The patch sites were pre-treated for 24 hours with 5% aqueous sodium lauryl sulfate under occlusion. Following a ten-day rest period, challenge patches of all materials were applied under occlusion to fresh sites for 48 hours. Challenge applications were preceded by one-hour applications of 10% aqueous sodium lauryl sulfate under occlusion. The challenge sites were read on removal of the patch and 24 hours thereafter.

RESULTS:

Individual subject data and results are found in the tables.

CONCLUSIONS:

RIFM 72-2-220 produced contact-sensitization in one subject, and RIFM 73-7-32 produced contact-sensitization in three subjects on the Maximization Test. Both of these materials must be considered mild sensitizers.

RIFM 73-8-09 and RIFM 72-4-197 produced no instances of contact-sensitization on the Maximization test.

It is unlikely that these two materials would present a danger of contact-sensitization in normal, intended use.

Respectfully submitted,

Albert M. Kligman, M.D., Ph.D.
October 31, 1973

SYNOPSIS

OBJECTIVE:

To determine the contact-sensitizing potential of:
RIFM 74-2-118R(1) Absolute Rose French

SUBJECTS:

Twenty-five healthy adult volunteers completed the experiment.

METHOD:

Pre-Testing: The materials were pre-tested on five subjects in order to determine whether sodium lauryl sulfate pre-treatment was required. A patch of each material was applied to normal sites on the backs for 48 hours under occlusion. No subject had any irritation from these materials and it was decided to use SLS pre-treatment in the test.

Maximization Test (J.I.D.; Vol. 47; No. 5; 393-409; 1966): The materials were applied under occlusion to the same sites on the volar forearms of all subjects for five alternate-day 48 hour periods. The patch sites were pre-treated for 24 hours with 5% aqueous sodium lauryl sulfate under occlusion. The challenge sites were read on removal of the patch and 24 hours thereafter.

RESULTS:

Individual subject data and results are found in the Tables.

CONCLUSIONS:

produced 16 cases of sensitization to a degree of 2+ and should be considered a very strong sensitizer. produced 1 case of sensitization to a degree of 1+ and should be considered a possible mild sensitizer. RIFM 74-2-118R(1) and produced no instances of contact-sensitization and therefore it is unlikely that these materials would present a danger of contact-sensitization in normal, intended use.

Respectfully submitted,

Albert M. Kligman, M.D., Ph.D.
June 4, 1974
AMK/bls

2036
07/18

TEMPLE UNIVERSITY
HEALTH SCIENCES CENTER
SCHOOL OF MEDICINE
PHILADELPHIA, PENNSYLVANIA 19140

SKIN AND CANCER HOSPITAL
FREDERICK URBACH, M.D.
PROFESSOR AND CHAIRMAN

AREA CODE 215-221-3924

July 18, 1973

Dr. Donald L. Opdyke, President
Research Institute for Fragrance Materials, Inc.
P.O. Box 1152, 375 Sylvan Avenue
Englewood Cliffs, New Jersey 07632

Dear Don:

The eighth and ninth reports on phototoxicity studies performed on fourteen compounds sent to us recently are enclosed for your information.

The technique was identical to that reported in our previous reports. A table is attached and the results in essence are as follows:

> Thirteen of the fourteen compounds showed no phototoxicity. Compound No. [redacted] had a slight irritant effect and slight phototoxicity response.

Enclosed are the absorption spectra of the compounds tested.

With my best personal regards,

Sincerely,

Frederick Urbach, M.D.

Enclosures

CC: Dr. P. Donald Forbes

/0

TABLE OF BIOLOGIC RESPONSES

RESEARCH REPORT FM-8

	COMPOUND	IRRITATING EFFECT	SKIN STAINING	PHOTOTOXICITY RESPONSE	ABSORPTION PEAK(S) (nm)
1.	[redacted]	--	--	--	270
2.		--	--	--	<250
3.		--	--	--	280
4.		--	--	--	270(shoulder)
5.		--	--	--	235
6.		+	--	+	320
7.		--	+	--	300(shoulder)
8.	Rose Absolute French 72-220	--	--	--	320(shoulder)

