Cosmetic Product Safety Report

Client : BenQ Materials (Wuhu) Corp.
Address : No.106 Huajin Nan Road, High-tech Development Zone, Yiiang District, Wuhu City.Anhui Province, P.R.China.

Description of the submitted sample(s):

Sample Name	:	SPOT PATCHES (FOR DAYTIME/9 PCS)
Sample Quantity	:	1 Document
Style / Item No.	:	Not Provided
Product Reference	:	Not Provided
Type of Product	:	Leave on
Labeled Age Grading	:	Adult
Physical Form	:	Solid
Mass or Volume	:	9 pcs
Buyer	:	Not Provided
Vendor	:	Not Provided
Manufacturer	:	BenQ Materials (Wuhu) Corp.
Destination	:	EU
Country of Origin	:	China
Sample Received Date	:	2025.01.10
Sample Reported Date	:	2025.02.21
Test Requested	:	EU Cosmetic Product Safety Report (EU CPSR)
Test Result(s)	:	Please refer to the following page(s).

EXECUTIVE SUMMARY

The sample(s) COMPLY with the following requirement(s):

- The product safety requirements of the EU Cosmetic Regulation (EC) No 1223/2009 and its amendments. The product must be manufactured according to Good Manufacturing Practice.

Note: The Cosmetic Product Safety Report was performed at a Centre Testing International Group Co., Ltd. approved subcontract lab.

For and on behalf of
Centre Testing International Group Co., Ltd.

Judy Zhu
Technical Manager of SFC

TEST RESULTS:

Cosmetic Product Safety Report

SPOT PATCHES (FOR DAYTIME/9 PCS)

CONCLUSIONS & RECOMMENDATIONS

Safety Labelling

Based on the overall safety assessment of the formulation, no warning phrases are required to be labelled.

Overall Safety & Compliance

Under normal or reasonably foreseeable conditions of use, a product made to this formulation is unlikely to produce an abnormally high number of adverse reactions. The product will give consumers the level of safety they can reasonably expect.

This product complies with the requirements of the EU Cosmetic Regulation (EC) No 1223/2009. The product must be manufactured according to Good Manufacturing Practice.

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QUANTITATIVE & QUALITATIVE COMPOSITION

This formulation is an overview of the composition, listing only the chemical name and quantities added.
For full details on the ingredients, including INCI names for cosmetic products, please see Annex I - Raw Material Information.

The Assessment relates only to the formulation as described below. If this information is incorrect, please contact Delphic HSE with the correct information.

Ingredients	CAS Number	[Product]
Cellulose Gum	9004-32-4; 99331-82-5; 9000-11-7	46.31
Hydrogenated Rosin	65997-06-0	33.3
Styrene/Isoprene Copolymer	25038-32-8	14
Paraffinum Liquidum (Mineral Oil) - N.O.S.	8012-95-1; 8042-47-5; 8020-83-5	5.8
Polysorbate 80	9005-65-6	.5
Salicylic Acid	69-72-7	.09

PHYSICAL / CHEMICAL CHARACTERISTICS AND STABILITY OF THE COSMETIC PRODUCT

Appearance:	Solid	**Viscosity:**	Not Provided
Odour:	Characteristic	**Water Solubility:**	Not Provided
Melting Point:	Not Provided	**Log Kow:**	Not Provided
pH:	5 - 8	**Particle Size:**	Not Applicable
Specific Gravity:	Not Provided		

The physical-chemical data supplied for review suggests it would be unlikely to significantly contribute to the toxicological profile of the product under normal conditions of use.

Product Stability:

A stability test was carried out at 25±2°C (36 months), 25-35°C (913 days; 35°C from 685 days) and 55±2°C, RH 85±5% (6 weeks). A 5-cycle freeze/thaw test (50±2°C, 25±2°C, -18±2°C) was also carried out. The product was observed for changes in appearance, odor, pH value, peeling (gf/12mm), liquid absorption (wt%) or bioburden. No significant changes were noted and the product passed the test according to the manufacturer's criteria.

PHYSICAL / CHEMICAL CHARACTERISTICS OF THE SUBSTANCES OR MIXTURES

The physical-chemical characteristics of the substances and mixtures used within the formulation are continued in Annex I of this document. Such data provided are representative of publicly available data, and is provided for information purposes only.

MICROBIOLOGICAL QUALITY

TVC:	≤100 cfu/g (Under 3, Eye Area, Mucous Membrane)
	≤1000 cfu/g (All other products)
Specific Pathogens:	Absent in test sample
Yeasts & Moulds:	≤10 cfu/g

Based on the documentation provided for review this product meets the recommended microbiological specifications.

Manufacturer/responsible person must ensure that all batches are produced in line with these requirements.

A non-aqueous formulation that would not be expected to support significant levels of microbial growth under normal conditions of usage and storage. Resultantly a challenge/preservative efficacy test is considered unnecessary.

Microbiological specifications of the substances and mixtures used within the product have not been reviewed, and will be subject to grade variation dependent upon manufacturer and batch. The Organisation responsible for placing the product on the market must ensure that all raw materials used in production are of a suitable cosmetic grade and would not contribute a microbial risk to consumers.

IMPURITIES, TRACES, INFORMATION ABOUT THE PACKAGING MATERIAL

The below information is a list of impurities & trace materials declared by the manufacturer / responsible person as being present within the product.
If no materials are identified it is understood that no impurities or trace materials have been disclosed to Delphic HSE Solutions at the time of review.

Substances	CAS Number	[Product]
Packaging Material:	Medical dialysis paper+PE/PET composite film Details on the grades of material used in packaging manufacture have not been supplied for review, however materials of this nature have a generally good history of safe use. The manufacturer/responsible person must ensure that suitable grades of packaging material are used, and that they will not interact with the product in such a way as to pose a toxicological or microbiological risk to consumers.	
Compatibility Testing	A 84 days compatibility test was carried out at 45°C. A cycle freeze/thaw test (45°C, 25°C, -18°C) was also carried out. The product was observed for changes in appearance/sealing integrity, appearance, pH, peeling and liquid absorption. No significant changes were noted and the product passed the test according to the manufacturer's criteria.	
Product Durability	The best before end date / PAO of the product: 5 years	

NORMAL & REASONABLY FORESEEABLE USE

Normal Use:

Spot Blemish Treatment (Rieder 2017) | Leave On

Reasonably Foreseeable Uses:

Manufacturers Instructions for Use:

1. Cleanse and dry your skin before using this product.
2. Tear off one patch from the sheet and apply it directly to the blemished area.
3. Press lightly with your finger pulp for 3-5 seconds for a better fit.
4. Peel off the patch after 12 hours of use.
5. Please use the spot patch before applying makeup.

EXPOSURE TO THE COSMETIC PRODUCT

Intended Consumer:	Adult Males & Females (16+)
Single Exposure:	0.12 g | 1 x per Day
Retention Factor:	1
Minimum Expected Body Weight	60kg
Diluted in use:	No
Retained Exposure:	2.000 mg/kg/day

Exposure to Neat Product:

Body Site(s):	Face
Surface Area:	526.7 cm^2
Exposure Level:	0.228 mg/cm^2
Exposure Time:	Left on

Exposure to Diluted Product: Product Not Diluted in Use

EXPOSURE TO THE SUBSTANCES & TOXICOLOGICAL PROFILE OF THE SUBSTANCES

The toxicological data of the substances and mixtures used within the formulation are continued in Annex II of this document. Such data provided are representative of publicly available data, and is provided for information purposes only.

UNDESIRABLE EFFECTS AND SERIOUS UNDESIRABLE EFFECTS

This is a new product to market, no previous sales or complaints data is available for review. Manufacturer / responsible person must ensure that details of any concerns or complaints relating to consumer safety and adverse health effects are provided to Delphic HSE so that the safety assessment can be updated accordingly.

INFORMATION ON THE COSMETIC PRODUCT

A heavy metal test report (Report No. A2250021033102001 by Centre Testing International Group Co., Ltd.) is provided for review. The level of Cadmium, Mercury, Lead, Arsenic, Antimony and Nickel (soluble) are measured according to ISO/TR 17276:2014 Cosmetics Analytical approach for screening and quantification methods for heavy metals in cosmetics. All heavy metals are not detected in the product and the test is concluded as pass.

ASSESSMENT CONCLUSION

Under normal or reasonably foreseeable conditions of use, a product made to this formulation is unlikely to produce an abnormally high number of adverse reactions. The product will give consumers the level of safety they can reasonably expect.

This product complies with the requirements of the EU Cosmetic Regulation (EC) No 1223/2009. The product must be manufactured according to Good Manufacturing Practice.

LABELLED WARNINGS & INSTRUCTIONS FOR USE

Based on the overall safety assessment of the formulation, no warning phrases are required to be labelled.

REASONING

A formulation of spot patch intended to be used by adults, for distribution to the EU market.

