Cosmetic Product Safety Assessment

Playboy Like A Queen Body Mist 21 GL

PRODUCT DETAILS

Type of Product: Body Mist (SCCS) | Leave on

Physical Form: Liquid

Client: SA Designer Parfums Ltd
Amertrans Park
Watford, Hertfordshire
WD24 7JG

Product Reference
764-1.01

CONCLUSIONS & RECOMMENDATIONS

Required Safety Labelling

Flammable Liquid. Keep away from sources of heat / sparks /open flames and Hot surfaces when in use.
Keep out of reach of children

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. Assuming the necessary warnings stated in the safety assessment are included on the product packaging it will give consumers the level of safety they can reasonably expect.

This product complies with the safety requirements of the Armonización de Legislaciones en materia de Productos Cosméticos (Harmonised Legislation on cosmetic products) Article 2 and 3 of Decision 516 for the ANDEAN Community. Manufacturer must ensure that the product complies with Decision 516 in all other respects and that a Compulsory Sanitary Notification with all other necessary documentation is submitted to the Competent National Authority and presented to the first Member Country where the product is to be marketed.

This product meets the requirements of the Australian Department of Health, Australian Industrial Chemicals Introduction Scheme (AICIS) and the Therapeutic Goods (Excluded Goods) Determination 2018.

To the best of our knowledge, we are not aware of specific regulations governing the safety and sale of Cosmetics within the majority of the Central America Countries; these countries adopted Resolution 124-2004 COMIECO XXIX of October 19, 2004 which states it adopts lists of of Prohibited Substances and Controlled Substances contained in the consolidated text of the Office for Official Publications of the European Communities and the list issued by the United States, taking prominence the least restrictive list. In addition, the following documents were adopted: Cosmetic Ingredient Review and International Cosmetic Ingredient Dictionary and Handbook by CTPA. As this item is in compliance with the EU Cosmetic Regulation (as amended) it should be considered safe for its intended use.

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.

This product complies with the requirements of the GCC Standardization Organization (GSO) Standard (1943/ 2016 (E)) on cosmetic product safety.

This formulation complies with the requirements in India of The Drugs and Cosmetics Act and Rules: The Drugs and Cosmetics Act, 1940 (as amended). Registration and Licensing by the Indian Authorities may be required before the product can be placed on the market.

This product meets the requirements of the Japanese Standards for Cosmetics, Ministry of Health and Welfare Notification No.331 of 2000.

The formulation of this product meets the restrictions outlined within the Mexican 'Agreement determining banned and restricted substances in the manufacture of perfume and beauty products' and is considered safe for its intended use. The manufacturer must ensure that the product is made in accordance with GMP and that any additional registrations are completed prior to placing the item(s) on the market within Mexico.

To the best of our knowledge, we are not aware of specific regulations governing the safety and sale of Cosmetics within the majority of the Middle Eastern Countries; although Saudi Arabia do have regulations based upon those used within the EU. As this item is in compliance with the EU Cosmetic Regulation (as amended) it should be considered safe for its intended use.

The Statute for Control of Cosmetic Hygiene requires that a product intended for sale within Taiwan be safe for use and a license / certificate for sale must be obtained from the Central Health Authorities. Direct contact with the Taiwan authorities should be made, in order to ensure suitable certification can be gained.

This product complies with the requirements set in Regulation 37, Schedule 34 of the Product Safety and Metrology (Amendment) (EU Exit) Regulation 2020. The product must be manufactured according to Good Manufacturing Practice.

Russia, Belarus and Kazakhstan are part of the Eurasian Economic Union (EEU), which has implemented Legislation as per TPTC 009/2009 on the safety of Cosmetic Products. This largely follows the EU Cosmetic Regulation, but requires submission of a dossier of information to the Relevant Authorities. This product is considered safe for use within the EU and complies with the EU Cosmetics Regulation and as such is expected to meet the requirements of TPTC 009/2009.

Turkey is working towards membership of the European Union and working towards convergence of Laws with the EU Regulations and Directives. Compliance with EU Regulations is therefore considered to be indicative of compliance in Turkey.