2022 FDA-VCRP Data-Rosa Centifolia

ROSA CENTIFOLIA (CABBAGE ROSE) FLOWER	02A	Bath Oils, Tablets, and Salts	4
ROSA CENTIFOLIA (CABBAGE ROSE) FLOWER	02D	Other Bath Preparations	2
ROSA CENTIFOLIA (CABBAGE ROSE) FLOWER	10C	Douches	1
ROSA CENTIFOLIA (CABBAGE ROSE) FLOWER	12C	Face and Neck (exc shave)	4
ROSA CENTIFOLIA (CABBAGE ROSE) FLOWER	12F	Moisturizing	2
ROSA CENTIFOLIA (CABBAGE ROSE) FLOWER	12H	Paste Masks (mud packs)	1

Total 14

ROSA CENTIFOLIA (CABBAGE ROSE) FLOWER EXTRACT	01B	Baby Lotions, Oils, Powders, and Creams	1
ROSA CENTIFOLIA (CABBAGE ROSE) FLOWER EXTRACT	02B	Bubble Baths	1
ROSA CENTIFOLIA (CABBAGE ROSE) FLOWER EXTRACT	03D	Eye Lotion	2
ROSA CENTIFOLIA (CABBAGE ROSE) FLOWER EXTRACT	03E	Eye Makeup Remover	1
ROSA CENTIFOLIA (CABBAGE ROSE) FLOWER EXTRACT	03G	Other Eye Makeup Preparations	2
ROSA CENTIFOLIA (CABBAGE ROSE) FLOWER EXTRACT	04B	Perfumes	1
ROSA CENTIFOLIA (CABBAGE ROSE) FLOWER EXTRACT	04E	Other Fragrance Preparation	4
ROSA CENTIFOLIA (CABBAGE ROSE) FLOWER EXTRACT	05A	Hair Conditioner	4
ROSA CENTIFOLIA (CABBAGE ROSE) FLOWER EXTRACT	05F	Shampoos (non-coloring)	3
ROSA CENTIFOLIA (CABBAGE ROSE) FLOWER EXTRACT	05G	Tonics, Dressings, and Other Hair Grooming Aids	1
ROSA CENTIFOLIA (CABBAGE ROSE) FLOWER EXTRACT	05I	Other Hair Preparations	1
ROSA CENTIFOLIA (CABBAGE ROSE) FLOWER EXTRACT	07E	Lipstick	7
ROSA CENTIFOLIA (CABBAGE ROSE) FLOWER EXTRACT	07F	Makeup Bases	2
ROSA CENTIFOLIA (CABBAGE ROSE) FLOWER EXTRACT	07I	Other Makeup Preparations	1
ROSA CENTIFOLIA (CABBAGE ROSE) FLOWER EXTRACT	10A	Bath Soaps and Detergents	3
ROSA CENTIFOLIA (CABBAGE ROSE) FLOWER EXTRACT	12A	Cleansing	8
ROSA CENTIFOLIA (CABBAGE ROSE) FLOWER EXTRACT	12C	Face and Neck (exc shave)	35
ROSA CENTIFOLIA (CABBAGE ROSE) FLOWER EXTRACT	12D	Body and Hand (exc shave)	15
ROSA CENTIFOLIA (CABBAGE ROSE) FLOWER EXTRACT	12F	Moisturizing	65
ROSA CENTIFOLIA (CABBAGE ROSE) FLOWER EXTRACT	12H	Paste Masks (mud packs)	4
ROSA CENTIFOLIA (CABBAGE ROSE) FLOWER EXTRACT	12I	Skin Fresheners	5
ROSA CENTIFOLIA (CABBAGE ROSE) FLOWER EXTRACT	12J	Other Skin Care Preps	8

Total 174

CENTIFOLIA (CABBAGE ROSE) FLOWER JUICE	12C	Face and Neck (exc shave)	1

Total 1

ROSA CENTIFOLIA (CABBAGE ROSE) FLOWER OIL	02A	Bath Oils, Tablets, and Salts	2
ROSA CENTIFOLIA (CABBAGE ROSE) FLOWER OIL	05A	Hair Conditioner	1
ROSA CENTIFOLIA (CABBAGE ROSE) FLOWER OIL	05E	Rinses (non-coloring)	1
ROSA CENTIFOLIA (CABBAGE ROSE) FLOWER OIL	05F	Shampoos (non-coloring)	1
ROSA CENTIFOLIA (CABBAGE ROSE) FLOWER OIL	07E	Lipstick	1
ROSA CENTIFOLIA (CABBAGE ROSE) FLOWER OIL	10A	Bath Soaps and Detergents	1
ROSA CENTIFOLIA (CABBAGE ROSE) FLOWER OIL	10C	Douches	1
ROSA CENTIFOLIA (CABBAGE ROSE) FLOWER OIL	12A	Cleansing	1
ROSA CENTIFOLIA (CABBAGE ROSE) FLOWER OIL	12C	Face and Neck (exc shave)	2
ROSA CENTIFOLIA (CABBAGE ROSE) FLOWER OIL	12D	Body and Hand (exc shave)	2