No Observed Adverse Effect Levels (NOAELs), or other suitable Points of Departure (PoD) were not available for review for some of the materials. For those materials where a Margin of Safety (MoS) was not derived this is due to either a history of safe use at similar levels in cosmetic products related to the product under review, lack of biological activity or for a reason explained in the individual ingredient toxicological summary in Annex II. For those substances where suitable PoDs were available, the resultant MoS are above the typical recommended values (see Preface to Annexes).

A number of materials have recommended safe levels in percentage terms, as established by bodies such as the Scientific Committee on Consumer Safety (SCCS) or Cosmetic Ingredients Review (CIR) expert panel, or legal limits that are described in percentage terms. All such materials are present at or below the recommended safe levels or legal maximums, as indicated by the relevant entries in Annex II.

The formulation contains Paraffinum Liquidum (Mineral Oil). In order for the product to comply with EU Regulations the full refining history of these materials must be known and are devoid of carcinogenic substances. **The manufacturer must ensure a high-quality grade is used and is free from contaminants which may harm the end consumer.**

The formulation contains 0.09% of Salicylic Acid. As per EU Cosmetics Regulations, when not used as preservatives (allowed max. level is 0.5% as preservative), Salicylic acid can be used in rinse-off hair products in concentrations up to 3% and other products - except body lotion, eye shadow, mascara, eyeliner, lipstick, roll-on deodorant - in concentrations up to 2.0% (Not to be used in preparations for children under 3 years of age). As the product is a face acne treatment products, the maximum concentration allowed would be 2% and the product is intended for use by adults, its usage level is within the maximum concentration as such the product is considered safe and compliant.

The Responsible Person/manufacturer must ensure that all raw materials are of suitably safe grade with the specification mentioned in this report and the polymers are fully polymerised with no free monomers or residual solvents.

Overall, assuming suitable grades of material are used during manufacture, this item can be considered safe for the intended use. It would not be expected to pose a significant risk of adverse effects in a majority of individuals and would be expected to provide consumers with the level of safety they might reasonably expect from a product of this nature.

Skin Toxicity - Neat Product

Not expected to cause skin irritation following prolonged or repeated use.
Exposure to this product is unlikely to result in photo-toxic effects.
Unlikely to cause sensitisation following repeated skin contact.
Unlikely to produce systemic toxicity following skin contact.

Eye Toxicity - Neat Product

May cause slight transient eye irritation.

Oral Toxicity - Neat Product

All materials if swallowed in large amounts have the potential to cause injury.
If incidentally swallowed in small amounts, the formulation as supplied is unlikely to cause any adverse effects.
Not expected to produce systemic toxicity following ingestion. All materials if swallowed in large amounts have the potential to cause injury.

Inhalation Toxicity

It is unlikely that inhalation will be a route of exposure.

Toxicological & Regulatory Assessor

Johnny Yip, BSc, MSc, MRSB 17 Feb 2025

This report consists of 6 pages plus a Regulatory, Ingredient Data, Allergens, Exposure & Specifications Annex.
It is only valid as the original, complete document.

Preface to Annexes

Annex II - Ingredient Data

Physical/Chemical and Toxicological data presented within these reviews are representative of publicly available data and provided for informational purposes only. Sources of data are identified (typically in brackets) following each data point, and there may be multiple data points for any given toxicological endpoint.

Margins of Safety (MoS) are calculated where suitable data are available, and may related to mg/kg, μg/cm^2 or percentage-based indications of safety.

MoS based on systemic (mg/kg) effects are calculated as 'Point of Departure (PoD)' / 'Systemic Exposure Dose (SED)', where:

PoD = Data point considered to be indicative of a 'safe' level of exposure. This may be an animal-derived No Observed Adverse Effect Level (NOAEL) or a value indicated as being safe to humans. In the case of the latter this would typically be in the form of an ADI (Acceptable Daily Intake) or DNEL (Derived No Effect Level) established by a governmental or scientific committee / body.

SED = (Product Used (mg) x Retention Factor x Concentration of Material in Product x Dermal Absorption) / intended user body weight (kg)

In the absence of material specific data a dermal absorption of 100% is assumed.
Where an animal-derived NOAEL is used as the PoD an MoS greater than 100 is typically considered acceptable for indicating safety to consumers.
For PoD based on established safe levels in humans an MoS of greater than 1 is typically considered as acceptable for indicating safety to consumers.

MoS based on localised (μg/cm^2) effects are calculated as 'Point of Departure (PoD)' / 'Dermal Exposure', where:

PoD = Data point considered to be indicative of a 'safe' level of exposure. This would typically be a μg/cm^2 value identified from either a Local Lymph Node Assay (LLNA) or Human Repeat Insult Patch Test (HRIPT).

Dermal Exposure = (Product Used (μg) x Retention Factor x Concentration of Material in Product) / Surface Area of Application

MoS based on percentage data are calculated as 'Point of Departure PoD' / 'Ingredient Concentration in Product', where:

PoD = Data point considered to be indicative of a 'safe' level of exposure. Typically a percentage identified as safe for use within a leave-on consumer product, as established by legislation or by a governmental or scientific committee / body.

Ingredient Concentration in Product = Concentration of Material in Finished Product x Retention Factor
(As safe levels are typically identified for leave-on products the retention factor is included within the calculation to account for use in rinse-off products)
For PoD based on established safe levels in finished products an MoS of greater than 1 is typically considered as acceptable for indicating safety to consumers.

Retention Factor is an estimation of the amount of product in prolonged contact with the skin under normal conditions of use, and expressed as the decimal form of a percentage. A retention factor of 1 relates to 100% of the product staying in prolonged contact with the skin and is typically used for all leave-on products. All other products have retention factors as determined by typical conditions of use, and these are presented under 'Exposure Scenario'.

Annex III - Allergen Levels

This annex details the total levels of individuals allergens within the finished product, either from direct addition to the product or as part of fragrances and essential oils. Information is provided in both percentage and μg/cm^2 terms.

Annex III will be omitted from the report if no allergens are present or declared.

Indicative Toxicological Data is provided for each allergen where available and may include:

Research Institute for Fragrance Materials No Effect Level (RIFM NEL, indicated as a percentage)
Patch Test Concentration (percentage)
Buehler Test
Guinea Pig Maximisation Test
Human Repeat Insult Patch Test (HRIPT, in either percentage or μg/cm2)
Human Repeat Open Application Test (HROAT, in either percentage or μg/cm2)
Human Maximisation Test (HMT, in either percentage or μg/cm2)

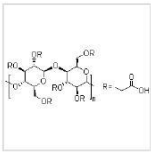
Annex IV - Foreseeable Exposures

This annex details additional exposure scenarios identified during the safety assessment as being reasonably foreseeable under normal conditions of use.

For the purposes of the safety assessment all MoS are calculated based on the intended product use, and any comments or concerns relating particularly to additional exposure scenarios is detailed in the Reasoning or Toxicological & Regulatory Review portions the assessment.

ANNEX I - REGULATORY CONTROLS

Substance: Cellulose Gum
CAS: 9004-32-4; 99331-82-5; 9000-11-7
Function: Emuslion Stabilising; Film Forming; Viscosity Controlling; Binding; Masking
Concentration in Product: 46.31%



Regulatory Listings

Europe:
EINECS: -
EU GHS Classification: Not Classified (self-classification)

REACh Annex XVII: Not Controlled

REACh SVHC: Not Controlled

EU Cosmetic Regulation: Not Controlled
EU INCI Name: Cellulose Gum
EN71 Toy Standards: Not listed in EN71-7 or 9
EU Toy Directive: Not Controlled
EU Biocides Regulation: Not Registered for any Biocidal uses.
EU Detergents Regulation: Not Controlled

Substance: Hydrogenated Rosin
CAS: 65997-06-0
Function: Film Forming; Perfuming; Viscosity Controlling
Concentration in Product: 33.3%

Regulatory Listings

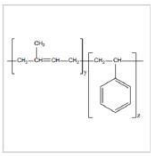
Europe:
EINECS: 266-041-3
EU GHS Classification: Not classified

REACh Annex XVII: Not controlled

REACh SVHC: Not controlled

EU Cosmetic Regulation: Not controlled
EU INCI Name: Hydrogenated Rosin
EN71 Toy Standards: Not listed in EN71 part 7 or 9
EU Toy Directive: Not controlled

Substance: Styrene/Isoprene Copolymer
CAS: 25038-32-8
Function: Film Forming; Opacifying
Concentration in Product: 14%



Regulatory Listings

Europe:
EINECS: Polymer
EU GHS Classification: Not Classified (Self-classified by 91 notifiers)
H412 (self-classified by 7 notifiers)
REACh Annex XVII: Not Controlled
REACh SVHC: Not Controlled
EU Cosmetic Regulation: Not Controlled (may contain traces of Styrene - Annex II)
EU INCI Name: Styrene/Isoprene Copolymer
EN71 Toy Standards: Not listed in EN71-7
One of the monomers, Styrene, is controlled by EN71-9, Table 2 D – Monomers (migration) to a max of 0,75 mg/l
EU Toy Directive: Not Controlled