This product complies with the requirements of the Singapore Health Products Act 2007 (ACT 15 OF 2007) Health Products (Cosmetic Products — ASEAN Cosmetic Directive) Regulations 2007 (Based on the ASEAN Guidelines for the Safety Assessment of a Cosmetic Product - Final Version as adopted by Brunei, Cambodia, Indonesia, Laos, Malaysia, Myanmar, Philipines, Singapore, Thailand and Vietnam). The product must be manufactured according to Good manufacturing Practice, utilising suitable Cosmetic Grades of Raw Materials.

The ingredients are legally permitted according to the Health Canada's List of Prohibited and Restricted Cosmetic Ingredients (The Cosmetic Ingredient "Hotlist") 2005 as amended, and must comply with the regulatory requirements of the Food and Drugs Act, R.S.C. 1985, c.F-27, Cosmetic Regulations (C.R.C., c. 869) as amended, and the Consumer Packaging and Labelling Act. The product must be made in accordance with Canadian Good Manufacturing Practices.

This formulation complies with the requirements of the Safety and Technical Standards for Cosmetics (2015 edition) and the Inventory of Existing Cosmetic Ingredients in China (IECIC). This assessment only indicates the ingredient acceptability and does not constitute a full safety assessment for China. In order to register cosmetic products in China a full safety assessment in Chinese must be conducted.

According to Egyptian Drug Authority (EDA) website, registration of cosmetics in Egypt needs to comply with Regulations of European Directive 76/768 EEC, COLIPA, FDA and publications of CIR. Compliance with EU, US and Canada Regulations is therefore considered to be indicative of compliance in Egypt.

Cosmetics are covered by chapter 456 of the Consumer Goods Safety Ordinance, which outlines that products must generally be safe. As this product complies with a number of Cosmetics Regulatory standards (including the EU and US Regimes) it is considered safe for its intended use and in compliance with Hong Kong requirements.

It is understood that Israel follow the EU in terms of restrictions on ingredients that are used in Cosmetics. 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.

This product complies with the requirements of the 'Korean Cosmetics Act' (as published under Food and Drug Administration Announcement No. 2012-137) and the 'Cosmetics tar dye types and standards and test methods' (as published under KFDA Notification No. 2014-105, 2014.3.21). Manufacturers / Importers are recommended to contact the KFDA and KPTA in order to complete any further testing and required pre-market registrations.

The formulation of this product meets the restrictions outlined within the 'MERCOSUR Technical Regulations on a list of substance that hygiene products, cosmetics and perfumes must not contain', the 'MERCOSUR list of substances allowed to dye personal hygiene products, cosmetics and fragrances' and the 'MERCOSUR list of permitted preservatives in personal hygiene products, cosmetics and fragrances'. The product is also considered safe for its intended use. The manufacturer must ensure that the product is made in accordance with GMP and that any additional registrations are completed prior to placing the item(s) on the market within each of the Mercosur countries.

This product complies with the requirements set out in the Hazardous Substances and New Organisms Act 1996: Cosmetic Products Group Standard 2006. To the best of our knowledge none of the ingredients included in this product are prohibited for use in Cosmetics within New Zealand. Any fragrances used within a Cosmetic Product intended for sale in NZ must comply with IFRA Guidelines.

South Africa follows the general EU Requirements in terms of safety and allowable materials in an industry initiative controlled by the South African Cosmetics Industry Association. As this product complies with the EU Cosmetics Regulation EC No. 1223/2009 , this product is considered acceptable for sale in South Africa. Additional Registration may be required before sale and it is recommended to contact the local authorities before placing the item on the market.