ROSA CENTIFOLIA (CABBAGE ROSE) FLOWER OIL	12F	Moisturizing	7
ROSA CENTIFOLIA (CABBAGE ROSE) FLOWER OIL	12H	Paste Masks (mud packs)	1
ROSA CENTIFOLIA (CABBAGE ROSE) FLOWER OIL	12J	Other Skin Care Preps	4
Total 25			

ROSA CENTIFOLIA (CABBAGE ROSE) FLOWER POWDER	02A	Bath Oils, Tablets, and Salts	1
ROSA CENTIFOLIA (CABBAGE ROSE) FLOWER POWDER	12C	Face and Neck (exc shave)	1
ROSA CENTIFOLIA (CABBAGE ROSE) FLOWER POWDER	12D	Body and Hand (exc shave)	1
ROSA CENTIFOLIA (CABBAGE ROSE) FLOWER POWDER	12F	Moisturizing	1
ROSA CENTIFOLIA (CABBAGE ROSE) FLOWER POWDER	12H	Paste Masks (mud packs)	1

Total 5

ROSA CENTIFOLIA (CABBAGE ROSE) FLOWER WATER	03D	Eye Lotion	1
ROSA CENTIFOLIA (CABBAGE ROSE) FLOWER WATER	03E	Eye Makeup Remover	4
ROSA CENTIFOLIA (CABBAGE ROSE) FLOWER WATER	03G	Other Eye Makeup Preparations	5
ROSA CENTIFOLIA (CABBAGE ROSE) FLOWER WATER	04E	Other Fragrance Preparation	1
ROSA CENTIFOLIA (CABBAGE ROSE) FLOWER WATER	05A	Hair Conditioner	1
ROSA CENTIFOLIA (CABBAGE ROSE) FLOWER WATER	05F	Shampoos (non-coloring)	1
ROSA CENTIFOLIA (CABBAGE ROSE) FLOWER WATER	07E	Lipstick	3
ROSA CENTIFOLIA (CABBAGE ROSE) FLOWER WATER	10A	Bath Soaps and Detergents	5
ROSA CENTIFOLIA (CABBAGE ROSE) FLOWER WATER	10C	Douches	1
ROSA CENTIFOLIA (CABBAGE ROSE) FLOWER WATER	10E	Other Personal Cleanliness Products	1
ROSA CENTIFOLIA (CABBAGE ROSE) FLOWER WATER	12A	Cleansing	7
ROSA CENTIFOLIA (CABBAGE ROSE) FLOWER WATER	12C	Face and Neck (exc shave)	25
ROSA CENTIFOLIA (CABBAGE ROSE) FLOWER WATER	12D	Body and Hand (exc shave)	5
ROSA CENTIFOLIA (CABBAGE ROSE) FLOWER WATER	12F	Moisturizing	23
ROSA CENTIFOLIA (CABBAGE ROSE) FLOWER WATER	12G	Night	3
ROSA CENTIFOLIA (CABBAGE ROSE) FLOWER WATER	12H	Paste Masks (mud packs)	1
ROSA CENTIFOLIA (CABBAGE ROSE) FLOWER WATER	12I	Skin Fresheners	7
ROSA CENTIFOLIA (CABBAGE ROSE) FLOWER WATER	12J	Other Skin Care Preps	5

Total 99

ROSA CENTIFOLIA (CABBAGE ROSE) FLOWER WAX	03F	Mascara	1
ROSA CENTIFOLIA (CABBAGE ROSE) FLOWER WAX	07E	Lipstick	3
ROSA CENTIFOLIA (CABBAGE ROSE) FLOWER WAX	10A	Bath Soaps and Detergents	1
ROSA CENTIFOLIA (CABBAGE ROSE) FLOWER WAX	12C	Face and Neck (exc shave)	1
ROSA CENTIFOLIA (CABBAGE ROSE) FLOWER WAX	12D	Body and Hand (exc shave)	2
ROSA CENTIFOLIA (CABBAGE ROSE) FLOWER WAX	12F	Moisturizing	1
ROSA CENTIFOLIA (CABBAGE ROSE) FLOWER WAX	12J	Other Skin Care Preps	1

Total 10