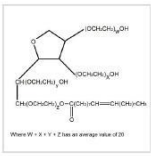
Substance: Paraffinum Liquidum (Mineral Oil) - N.O.S.
CAS: 8012-95-1; 8042-47-5; 8020-83-5
Function: Antistatic; Emollient; Perfuming; Skin protecting; Solvent
Concentration in Product: 5.8%

No Structure Available

Regulatory Listings

Europe:
EINECS: 265-148-2; 232-384-2; 232-455-8
EU GHS Classification: 8042-47-5: H350(1B) (Need not apply if refining history is known and not produced from carcinogen, Harmonised classification)
8012-95-1: H304 (Depending upon product viscosity, self-classification)
REACh Annex XVII: Not Controlled
REACh SVHC: Not Controlled
EU Cosmetic Regulation: Controlled - Purity and refining history must be known
EU INCI Name: Paraffinum Liquidum
EN71 Toy Standards: Not Controlled
EU Toy Directive: Not controlled providing that the grade is not carcinogenic - refining history showing solvent extraction or severe hydrogenation has been applied and/or concentrations of polycyclic aromatic hydrocarbons measured by IP 346 <3%.
EU Biocides Regulation: Not Controlled

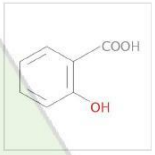
Substance: Polysorbate 80
CAS: 9005-65-6
Function: Denaturant; Emulsifying; Surfactant
Concentration in Product: 0.5%



Regulatory Listings

Europe:
EINECS: 500-019-9
EU GHS Classification: Not Classified (self-classified)
REACh Annex XVII: Not listed
REACh SVHC: Not listed
EU Cosmetic Regulation: Not controlled
EU INCI Name: Polysorbate 80
EN71 Toy Standards: Not listed in EN71 part 7 or 9
EU Toy Directive: Not controlled
EU Biocides Regulation: Not Controlled
EU Detergents Regulation: Not Controlled

Substance: Salicylic Acid
CAS: 69-72-7
Function: Antidandruff; Hair conditioning; Keratolytic; Masking; Preservative; Skin conditioning
Concentration in Product: 0.09%



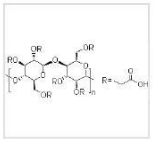
Regulatory Listings

Europe:
EINECS: 200-712-3
EU GHS Classification: Harmonised classification:
H302 Harmful if swallowed.
H318 Causes serious eye damage.
H361d suspected of damaging unborn child.
REACh Annex XVII: Not Controlled
REACh SVHC: Not Controlled
EU Cosmetic Regulation: Permitted Preservative - Annex V/3 - Max 0.5% (Not to be used in products for children under 3 years of age. Not to be used in oral products. Not to be used in applications that may lead to exposure of the end-user's lungs by inhalation.) ; Controlled - Annex III/98 - (a) Rinse-off hair products 3%, (b) Other products except body lotion, eye shadow, mascara, eyeliner, lipstick, roll-on deodorant 2.0% (Not for children under 3, except shampoos - Solely for products which might be used for children under 3 years of age and which remain in prolonged contact with the skin), (c) Body lotion, eye shadow, mascara, eyeliner, lipstick, roll-on deodorant 0.5%.
((a) (b) (c) Not to be used in preparations for children under 3 years of age. Not to be used in applications that may lead to exposure of
Annex V/3: "Not to be used for children under 3 years of age" (Note 12: Solely for products which might be used for children under 3 years of age.)
Annex III/98: "Not to be used for children under 3 years of age" (Note 10: Solely for products which might be used for children under 3 years of age.)
EU INCI Name: Salicylic Acid
EN71 Toy Standards: Not Listed in EN71 parts 7 and 9
EU Toy Directive: Not Controlled
EU Biocides Regulation: Not supported as a biocidal active. To be phased out for preservative use in general products by 25/10/2009
EU Detergents Regulation: Not a detergent preservative

ANNEX II - INGREDIENT DATA

Substance:	Cellulose Gum	**Concentration in Product:**	46.31%
CAS:	9004-32-4; 99331-82-5; 9000-11-7	**Dermal Exposure Level:**	.105509778 mg/cm^2
Function:	Emuslion Stabilising; Film Forming; Viscosity Controlling; Binding; Masking	**Daily Body Burden:**	0.9262000000mg/kg

Chemical Structure



Physical/Chemical Characteristics

Appearance	White powdered solid
Flammability	Auto-Ignition Temperature: 370°C
Water Solubility	Readily soluble
Odour	Odourless

Toxicological Summary

The below information is a summary of the toxicological profile for this raw material, including a description of general hazards associated with the material as well as discussion of the most critical studies relating to the overall safety in use of this substance/mixture in consumer products. Details of the available toxicological data can be found overleaf.

Overall Toxicity Review:

Cellulose Gum is a sodium salt of carboxymethylcellulose, which is essentially an inert thickening agent with a long history of safe use in consumer products. It is an approved food additive in EU (E 466) and given the generally recognized as safe (GRAS) status by US FDA Select Committee on GRAS Substances (SCOGS) as a multiple purpose food substance upon fulfilling required specifications (21CFR182.1745). In cosmetics it is commonly used as a binding, emulsion stabilising, film forming, masking and viscosity controlling agent.

It was not irritating to rabbit skin and eyes, and the undiluted material was neither a dermal irritant nor sensitiser in patch tests of human subjects. It is practically non-toxic from acute oral exposures, with a high oral LD50 of 27000 mg/kg bw in rats.

Repeated dose oral and dermal studies also found no systemic toxic effects in treated animals. In subchronic studies, rats fed with a diet containing up to 10% Cellulose Gum (equivalent to 6800 mg/kg bw/day) for 90-102 days showed some findings in the gastrointestinal tract, kidneys and urinary bladder that were not concluded of toxicological concern but attributed to the accumulation of poorly absorbed water-soluble material in the caecum and colon and to the 4 times higher sodium concentration in the treatment diet compared with the basal diet. In chronic studies, rats fed with a diet containing up to 1.0 g/kg Cellulose Gum for 25 months showed no significant differences between the controls and test animals in urinalyses, haematological values, fertility, or findings at necropsy, and no neoplasms were found in the test rats. Rats fed with a diet containing up to 5% Cellulose Gum (equivalent to 2500 mg/kg bw/day) for 201-250 days showed no adverse effect on growth rate, mortality, organ weights and histopathological examinations. Rats fed up to 1000 mg/kg bw/day of Cellulose Gum for 2 years and up to 3 generations showed no treatment-related adverse findings in weight curves, urine, haematological and histological examinations.

A three-generation study in rats fed with a diet containing up to 1.0 g/kg Cellulose Gum found no significant adverse effects in fertility. A prenatal study in rats gavaged at up to 1600 mg/kg bw/day of Cellulose Gum from gestation day 6 to 15 found no adverse effects on implantation or fetal survival and no increase in abnormalities of soft or skeletal tissues compared with control animals. Moreover, the Cosmetic Ingredients Review (CIR) Expert Panel reported Cellulose Gum being used as negative control in multiple reproductive studies at up to 2% (CIR, 2009).

It was demonstrated to be negative in an Ames test as well as in a mammalian chromosomal aberration test. Although there are no carcinogenicity data, the long history of safe use in cosmetics, food, pharmaceuticals, and consumer products suggests such potential is unlikely.

The available data in humans indicate that oral ingestion of some modified celluloses up to 6000 mg/person per day for 8 months in patients suffering from diarrhoea or constipation was well tolerated (EFSA ANS Panel, 2018).

In 2018, the European Food Safety Authority (EFSA) reported that the combined exposure to celluloses (E 460-466, E 468 and E 469) including Cellulose Gum at 95th percentile of the refined (brand-loyal) exposure assessment for the general population was up to 506 mg/kg bw/day. The Panel concluded that there was no need for a numerical Acceptable Daily Intake (ADI) and that there would be no safety concern at the reported uses and use levels for the unmodified and modified celluloses reviewed (EFSA ANS Panel, 2018).

Although it may not be the true No Observed Adverse Effect Level (NOAEL) as the highest tested dose in the study, 1000 mg/kg bw/day identified from the chronic rat oral study of Cellulose Gum is chosen as a conservative Point of Departure (PoD) for Margin of Safety (MoS) calculation.

As dermal absorption is dependent on the molecular properties, concentration, exposure time and vehicle simultaneously, in the absence of relevant experimental data it is difficult to assess an exact value. If not stated otherwise within the risk assessment, we assume 100% dermal absorption, however it must be noted that for the majority of compounds, even low molecular weight, lipophilic compounds, dermal absorption is expected to be significantly lower than 100%.