The ingredients are legally permitted as per the Federal Food, Drug, and Cosmetic Act (FD&C Act - CFR21) and its amendments. They must comply with the relevant purity

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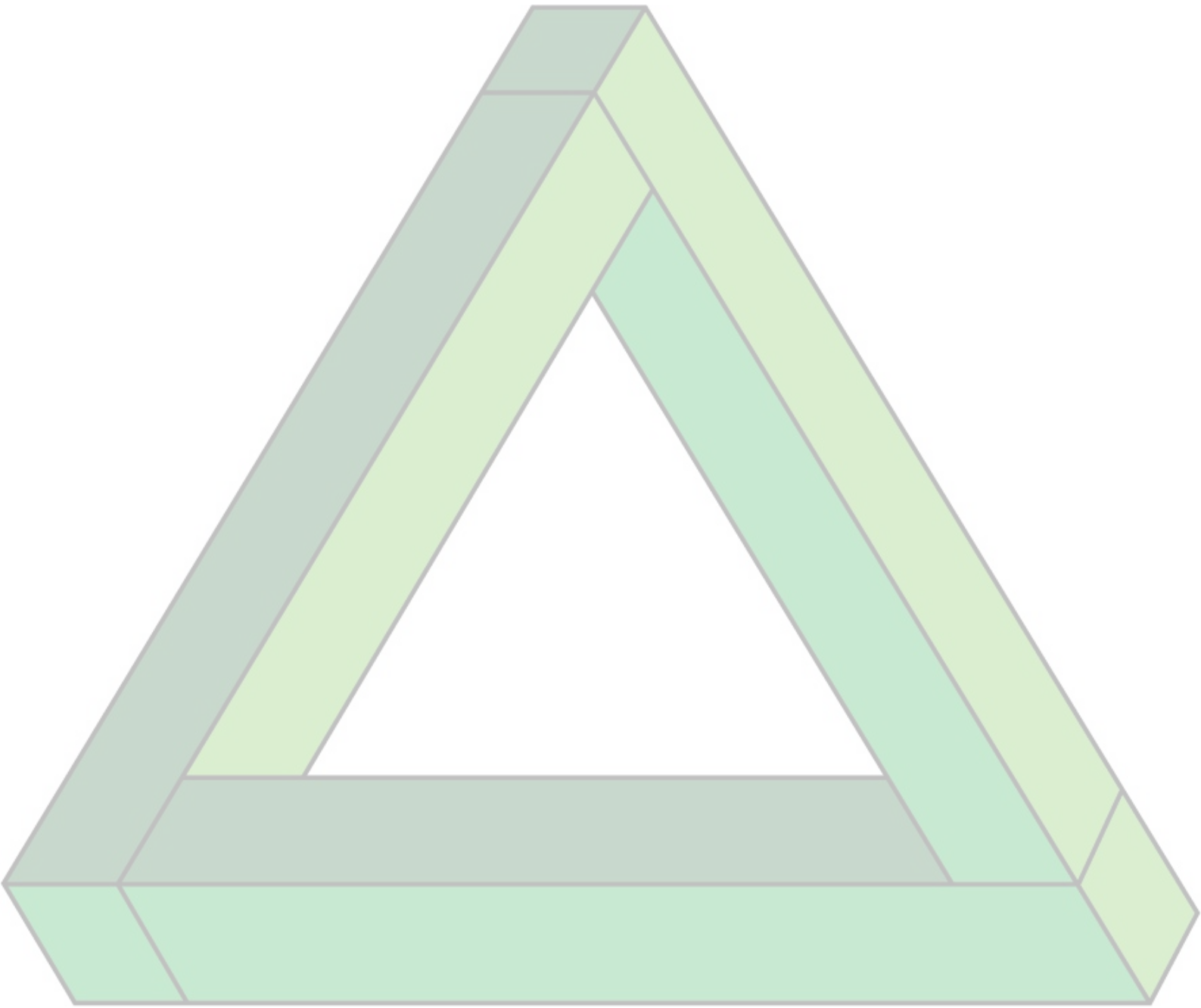
standards. The product must be manufactured in accordance with FD&C guidance on Good Manufacturing Practice.

Switzerland cosmetic legislation follows closely that of the EU and as this product complies with the EU Cosmetic Regulation (1223/2009) it should be acceptable for sale within Switzerland. It is generally not required to perform a pre-market notification of Cosmetic Products in Switzerland. However it is recommended that the manufacturer should contact the Swiss authorities to ensure no specific registrations or notifications are required and that there are no country specific prohibitions on any materials.