In 2009, the CIR Expert Panel reported the use of up to 20% Cellulose Gum in cosmetic products (other oral hygiene products, and up to 10% in leave-on products (face powders)), and the Panel concluded it is safe in the practices of use and concentration described in the assessment (CIR, 2009).

Overall, this material is not expected to produce significant localised or systemic toxicity at typical levels found within cosmetic and consumer products.

References:

CIR (2009). Amended Safety Assessment of Cellulose and Related Polymers as used in Cosmetics, Cosmetic Ingredient Review,

EFSA ANS Panel (EFSA Panel on Food Additives and Nutrient Sources added to Food) (2018). Scientific Opinion on the re-evaluation of celluloses E 460(i), E 460(ii), E 461, E 462, E 463, E 464, E 465, E 466, E 468 and E 469 as food additives. EFSA Journal 2018;16(1):5047, 104 pp. https://doi.org/10.2903/j.efsa.2018.5047

FDA GRAS. https://www.fda.gov/food/ingredientspackaginglabeling/foodadditivesingredients/ucm091048.htm (last accessed15:54:47 25/03/2019)

Margin(s) of Safety

Point of Departure - Animal Study:	1000.0000mg/kg	**Exposure from Product**	0.92620000mg/kg	**Margin of Safety**	1079.68041

ANNEX II - INGREDIENT DATA

Cellulose Gum

Acute Toxicity Acute Toxicity, Lethality [Other]		LD50 = 27000 mg/kg bw
Rat	Oral, NOS	
Eye Irritation Draize [Other]		Non-irritating (score of 0 out of 110) [0.1 mg in water or 0.01 g as solid, no rinse, exposure and observation up to 7 days]
Rabbit	Instillation	
Genotoxicity Bacterial reverse mutation test (Ames) [OECD 471]		Negative with and without metabolic activation.
Bacteria	In vitro exposure	
Genotoxicity In vitro genotoxicity assay [Other]		Negative with and without metabolic activation.
In-vitro culture	In vitro exposure	
Phototoxicity In vivo phototoxicity		Minimally irritating but not phototoxic [0.5% in liquid eyeliner formulation]
Rabbit	Dermal	
Repeated Dose Repeat Dose Oral Toxicity Study [Other]		No toxic effects (slight decrease in growth was attributed to a decrease in nutrient food intake resulting from the bulkiness of the diet) [20% in diet, 63 day exposure]
Rat	Oral, Feed	
Repeated Dose Repeat Dose Dermal Toxicity Study [Other]		Not systemically toxic (No significant adverse effects were noted) [3% in wrinkle smoother product or 1.1% in lotion, 13 week exposure]
Rat	Dermal	
Repeated Dose Repeat Dose Oral Toxicity Study [Other]		NOAEL = 1.0 g/kg feed No significant differences were noted between the controls and test animals in urinalyses, hematological values, fertility (through three generations), or findings at necropsy. No neoplasms were found in the test rats [0, 0.1, 0.5, 1.0 g/kg feed of Cellulose Gum, 25 months]
Rat	Oral, Feed	
Repeated Dose Repeat Dose Oral Toxicity Study [Other]		For all the reported findings (GIT, kidney & bladder), a toxicological concern was not concluded, but were attributed to accumulation of poorly absorbed water-soluble material and increased sodium concentration [0, 2.5, 5 or 10% in diet (up to 6800 mg/kg bw/day) for 90-102 days, 20/sex/dose]
Rat	Oral, Feed	
Repeated Dose Repeat Dose Oral Toxicity Study [Other]		NOAEL = 2500 mg/kg bw/day. No adverse effects on growth rate, mortality and organ weights. No significant differences in histopathological examination of the liver, kidney, spleen, pancreas, adrenal gland, testis and GI tract. [0 or 5% in diet for 201-250 days, 10 males + 15 females in treatment group]
Rat	Oral, Feed	
Repeated Dose Repeat Dose Oral Toxicity Study [Other]		NOAEL = 1000 mg/kg bw/day [0, 100, 500 or 1,000 mg/kg bw/day for over 2 years, litters produced were fed the same diet as parents, this was carried out into the third generation. Parameters: weight curves, urine analysis, haematology & histology]
Rat	Oral, Feed	
Reproductive Toxicity In vivo reproductive toxicity study [Other]		No significant adverse effects were noted in fertility, gross or microscopic lesions, urinalyses, and hematological values [0, 0.1, 0.5, and 1.0 g/kg feed, 3-generation study]
Rat	Oral, Feed	
Reproductive Toxicity In vivo reproductive toxicity study [Other]		NOAEL = 1600 mg/kg bw/day No mortality, no adverse effects on implantation or fetal survival, no treatment-related increase in abnormalities of soft or skeletal tissues [0, 16, 74, 345 or 1,600 mg/kg bw/day from GD 6 to 15, 19-22/dose]
Rat	Oral, Gavage	
Skin Irritation In vivo skin irritation [Other]		No signs of skin irritation [Undiluted, application on shaved abdominal area, 5 times per week, 4-week exposure]
Rabbit	Dermal	
Skin Sensitisation In vivo skin sensitisation [Other]		Non-irritating and non-sensitising [Undiluted, SIPT with challenge (applied under a lintine disc for 5 days followed by a repeat application for 48 hours after 3 weeks), 200 subjects (100 males + 100 females)]
Human	Dermal	
Skin Sensitisation In vivo skin sensitisation [Other]		No primary dermal irritation, did not appear to be a sensitiser [Undiluted, patch test (unspecified), 200 subjects]
Human	Dermal	

ANNEX II - INGREDIENT DATA

Substance:	Hydrogenated Rosin	**Concentration in Product:**	33.3%
CAS:	65997-06-0	**Dermal Exposure Level:**	.075868616 mg/cm^2
Function:	Film Forming; Perfuming; Viscosity Controlling	**Daily Body Burden:**	0.6660000000mg/kg

Chemical Structure

Physical/Chemical Characteristics

Log Kow	3.4
Water Solubility	1.2 mg/L

Toxicological Summary

The below information is a summary of the toxicological profile for this raw material, including a description of general hazards associated with the material as well as discussion of the most critical studies relating to the overall safety in use of this substance/mixture in consumer products. Details of the available toxicological data can be found overleaf.

Overall Toxicity Review:

Hydrogenated Rosin is used as film forming, perfuming and viscosity controlling agent in cosmetics.

Experimental data showed that Hydrogenated Rosin is not irritating to skin and eyes, not sensitising in both guinea pig maximisation tests and human repeat insult patch test. It has a low acute toxicity with both oral and dermal LD50 > 2000 mg/kg. Hydrogenated Rosin showed negative results in Ames test with and without metabolic activation.

A NOAEL of 0.2% in diet (approximately 200 mg/kg bw/day) was found in a 90-day repeat dose study in rats.

As dermal absorption is dependent on the molecular properties, concentration, exposure time and vehicle simultaneously, in the absence of relevant experimental data it is difficult to assess an exact value. If not stated otherwise within the risk assessment, we assume 100% dermal absorption, however it must be noted that for the majority of compounds, even low molecular weight, lipophilic compounds, dermal absorption is expected to be significantly lower than 100%.

Hydrogenated Rosin itself is not sensitising in both animal and human tests. However, Rosin is a well known sensitiser and NICNAS suggested that the skin sensitisation classification should apply to all members of the group in preparations where oxidation may occur based on storage and shelf life. The manufacturer must ensure the Hydrogenated Rosin is fully hydrogenated and won't be oxidised during storage.

On the basis of the available data, when fully hydrogenated with no oxidation during storage, the use of this material at low levels within a consumer product would be expected to pose undue risk of significant adverse effects to the majority of individuals under normal conditions of use.

References:

NINCNAS, Rosin, hydrogenated rosin and salts: Human health tier II assessment. Available at: https://www.nicnas.gov.au/chemical-information/imap-assessments/imap-group-assessment-report?assessment_id=872#cas-A_65997-06-0 (Accessed 24 Sep 2019)

Margin(s) of Safety

Point of Departure - Animal Study:	200.0000mg/kg	**Exposure from Product**	0.66600000mg/kg	**Margin of Safety**	300.3003

ANNEX II - INGREDIENT DATA

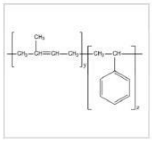
Hydrogenated Rosin

Acute Toxicity Acute Oral Toxicity, Non-lethal [OECD 420]		LD50 > 2000 mg/kg bw Resin acids and Rosin acids, hydrogenated, potassium salts
Rat	Oral, Gavage	
Acute Toxicity Acute Dermal Toxicity, Lethality [OECD 402]		LD50 > 2000 mg/kg bw Resin acids and Rosin acids, hydrogenated, potassium salts
Rat	Dermal	
Eye Irritation Reconstructed human Cornea-like Epithelium (RhCE) Test [OECD 492]		Not irritating Resin acids and Rosin acids, hydrogenated calcium salts
In-vitro culture	In vitro exposure	
Genotoxicity Bacterial reverse mutation test (Ames) [OECD 471]		Negative with and without metabolic activation Resin acids and Rosin acids, hydrogenated, potassium salts
Bacteria	In vitro exposure	
Repeated Dose Repeat Dose Oral Toxicity Study [Other]		NOAEL = 200 mg/kg bw/day 90 days sub-chronic study in rats. Doses: 0, 0.01, 0.05, 0.2, 1, or 5% for 90 days. NOAEL = 0.2% (approximate 200 mg/kg bw/day). In the 1% group, body weight was significantly decreased in both males and females, and food consumption was decreased.
Rat	Oral, Feed	
Skin Irritation Draize Test [OECD 404]		Not irritating Resin acids and Rosin acids, hydrogenated, potassium salts
Rabbit	Dermal	
Skin Sensitisation Maximisation Test [OECD 406]		Not sensitising Hydrogenated gum rosin. Induction: 10% and 40% in olive oil. Challenge: 3, 10, 30, and 40%
Guinea Pig	Dermal	
Skin Sensitisation Maximisation Test [OECD 406]		Not sensitising Hydrogral (Rosin, hydrogenated), intradermally injected and topically exposed 0.5g, challenged with 25 and 50% of the test substance in paraffin oil. the test substance did not indicate a potential for dermal irritation or sensitisation.
Guinea Pig	Dermal	
Skin Sensitisation Repeat Insult Patch Test (RIPT) [Other]		Hydrogenated rosin (Foral AX) was found not to be irritating and did not elicit evidence of skin sensitization in humans when tested in a Human Repeat Insult Patch Test (53 panelists).
Human	Dermal	

ANNEX II - INGREDIENT DATA

Substance:	Styrene/Isoprene Copolymer	**Concentration in Product:**	14%
CAS:	25038-32-8	**Dermal Exposure Level:**	.031896715 mg/cm^2
Function:	Film Forming; Opacifying	**Daily Body Burden:**	0.2800000000mg/kg

Chemical Structure



Physical/Chemical Characteristics

Appearance	Solid
Molecular Mass	150000
Boiling Point	145.2ºC at 760 mmHg

Toxicological Summary

The below information is a summary of the toxicological profile for this raw material, including a description of general hazards associated with the material as well as discussion of the most critical studies relating to the overall safety in use of this substance/mixture in consumer products. Details of the available toxicological data can be found overleaf.

Overall Toxicity Review:

Styrene/Isoprene Copolymer is a copolymer of styrene and isoprene monomers with a high molecular weight. In cosmetics, it functions as a film forming and opacifying agent.

Based on manufacturers self-classification data in ECHA, it is not classified as hazardous to human health.

The International Agency for Research on Cancer has classified styrene and isoprene as possibly carcinogenic to humans (Group 2B) (IARC, 2019).

It is classified by NICNAS in Australia as a low concern polymer based on their Tier I IMAP human health assessment (NICNAS, 2017).

In 2014, the CIR Expert Panel reviewed the use of this ingredient in cosmetic products, and concluded it is safe in the present practices of use in product categories and at concentrations comparable to other Styrene and Vinyl-type Styrene Copolymers despite not reported to be in current use (CIR 2014).

The CIR Panel agreed that percutaneous absorption is not expected because of the large size of this molecule. The absence of the potential for percutaneous absorption and the negative results of toxicity tests provided the Panel with a sufficient basis to assess the safety of these polymers as used in cosmetics. Manufacturer must make sure that highly pure grades of raw material are used in cosmetics (CIR 2014).

CIR report (2014) indicated that Hydrogenated Styrene/Isoprene Copolymer is used in the products that are expected to come in contact with the skin (leave-on) at 0.89-4% and up to 4.2% for rinse off product, in products of incidental ingestion up to 2,5-3% and in products of incidental inhalation at 4% in sprays and 3% in powders. The Expert Panel also concluded that this ingredient is safe in the present practices of use and concentration in cosmetics, as described in this safety assessment.

An NOAEL is not available for review, however, based on its large molecular size and as a low concern polymer, at typical levels of use incorporation within a consumer product would not be expected to pose an undue risk of significant adverse effects in a majority of individuals as long as residual monomers are controlled below hazardous levels.

Reference:

NICNAS (2017). Assessment detail. Benzene, ethenyl-, polymer with 2-methyl-1,3-butadiene. Available at: https://services.industrialchemicals.gov.au/assessment-detail/?id=5cfb433e-f36b-1410-8e4e-00f1fcf8411a

CIR (2014). Safety Assessment of Styrene and Vinyl-type Styrene Copolymers as Used in Cosmetics. Available at: https://www.cir-safety.org/sites/default/files/styren092014final.pdf

IARC (2019). IARC MONOGRAPHS ON THE IDENTIFICATION OF CARCINOGENIC HAZARDS TO HUMANS. Available at: https://monographs.iarc.who.int/list-of-classifications

Margin(s) of Safety

ANNEX II - INGREDIENT DATA

Styrene/Isoprene Copolymer

Details on specific toxicological studies related to endpoints of concern are not available for Styrene/Isoprene Copolymer, please see the previous page for a justification of safety based on history of use &/or weight of evidence.

ANNEX II - INGREDIENT DATA

Substance:	Paraffinum Liquidum (Mineral Oil) - N.O.S.	**Concentration in Product:**	5.8%
CAS:	8012-95-1; 8042-47-5; 8020-83-5	**Dermal Exposure Level:**	.013214354 mg/cm^2
Function:	Antistatic; Emollient; Perfuming; Skin protecting; Solvent	**Daily Body Burden:**	0.0116000000mg/kg

Chemical Structure

No Structure Available

Physical/Chemical Characteristics

Appearance	Clear colourless Liquid	Log Kow	>3.5
Boiling Point	>320°C	Odour	Odourless
Evaporation Rate	n.a.	pH	n.a.
Flammability	Autoignition > 250°C	Specific Gravity	0.86
Flash Point	190°C		

Toxicological Summary

The below information is a summary of the toxicological profile for this raw material, including a description of general hazards associated with the material as well as discussion of the most critical studies relating to the overall safety in use of this substance/mixture in consumer products. Details of the available toxicological data can be found overleaf.

Overall Toxicity Review:

An unspecified grade of Mineral Oil, CAS Number 8012-95-1. The CAS number supplied for this mineral oil falls under the title of 'Other Petroleum Substances' in CONCAWE guidance documents. This would mean that it is not automatically 'highly refined', and that each grade should be treated on a case-by-case basis.

Available data from the ECHA Registration Dossier on Paraffin Oil, CAS 8012-95-1, indicates the material has little irritation potential when in contact with the skin or eyes. As it is mostly composed saturated hydrocarbons it is unlikely to cause phototoxicity: the compound's structure does not contain conjugated double bonds, therefore, it will not absorb UV light which is a prerequisite for phototoxicity.

The ingredient was found to be not dermal sensitising and irritating from a Buehler study (ECHA) and Draize test (ECHA) respectively, when applied 0.5 millilitres of undiluted highly refined base oil (8042-47-5). Therefore, the ingredient can be considered as a non-sensitiser and non-irritant.

The Oral and Dermal LD50s of Mineral Oils is high, though certain viscosity Oils may pose an aspiration hazard if significant quantities of material are ingested.

The systemic toxicity of Mineral Oils is largely determined by their viscosity and refining history; therefore, all grades utilised in consumer products must have a suitable safety profile. Although known to accumulate within the Liver and Spleen following ingestion there is little evidence of long-term adverse effects arising as a result of this. Nevertheless, in products where ingestion is likely, either a High Viscosity (as defined by the Joint WHO/FAO Expert Committee on Food Additives (JECFA) or Medium / Low Viscosity Grade 1 (as defined by JECFA) Oil should be used. The JECFA ADIs are 20 mg/kg/day and 10 mg/kg/day respectively for such Grades (as mentioned in the EFSA report, 2009).

The EFSA Panel on Food Additives and Nutrient Sources added to Food (ANS) established an ADI of 12 mg/ kg b.w./day for high viscosity white mineral oils (2009) when used as food additives. Based on a NOAEL of 1200 mg/kg b.w. per day in a chronic (12 months) dermal toxicity study in Fischer 344 rats (highest dose tested). EFSA concluded that the ADI established for high viscosity mineral oil could have been potentially applicable also to medium- and low-viscosity mineral oil class I. In order to ensure the grade used is non-carcinogenic, the IP346 DMSO Extract should be < 3%.

Moreover, the compound showed no reproductive toxicity effects in concentrations up to 2000 mg/kg bw/day.