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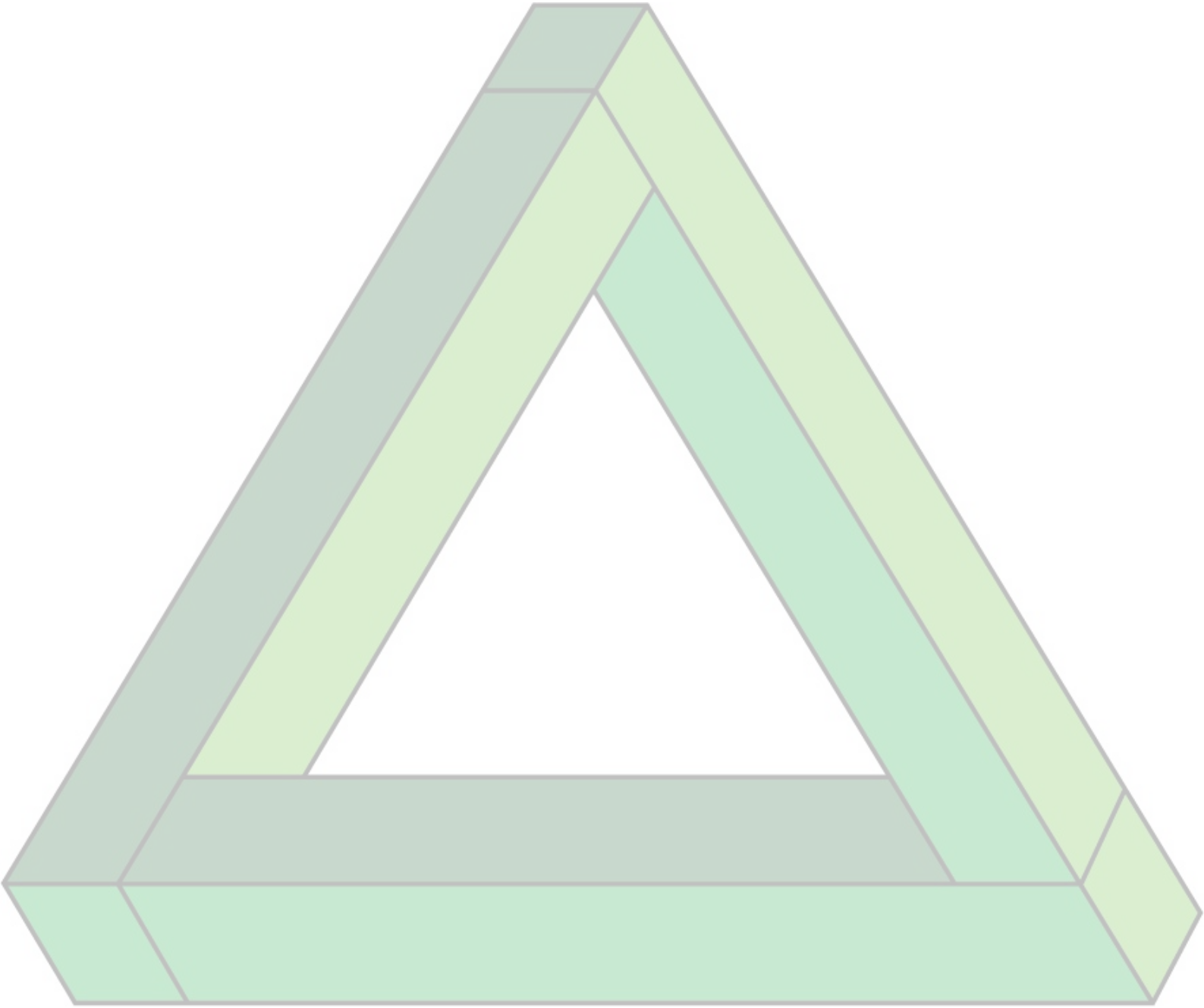
QUANTITATIVE & QUALITATIVE COMPOSITION

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]
Alcohol Denat	64-17-5	56.31
Aqua	7732-18-5	40.39
Perfume - DRIVE ME NUTS - symrise	Mixture	2.5
Propylene Glycol	57-55-6; 4254-14-2	.5
Glycerin	56-81-5; 8013-25-0	.3

Review of the Fragrance & Essential Oil components of this product indicate that the following allergens need to be declared on the product label: Alpha-Isomethyl Ionone. Benzyl salicylate. Coumarin. Geraniol. Hydroxycitronellal. Linalool.