A review of data on the dermal penetration of mineral oils and waxes used in cosmetic applications was reported by Petry et al (Petry 2017). A total of 13 in vivo (human, animal - animal studies published at/before 2006) and in vitro studies investigating the dermal penetration of mineral oils and waxes has been identified and analysed. The majority of the substances were dermally adsorbed to the stratum corneum and only a minor fraction reached deeper skin layers. There is no evidence from the various studies that mineral oils and waxes are percutaneously absorbed and become systemically available. The review concluded that, given the absence of dermal uptake, mineral oils and waxes as used in cosmetic products do not present a risk to the health of the consumer. Thus, 10% dermal absorption is assumed conservatively for calculating margin of safety. This also precludes the potential for sensitisation reactions to take place.

Cosmetic formulations containing 29.2-55% Petroleum Distillate (broad term used for several petroleum fractions including mineral oil) were generally nonirritating, nonsensitizing, and nonphotosensitizing to human skin. It is concluded that Petroleum Distillate, as characterised in the report, is safe as a cosmetic ingredient at the current concentrations of use (CIR, 1986). In addition, as of October, 2021, approximately 61,000 beauty and personal care products are reported to contain this ingredient.

Assuming a suitable grade of Mineral Oil is used it is not expected to produce significant localised or systemic toxicity. In products where ingestion is likely a food grade of material should be used and predicted exposure should not exceed the EFSA ADI.

References:

ECHA Regisration Dossier of Paraffin Oil, CAS: 8012-95-1. Acute Tox. Oral. 001. Available at: https://echa.europa.eu/registration-dossier/-/registered-dossier/6391/1. (Accessed: 6 September 2018).

EFSA, 2009. Scientific Opinion on the use of high viscosity white mineral oils as a food additive. EFSA Journal 7(11):1387:1-39

Petry et al. 2017. Review of data on the dermal penetration of mineral oils and waxes used in cosmetic applications. Toxicol Lett. 280, P70-78. doi: 10.1016/j.toxlet.2017.07.899.

CIR (1986). Final Report on the Safety Assessment of Petroleum Distillate. Journal of the American College of Toxicology. 5 (3), 225 - 248.

Margin(s) of Safety

Point of Departure - Human Data:	12.0000mg/kg	**Exposure from Product**	0.01160000mg/kg	**Margin of Safety**	1034.48276

ANNEX II - INGREDIENT DATA

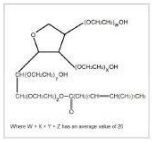
Paraffinum Liquidum (Mineral Oil) - N.O.S.

Acute Toxicity Acute Toxicity, Lethality [Other]		LD50 > 5g/kg
Rat	Oral, NOS	
Acute Toxicity Acute Toxicity, Lethality [Other]		LD50 > 2g/kg
Rabbit	Dermal	
Eye Irritation Draize, Standard [OECD 405]		Mild reversible effect
Rabbit	Instillation	
Eye Irritation Draize, Standard [OECD 405]		Not irritating. [Concentration: 0.1 mL of undiluted highly refined base oil [F-52-01; ARCOprime 70 (100% petroleum hydrocarbons)]] [Read-across based on grouping of substances, highly refined base oil (8042-47-5)]
Rabbit	Instillation	
Repeated Dose Chronic Toxicity Studies in Rodents [OECD 452]		24 month study; doses: 0, 60, 120, 240, 1200 mg/kg/day NOAEL is greater than 1200 mg/kg/day. No adverse effects nor carcinogenic potential
Rat	Dermal	
Reproductive Toxicity One-Generation Reproduction Toxicity Study [OECD 415]		doses, by dermal route: 0, 125, 500, 2000 mg/kg/day No effects observed on reproductive parameters. NOAEL > 2000 mg/kg/day
Rat	Dermal	
Skin Irritation Draize Test [OECD 404]		Not irritating. [Concentration: 0.5 mL of undiluted highly refined base oil] [Read-across based on grouping of substances, highly refined base oil (8042-47-5)]
Rabbit	Dermal	
Skin Sensitisation Repeat Insult Patch Test (RIPT) [Other]		309 women using 35% petroleum distillate in three mascara varieties underwent a repeat insult patch test of all products. No reactions observed
Human	Dermal	
Skin Sensitisation Buehler [OECD 406]		Not sensitising. [Concentration: 0.5 millilitres of undiluted test material [highly refined base oil; F-52-01] and 0.3% DNCB in 80% ethanol/water (induction phase) and 0.2% DNCB in 80% ethanol/water (challenge phase)] [Read-across based on grouping of substances, highly refined base oil (8042-47-5)]
Guinea Pig	Dermal	

ANNEX II - INGREDIENT DATA

Substance:	Polysorbate 80	**Concentration in Product:**	0.5%
CAS:	9005-65-6	**Dermal Exposure Level:**	.001139168 mg/cm^2
Function:	Denaturant; Emulsifying; Surfactant	**Daily Body Burden:**	0.0010000000mg/kg

Chemical Structure



Physical/Chemical Characteristics

Appearance	yellow oily liquid	pH	6.5 (3% aqu.)
Boiling Point	>100 C	Specific Gravity	1.06 - 1.10
Flash Point	280C	Vapour Pressure	<0.1 kPa (@ 20°C)
Melting Point	-20.5 C	Water Solubility	Soluble
Odour	Slight fatty		

Toxicological Summary

The below information is a summary of the toxicological profile for this raw material, including a description of general hazards associated with the material as well as discussion of the most critical studies relating to the overall safety in use of this substance/mixture in consumer products. Details of the available toxicological data can be found overleaf.

Overall Toxicity Review:

A highly ethoxylated oleate ester of sorbitol. Low potential to cause skin and eye irritation. Various grades are available with different degrees of ethoxylation, however the toxicological properties are similar. Materials have an extensive history of safe use in cosmetics and food.

Polysorbate 80 has low acute toxicity (oral LD50 > 38.0 g/kg) and is not or mildly irritating to skin, not irritating to the eyes, not sensitising. Polysorbate 80 was non-genotoxic in an Ames Assay.

A 28-day Oral Gavage study in rats identified a NOAEL of 3,700mg/kg/day, the highest tested dose. Whilst not likely to represent a true NOAEL.

A NOAEL of 5% in diet (equivalent to 2500 mg/kg bw/day) of polyoxyethylene (20) sorbitan monostearate (polysorbate 60) was found in life-span studies in rats. Based on it, JECFA set the group ADI of 0-25 mg/kg bw/day for polyoxyethylene (20) sorbitan monoesters of lauric, oleic, palimitic and stearic acid and triester of steatic acid (Polysorbates 20, 40, 60, 65 and 80) using a safety factor of 100 (JECFA 1973).

The EFSA panel re-evaluated the polyoxyethylene sorbitans (E432-E436). The Panel concluded that based on the NOAEL of 2500 mg/kg bw/day, identified from an oral carcinogenicity study with polysorbate 80 in rats and applying an uncertainty factor of 100, a group ADI of 25 mg/kg bw/day for polysorbates 20, 80, 40, 60 and 65 (E432, E433, E434, E435 and E436, respectively) can be established (EFSA 2015).

The molecular weight of Polysorbate 80 is 604.8 Da, that is over 500 Da, thus it is expected that a very low dermal absorption and a skin absorption rate of 10% is assumed for safety assessment according to SCCS (SCCS/1602/18) guidance.

CIR (Moore, 2015) reported that Polysorbate 80 was used in 932 products at a range of 0.00031-11.9% in leave-on products and 0.0038-18.1% in rinse-off products and concluded that it is safe in cosmetic when formulated to be non-irritating.

Overall, based on the available data and history of safe use in cosmetics and food, the inclusion of Polysorbate 80 at typical levels within consumer products is considered most unlikely to pose an undue risk of significant adverse effects.

References:

JECFA, Polyethylene (20) sorbitan Monooleate (Synonyms: Polysorbate 80). CAS no. 9005-65-6. Available at: http://apps.who.int/food-additives-contaminants-jecfa-database/chemical.aspx?chemID=2507. Report: NMRS 53/TRS 539-JECFA 17/20. Tox Monograph: FAS 5/NMRS 53A-JECFA 17/254.

EFSA Panel on Food Additives and Nutrient Sources added to Food (ANS). (2015). 'Scientific Opinion on the re-evaluation of polyoxyethylene sorbitan monolaurate (E 432), polyoxyethylene sorbitan monooleate (E 433), polyoxyethylene sorbitan monopalmitate (E 434), polyoxyethylene sorbitan monostearate (E 435) and polyoxyethylene sorbitan tristearate (E 436) as food additives'. *EFSA Journal*, 13(7), 4152.

Moore, J. (1984). 'Final report on the safety assessment of polysorbates 20, 21, 40, 60, 61, 65, 80, 81, and 85'. J Am Coll Toxicol, 3, 1-82.

CIR (2015). Safety Assessment of Polysorbates as Used in Cosmetics.

Margin(s) of Safety

Point of Departure - Animal Study:	2500.0000mg/kg	**Exposure from Product**	0.00100000mg/kg	**Margin of Safety**	2500000
Point of Departure - Human Data:	25.0000mg/kg	**Exposure from Product**	0.00100000mg/kg	**Margin of Safety**	25000

ANNEX II - INGREDIENT DATA

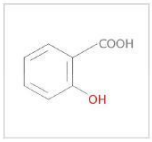
Polysorbate 80

Acute Toxicity Acute Toxicity, Lethality [Other]		Oral LD50 > 38.0 g/kg
Rat	Oral, NOS	
Carcinogenicity Carcinogenicity studies [OECD 451]		NOAEL = 5% in diet (2500 mg/kg bw/day), Polysorbate 80, 2 years feed study.
Rat	Oral, Feed	
Eye Irritation Draize [Other]		Non-irritant 100% Polysorbate 80 applied, 6 unwashed and 3 washed with water after 2 seconds. No irritation.
Rabbit	Instillation	
Genotoxicity Bacterial reverse mutation test (Ames) [OECD 471]		Non-genotoxic, with and without metabolic activation. (S. typhimurium TA1535, TA1537, TA98 and TA100 | E. coli strain WP2 uvr A)
Bacteria	In vitro exposure	
Repeated Dose Repeat Dose Oral Toxicity Study [Other]		NOAEL = 3,700mg/kg/day (6 rats/dose, 148, 740 and 3,700mg/kg/day. 28-day dosing following 28 days of high-fat diet. No adverse effects at any dose.)
Rat	Oral, Gavage	
Repeated Dose Chronic Toxicity Studies in Rodents [OECD 452]		NOEL = 5% (equivalent to 2500 mg/kg bw) Doses: 2%, 5%, 10% and 25% of Polysorbate 80. The whole life-span study. No effect at 2% and 5% levels.
Rat	Oral, Feed	
Reproductive Toxicity In vivo reproductive toxicity study [Other]		NOAEL = 5% (equivalent to 2500 mg/kg bw) Doses: 5%, 10%, 20% in diet. The whole life-span study. Observations were also made on three successive generations. This extensive study included tests on gestation and fertility, mortality, blood and urine constituents, and histopathology. No abnormalities were found at the 5% level.
Rat	Oral, Feed	
Skin Irritation In vivo skin irritation [Other]		Not irritating (100% Polysorbate 80 applied under occlusion from 15mins to 4hrs to human volunteers. 1 positive reaction from 29 volunteers.)
Human	Dermal	
Skin Irritation In vivo skin irritation [Other]		Non to minimal irritating 100% Polysorbate 80 applied. 6 rabbits: PII: 0.0, no signs of irritation. 9 rabbits: PII 0.17 (max = 4.0), minimal irritation
Rabbit	Dermal	
Skin Sensitisation Maximisation Test [Other]		Not sensitising. Polysorbate 80 tested in guinea pigs by repeated intradermal infections of a 0.1% in saline followed by a challenge dose after 2 weeks. There was no indication of sensitisation reported.
Guinea Pig	Dermal	
Skin Sensitisation Repeat Insult Patch Test (RIPT) [Other]		Minimal irritation; no sensitisation. 2.5% Polysorbate 80 in cream. 210 subjects.
Human	Dermal	

ANNEX II - INGREDIENT DATA

Substance:	Salicylic Acid		**Concentration in Product:**	0.09%	
CAS:	69-72-7		**Dermal Exposure Level:**	.00020505	mg/cm^2
Function:	Antidandruff; Hair conditioning; Keratolytic; Masking; Preservative; Skin conditioning		**Daily Body Burden:**	0.0010800000mg/kg	

Chemical Structure



Physical/Chemical Characteristics

Appearance	Fine white crystals	Melting Point	158°C
Boiling Point	211°C	Odour	Slight phenolic
Flash Point	157°C	pH	2.4
Log Kow	2.21	Specific Gravity	1.44
Molecular Mass	138.12		

Toxicological Summary

The below information is a summary of the toxicological profile for this raw material, including a description of general hazards associated with the material as well as discussion of the most critical studies relating to the overall safety in use of this substance/mixture in consumer products. Details of the available toxicological data can be found overleaf.

Overall Toxicity Review:

A lipophilic monohydroxybenzoic acid, a type of phenolic acid, and a beta hydroxy acid. A common OTC medication, especially for acne treatment. In cosmetics, it is commonly used as a preservative, as well as being an antidandruff, hair conditioning, keratolytic, masking, and skin conditioning agent.

It is approved in EU as a cosmetic preservative at up to 0.5% (EC/1223/2009 , annex V/3). When incorporated with functions other than a preservative, the regulation allows its use at up to 3% in rinse-off hair products, and up to 2% in other products, except body lotion, eye shadow, mascara, eyeliner, lipstick, roll-on deodorant (III/98). For all cases, the ingredient is not to be used in products for children under 3 years of age, not to be used in oral products and applications that may lead to exposure of the end-user's lungs by inhalation. It should also be noted that for purposes other than inhibiting the development of micro-organisms in the product, this has to be apparent from the presentation of the product.

The ingredient is not expected to be dermally irritating or sensitising, but has been demonstrated to produce irreversible ocular damage when applied neat to rabbit's eyes.

It is demonstrated to be harmful if swallowed (above certain levels), but not toxic from acute dermal exposures based on animal data. Repeated dermal exposure also identified no relevant toxicological effects, but repeated oral consumption of significant levels of this substance would induce salicylism, marked by ringing in the ears, nausea, and vomiting. Oral exposure during gestation is associated with fetal abnormalities. Based on in-vitro and in-vivo data, the ingredient is not expected to be genotoxic or carcinogenic.

A NOAEL of 75 mg/kg bw/day, based on oral reproductive toxicity data in rats, was chosen as the point of departure for assessment (SCCNFP, 2002)

The ingredient is readily absorbed when applied to human skin, but the absorption is strongly dependent on the vehicle composition, pH, structure of the skin, conditions of the application on the skin. SCCS opinion (2019) estimates a dermal absorption rate of 60% for Salicylic acid.

In 2018, the Cosmetic Ingredients Review (CIR) Expert Panel reported the use of up to 2% in leave-on cosmetics, up to 30% in rinse off cosmetics, and concluded it is safe in cosmetics in the practices of use and concentration described in the safety assessment, when formulated to be non-irritating.

In 2002, the SCCNFP (now known as SCCS) considered that salicylic acid is safe for "other uses" than as a preservative, at a concentration up to 2.0 % for the leave-on and rinse-off cosmetic products and at a concentration up to 3.0 % for the cosmetic rinse-off hair products.

In 2019, the SCCS considers salicylic acid safe when used as preservative at a concentration of 0.5 % in cosmetic products considering its current restrictions in place. The SCCS opinion is not applicable to any oral products, nor to sprayable products that could lead to exposure of the consumer's lungs by inhalation. The SCCS also considers salicylic acid safe when used for purposes other than preservative at a concentration up to 3.0 % for the cosmetic rinse-off hair products and up to 2.0 % for other products, considering its current restrictions in place. However, in body lotion, eye shadow, mascara, eyeliner, lipstick and roll on deodorant applications, salicylic acid is considered safe up to 0.5 %. The SCCS position is that these levels are inclusive of any use of salicylic acid, i.e. should not exceed the stated levels with additional use as a preservative. Moreover, the conclusions of this SCCS Opinion refer only to Salicylic Acid and should not be applied to other salicylates or salicylic acid salts (SCCS 2019).

When used at typical levels within a consumer product and within the legal limits of relevant countries of sale, this material is unlikely to pose a risk of significant adverse effects.

References

Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products (Text with EEA relevance)

SCCNFP, 2002. Opinion Of The Scientific Committee On Cosmetic Products And Non-Food Products Intended For Consumers Concerning Salicylic Acid. Report No. SCCNFP/0522/01. Available at: http://ec.europa.eu/health/ph_risk/committees/sccp/documents/out170_en.pdf

SCCS 2019. Opinion on Salicylic acid Subbmission I. Report No. SCCS/1601/18. Available at: https://ec.europa.eu/health/sites/health/files/scientific_committees/consumer_safety/docs/sccs_o_223.pdf

Margin(s) of Safety

Maximum Recommended Exposure	0.5000%	**Exposure from Product**	0.09000000%	**Margin of Exposure**	5.56
Point of Departure - Animal Study:	75.0000mg/kg	**Exposure from Product**	0.00108000mg/kg	**Margin of Safety**	69444.4444