PHYSICAL / CHEMICAL CHARACTERISTICS AND STABILITY OF THE COSMETIC PRODUCT

Appearance:	Liquid	**Viscosity:**	Not Provided
Odour:	Characteristic - Perfumed	**Water Solubility:**	Not Provided
Melting Point:	Not Provided	**Log Kow:**	Not Provided
pH:	Not Provided	**Particle Size:**	Not Applicable

Specific Gravity: 0.900 (+/-0.005)

Limited physical-chemical data were supplied for review. The manufacturer/organisation responsible for placing the product on the market must ensure the physical-chemical properties of the product do not significantly impact on the toxicological profile of the product under normal conditions of use.

Product Stability:

A 3 month stability test was carried out at 4°C, 40°C, room temperature and in light conditions. The product was observed for weight loss, changes in appearance, odour and density. The product passed the test according to 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

Documentation surrounding microbiological specifications have not been provided for review.

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

This product contains high levels of solvent materials that will produce an environment hostile to bacterial growth. Under normal conditions of usage and storage it would not be expected to support significant levels of microbial growth. 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.

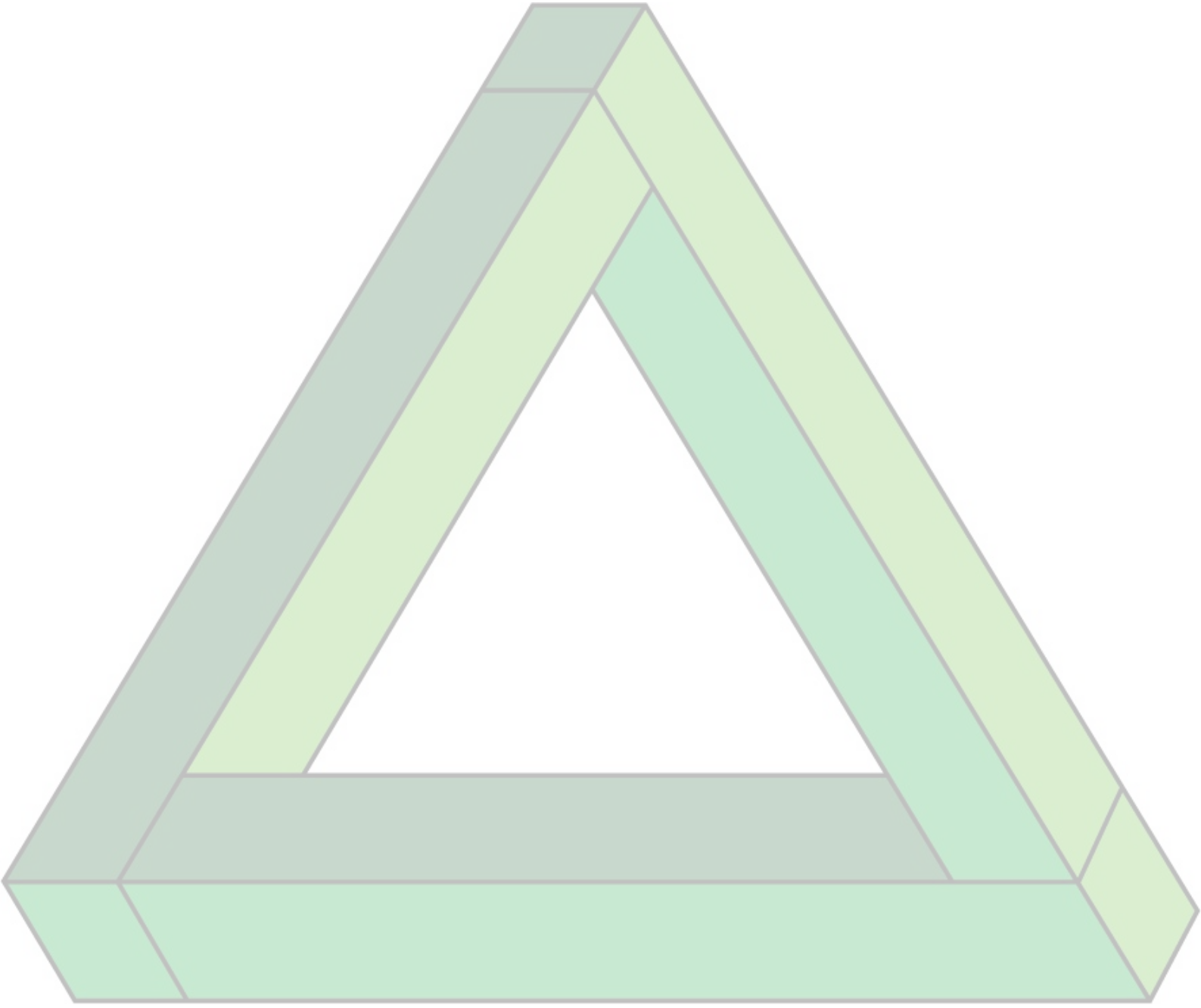
Substances	CAS Number	[Product]