ANNEX II - INGREDIENT DATA

Salicylic Acid

Acute Toxicity Acute Oral Toxicity, Lethality [OECD 401, OECD 423, OECD 425]		LD50 = 891 mg/kg bw
Rat	Oral, Gavage	
Acute Toxicity Acute Dermal Toxicity, Lethality [OECD 402]		LD50 > 2000 mg/kg bw
Rat	Dermal	
Eye Irritation Draize [Other]		Highly irritating (Equivalent to Cat. 1 Eye Damage, severe irritation not recovering within 21 days of treatment) [Undiluted, 100mg, unwashed, 21day observation]
Rabbit	Instillation	
Genotoxicity Mammalian chromosome aberration test [OECD 473]		Not clastogenic with and without metabolic activation
In-vitro culture	In vitro exposure	
Genotoxicity Bacterial reverse mutation test (Ames) [OECD 471]		Not mutagenic with and without metabolic activation
Bacteria	In vitro exposure	
Genotoxicity Mammalian cell gene mutation test [OECD 476]		Not mutagenic with and without metabolic activation
In-vitro culture	In vitro exposure	
Genotoxicity Mammalian bone marrow chromosome aberration test [OECD 475]		Did not induce a genotoxic effect
Mouse	Intraperitoneal	
Repeated Dose Repeat Dose Dermal Toxicity Study [Other]		NOAEL = 120 mg/kg bw/day (No systemic toxicity was observed other than causing local irritation) [Dose: 10, 20, 40, 120 mg/kg bw/day; 0.5 - 6% salicylic acid in cleansing formulation at 2 ml/kg, 7hrs/day, 5days/week, 91-days]
Rabbit	Dermal	
Repeated Dose Repeat Dose Oral Toxicity Study [Other]		Oral doses of acetylsalicylic acid of 100 mg/kg or higher induce salicylism. Plasma levels are indicative of salicylic intoxication, symptoms are occuring at plasma levels of 35 mg/100 ml or greater.
Human	Oral, NOS	
Reproductive Toxicity In vivo reproductive toxicity study [Other]		NOAEL = 75 mg/kg bw/day (low incidence of skeletal and external malformations, also considered as LOEL, significant fetal abnormalities at higher dose) [Dose: 75, 150, 300 mg/kg bw/day, GD 8-14]
Rat	Oral, NOS	
Skin Irritation Draize Test [OECD 404]		Not irritating [50% (0.5g in 0.5mL water), 4hr exposure, semiocclusive]
Rabbit	Dermal	
Skin Sensitisation Local Lymph Node Assay [OECD 429, OECD 442A, OECD 442B]		Not sensitising (SI for 5, 10, 25% are 0.8, 1.5, 2.5, respectively)
Mouse	Dermal	

SPOT PATCHES (FOR DAYTIME/9 PCS)

ANNEX IV - ADDITIONAL REASONABLY FORESEEABLE EXPOSURES

SPOT PATCHES (FOR DAYTIME/9 PCS)

ANNEX V - RAW MATERIAL SPECIFICATIONS

Substance: Cellulose Gum
CAS: 9004-32-4; 99331-82-5; 9000-11-7

Specification

Cellulose Gum does not have minimum purity specifications set within the EU Cosmetic (or related) Regulations. Manufacturer should ensure that a suitably safe grade is used, including:

≤ 10 ppm Heavy Metals (sum of)

< 0.1% substances classified as H317 (May cause an allergic skin reaction) in accordance with the EU Classification, Labelling & Packaging Regulation (1272/2008)

< 1ppm substances classified as Carcinogenic, Mutagenic or Reproductive Toxins in accordance with the EU Classification, Labelling & Packaging Regulation (1272/2008)

< 10ppm substances Prohibited or Restricted for use under Annex II or Annex III of the EU Cosmetic Regulation (1223/2009)

< 0.1% Substances of Very High Concern (SVHC), as defined under EU REACH Regulation (1907/2006)

Microbiological Specification: TVC ≤ 1,000 cfu/g, absence of specific pathogens

Substance: Hydrogenated Rosin
CAS: 65997-06-0

Specification

Hydrogenated Rosin does not have minimum purity specifications set within the EU Cosmetic (or related) Regulations. Manufacturer should ensure that a suitably safe grade is used, including:

≤ 10ppm Heavy Metals (total sum of)

< 0.1% substances classified as H317 (May cause an allergic skin reaction) in accordance with the EU Classification, Labelling & Packaging Regulation (1272/2008)

< 1ppm substances classified as Carcinogenic, Mutagenic or Reproductive Toxins in accordance with the EU Classification, Labelling & Packaging Regulation (1272/2008)

< 10ppm substances Prohibited or Restricted for use under Annex II or Annex III of the EU Cosmetic Regulation (1223/2009)

< 0.1% Substances of Very High Concern (SVHC), as defined under EU REACH Regulation (1907/2006)

Microbiological Specification: TVC ≤ 1,000 cfu/g, absence of specific pathogens

Substance: Styrene/Isoprene Copolymer
CAS: 25038-32-8

Specification

Styrene Isoprene Styrene Block Copolymer does not have minimum purity specifications set within the EU Cosmetic (or related) Regulations. Manufacturer should ensure that a suitably safe grade is used, including:

≤ 10 ppm Heavy Metals (sum of)

< 0.1% substances classified as H317 (May cause an allergic skin reaction) in accordance with the EU Classification, Labelling & Packaging Regulation (1272/2008)

< 1 ppm substances classified as Carcinogenic, Mutagenic or Reproductive Toxins in accordance with the EU Classification, Labelling & Packaging Regulation (1272/2008)

< 10 ppm substances Prohibited or Restricted for use under Annex II or Annex III of the EU Cosmetic Regulation (1223/2009)

< 0.1% Substances of Very High Concern (SVHC), as defined under EU REACH Regulation (1907/2006)

Microbiological Specification: TVC ≤ 1,000 cfu/g, absence of specific pathogens

Substance: Paraffinum Liquidum (Mineral Oil) - N.O.S.
CAS: 8012-95-1; 8042-47-5; 8020-83-5

Specification

Mineral oil intended for use in cosmetic products should have a full refining history such that it can be shown that the substance from which it is produced is not a carcinogen.

Mineral oil does not have minimum purity specifications set within the EU Cosmetic (or related) Regulations. Manufacturer should ensure that a suitably safe grade is used, including:

≤ 10ppm Heavy Metals (total sum)

< 0.1% substances classified as H317 (May cause an allergic skin reaction) in accordance with the EU Classification, Labelling & Packaging Regulation (1272/2008)

< 1ppm substances classified as Carcinogenic, Mutagenic or Reproductive Toxins in accordance with the EU Classification, Labelling & Packaging Regulation (1272/2008)

< 10ppm substances Prohibited or Restricted for use under Annex II or Annex III of the EU Cosmetic Regulation (1223/2009)

< 0.1% Substances of Very High Concern (SVHC), as defined under EU REACH Regulation (1907/2006)

Microbiological Specification: TVC ≤ 1,000 cfu/g, absence of specific pathogens

When used in lip care or oral product, the following grade should be met according to Cosmetics Europe No 14: mineral hydro carbons.

Waxes with Viscosity ≥ 11 cSt at 100°C; Carbon number ≥ 25 at the 5% boiling point; Average molecular weight ≥ 500

High and medium and low viscosity oils class I with Viscosity ≥ 8.5 cSt at 100°C; Carbon number ≥ 25 at the 5% boiling point; Average molecular weight ≥ 480

Substance: Polysorbate 80
CAS: 9005-65-6

Specification

Polysorbate 80 does not have minimum purity specifications set within the EU Cosmetic (or related) Regulations. Manufacturer should ensure that a suitably safe grade is used, including:

≤ 10ppm Heavy Metals (sum of)

< 0.1% substances classified as H317 (May cause an allergic skin reaction) in accordance with the EU Classification, Labelling & Packaging Regulation (1272/2008)

< 1ppm substances classified as Carcinogenic, Mutagenic or Reproductive Toxins in accordance with the EU Classification, Labelling & Packaging Regulation (1272/2008)

< 10ppm substances Prohibited or Restricted for use under Annex II or Annex III of the EU Cosmetic Regulation (1223/2009)

< 0.1% Substances of Very High Concern (SVHC), as defined under EU REACH Regulation (1907/2006)

Microbiological Specification: TVC ≤ 1,000 cfu/g, absence of specific pathogens

Substance: Salicylic Acid
CAS: 69-72-7

Specification

Salicylic Acid not have minimum purity specifications set within the EU Cosmetic (or related) Regulations. Manufacturer should ensure that a suitably safe grade is used, including:

Minimum Purity: 99%

≤ 10 ppm Heavy Metals (sum of)

< 0.1% substances classified as H317 (May cause an allergic skin reaction) in accordance with the EU Classification, Labelling & Packaging Regulation (1272/2008)

< 1ppm substances classified as Carcinogenic, Mutagenic or Reproductive Toxins in accordance with the EU Classification, Labelling & Packaging Regulation (1272/2008)

< 10ppm substances Prohibited or Restricted for use under Annex II or Annex III of the EU Cosmetic Regulation (1223/2009)

< 0.1% Substances of Very High Concern (SVHC), as defined under EU REACH Regulation (1907/2006)

Microbiological Specification: TVC ≤ 1,000 cfu/g, absence of specific pathogens

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