Packaging Material: PET

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 3 month compatibility test was carried out at 4°C, 40°C, room temperature and in light conditions. The product was observed for weight loss, changes in appearance, odour and density. The product packaging passed the test according to manufacturer's criteria.

Product Durability: PAO: 36 months



NORMAL & REASONABLY FORESEEABLE USE

Normal Use:

Body Mist (SCCS) | Leave on

Manufacturers Instructions for Use:

No specific instructions for use were provided for review.

Reasonably Foreseeable Uses:

Facial Mist / Spritz

EXPOSURE TO THE COSMETIC PRODUCT

Intended Consumer:	Adult Males & Females (16+)	Minimum Expected Body Weight	60kg
Single Exposure:	8 g | 1 x Day	Diluted in use:	No
Retention Factor:	1	Retained Exposure:	133.333 mg/kg/day

Exposure to Neat Product:

Body Site(s):	Whole Body
Surface Area:	15,521 cm^2
Exposure Level:	0.515 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

Details of previous sales and complaints data has not been supplied for review. This assessment is, therefore, completed on the assumption that no previous health-related complaints have been reported by consumers. If this is incorrect the manufacturer/responsible person must notify Delphic HSE of all such reported complaints so that the assessment can be updated.

Going forward the 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

Details of user trials/additional product safety testing have not been supplied for review, and this assessment is conducted on the basis that no such testing has been undertaken. Should this be inaccurate, or additional testing be conducted in the future, Delphic HSE should be notified of the details of such testing so this safety assessment can be updated accordingly.

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. Assuming the necessary warnings stated in the safety assessment are included on the product packaging it will give consumers the level of safety they can reasonably expect.

This product complies with the safety requirements of the Armonización de Legislaciones en materia de Productos Cosméticos (Harmonised Legislation on cosmetic products) Article 2 and 3 of Decision 516 for the ANDEAN Community. Manufacturer must ensure that the product complies with Decision 516 in all other respects and that a Compulsory Sanitary Notification with all other necessary documentation is submitted to the Competent National Authority and presented to the first Member Country where the product is to be marketed.

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This product complies with the requirements set out in the Hazardous Substances and New Organisms Act 1996: Cosmetic Products Group Standard 2006. To the best of our knowledge none of the ingredients included in this product are prohibited for use in Cosmetics within New Zealand. Any fragrances used within a Cosmetic Product intended for sale in NZ must comply with IFRA Guidelines.

South Africa follows the general EU Requirements in terms of safety and allowable materials in an industry initiative controlled by the South African Cosmetics Industry Association. As this product complies with the EU Cosmetics Regulation EC No. 1223/2009 , this product is considered acceptable for sale in South Africa. Additional Registration may be required before sale and it is recommended to contact the local authorities before placing the item on the market.

The ingredients are legally permitted as per the Federal Food, Drug, and Cosmetic Act (FD&C Act - CFR21) and its amendments. They must comply with the relevant purity standards. The product must be manufactured in accordance with FD&C guidance on Good Manufacturing Practice.

Switzerland cosmetic legislation follows closely that of the EU and as this product complies with the EU Cosmetic Regulation (1223/2009) it should be acceptable for sale within Switzerland. It is generally not required to perform a pre-market notification of Cosmetic Products in Switzerland. However it is recommended that the manufacturer should contact the Swiss authorities to ensure no specific registrations or notifications are required and that there are no country specific prohibitions on any materials.

LABELLED WARNINGS & INSTRUCTIONS FOR USE

Flammable Liquid. Keep away from sources of heat / sparks /open flames and Hot surfaces when in use.
Keep out of reach of children

REASONING

A body mist spray for adult males & females(16+).

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 Inok, so gredients 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 product contains a high level of denatured alcohol. Based on the alcohol content of the product it will be highly narcotic. Although there will be some inhalation of the product when it is used, much of the alcohol component will readily evaporate and use as a EDP will minimise the amount that is available for inhalation or ingestion at any point in time. The denaturant component will also make the end product unpalatable reducing incidental ingestion. Resultantly only minor levels of inhalation are predicted under normal conditions of use and the levels are not expected to produce adverse effects. Due to the high alcohol content the product may cause stinging if sprayed into the eyes or damaged skin.

The concentration of the fragrance ingredients 2-(Isobutyl)-4-hydroxy-4-methyl tetrahydropyran and 5-(2,2,3-Trimethyl-3-cyclopentenyl)-3-methylpentan-2-ol are higher than would normally be considered safe based solely on the % in the final product. However, it is the amount of material per unit area of skin that is the key factor in determining allergy and the safe levels in terms of skin loading (micrograms per cm2), has been determined as: 900 and 500, respectively. The calculated skin loading levels for this product of these ingredients are both 0.64 micrograms per cm2. This gives margin of safety of 1397 for 2-(Isobutyl)-4-hydroxy-4-methyl tetrahydropyran, and 776 for 5-(2,2,3-Trimethyl-3-cyclopentenyl)-3-methylpentan-2-ol. Based on the margins of safety values, the product is not expected to pose adverse reactions in normal population but sensitive individuals may react to the product.

The fragrance contains Ocean Propanal (CAS 1205-17-0) at up to 0.025% in the final product, which has been self classified as H361 (reproductive toxicant). Ocean propanal has no official Classification under CLP regulation. Using current available information, such as the levels present in this product and its foreseeable exposure, the amount of the Ocean propanal allergen in the product is considered acceptable in terms of safety. A NOAEL of >300 mg/kg/day (highest tested dose) for systemic toxicity and 50 mg/kg/day for dermal irritation, was identified from from a 90-day dermal toxicity study conducted to OECD Test Guideline 411 in rats, conducted in 2007 (ECHA registration dossier of Ocean Propanal (Cas number 1205-17-0)). This study included an assessment of male reproductive morphology/function as well as female oestrous cycling. Mean sperm count, total sperm count and sperm morphology did not differ with dose or between treated and control rats. Oestrous cycles did not differ with dose or between control and test item treated rats. Using 50 mg/kg/day as the more conservative point of departure, the MoS will be >100 and It is not expected to cause adverse effects at the concentration present in the current product.

Some of the ingredients are not listed on some national inventories (see Annex I) and may require further notification prior to exporting the product. It is recommended to first contact the raw material supplier(s), to check the registration process of this ingredient. Eventually, the relevant authorities should be consulted

(It is noted that the sale of Solvents, particularly narcotic / intoxicating ones, to children (including teenagers) is controlled / restricted in a number of countries. As such whilst the product could be safe for a teenager to use, the sale of such a product to teenagers may not be allowable in some countries (and is generally always prohibited if there is concern over abuse of the product). This would be a concern for retailers in the countries of sale to address on the basis of local laws.)

The manufacturer must ensure that the ingredients meet regulatory purity criteria and that the final products are of suitably safe cosmetic grade and within the specification mentioned in this report.

Overall, assuming suitable grades of material are used during manufacture and the product is labelled appropriately, 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

The high alcohol content may cause a brief stinging sensation when the product is applied to newly shaved skin.
Exposure to this product is unlikely to result in photo-toxic effects.
There are low levels of substances present in this product which are known to cause an allergic reaction. The concentrations are sufficiently low not to present a risk of inducing allergy. However people already sensitised may show an adverse reaction when using this product. The identity of these ingredients will be shown on the label, enabling those potentially affected to avoid contact.
Unlikely to produce systemic toxicity following skin contact.

Eye Toxicity - Neat Product

May cause significant eye irritation and discomfort.

Oral Toxicity - Neat Product

The presence of Bitrex in this product should reduce the likelihood of significant quantities being ingested
The product contains ingredients that if swallowed, may cause depression of the central nervous system. Depending on dose, symptoms could include drowsiness, unconsciousness and in extreme cases possibly even death.

Inhalation Toxicity

An intermittent spray which will result in a mixture of particulates / droplets
Inhalation of the product may cause irritation of the nose and upper respiratory tract.

Toxicological & Regulatory Assessor

Sam Loveridge BSc, MSc, MRSB, CBiol, ERT 27 Jan 2021

This report consists of 8 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 ug/cm^2 terms.

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 ug/cm2)
Human Repeat Open Application Test (HROAT, in either percentage or ug/cm2)
Human Maximisation Test (HMT, in either percentage or ug/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.

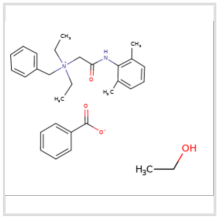
ANNEX I - REGULATORY CONTROLS

Substance: Alcohol Denat

CAS: 64-17-5

Function: Antifoaming; Antimicrobial; Astringent; Masking; Solvent; Viscosity Controlling

Concentration in Product: 56.31%



Regulatory Listings

Europe:

EINECS: 200-578-6

EU GHS Classification: Flam. Liq. 2 H225 Highly flammable liquid and vapour

REACh Annex XVII: Not Controlled

REACh SVHC: Not Controlled

EU Cosmetic Regulation: Not Controlled

EU INCI Name: Alcohol Denat.

EN71 Toy Standards: Not controlled in EN71 Parts 7 and 9

EU Toy Directive: Not controlled

EU Biocides Regulation: Permitted for product type- 1, 2 and 4
No longer supported for PT 11, 18, 19, 20, 22, 05, 06, 08, 09 (Phased out on 1st September 2006)
No longer supported for PT 03 (Phased out on 1st March 2009)

EU Detergents Regulation: Not Controlled

United Kingdom

UK Cosmetic Regulation: Not Controlled

UK Toy Legislation: Not controlled

ANDEAN Community

Cosmetic Regulation: Not Controlled

ASEAN Countries

Cosmetic Regulation: Not Controlled

Australia

AICIS Inventory: Listed

Inventory Obligations: Listed

SUSMP: Not Listed

Cosmetic Regulation: Not Controlled

Canada

DSL: Listed on the Canadian DSL Inventory

WHMIS: B2 - Flammable liquid ; D2B - Poisonous and infectious material - Other effects - Toxic

Cosmetic Regulation: Not Controlled

OTC Monographs: Ethanol at 60 to 80% is listed in the Antiseptic Skin Cleansers (Personal Domestic Use).

China

IECSC: Listed

Cosmetic Regulation: Listed on IECIC inventory 2015 - Highest use level of approved products = 94.5%(2014)
Not controlled

Eurasian Economic Community

Cosmetic Regulation: Not controlled

GCC Countries

Cosmetic Regulation: Not Controlled

Hong Kong Not Controlled

Cosmetic Regulation:

India

Cosmetic Regulation: Not controlled

Japan

Chemical Inventory: Listed

Cosmetic Regulation: Not Controlled

Korea

Chemical Inventory: Listed

Cosmetic Regulation: Not Controlled

MERCOSUR

Cosmetic Regulation: Not Controlled

Mexico

Cosmetic Regulation: Not Controlled

Morocco

Cosmetic Regulation: Not controlled

New Zealand

Cosmetic Regulation: Not controlled

South Africa

Cosmetic Regulation: Not Controlled

Taiwan

Chemical Inventory: Not Controlled

Turkey

Cosmetic Regulation: Not controlled

USA

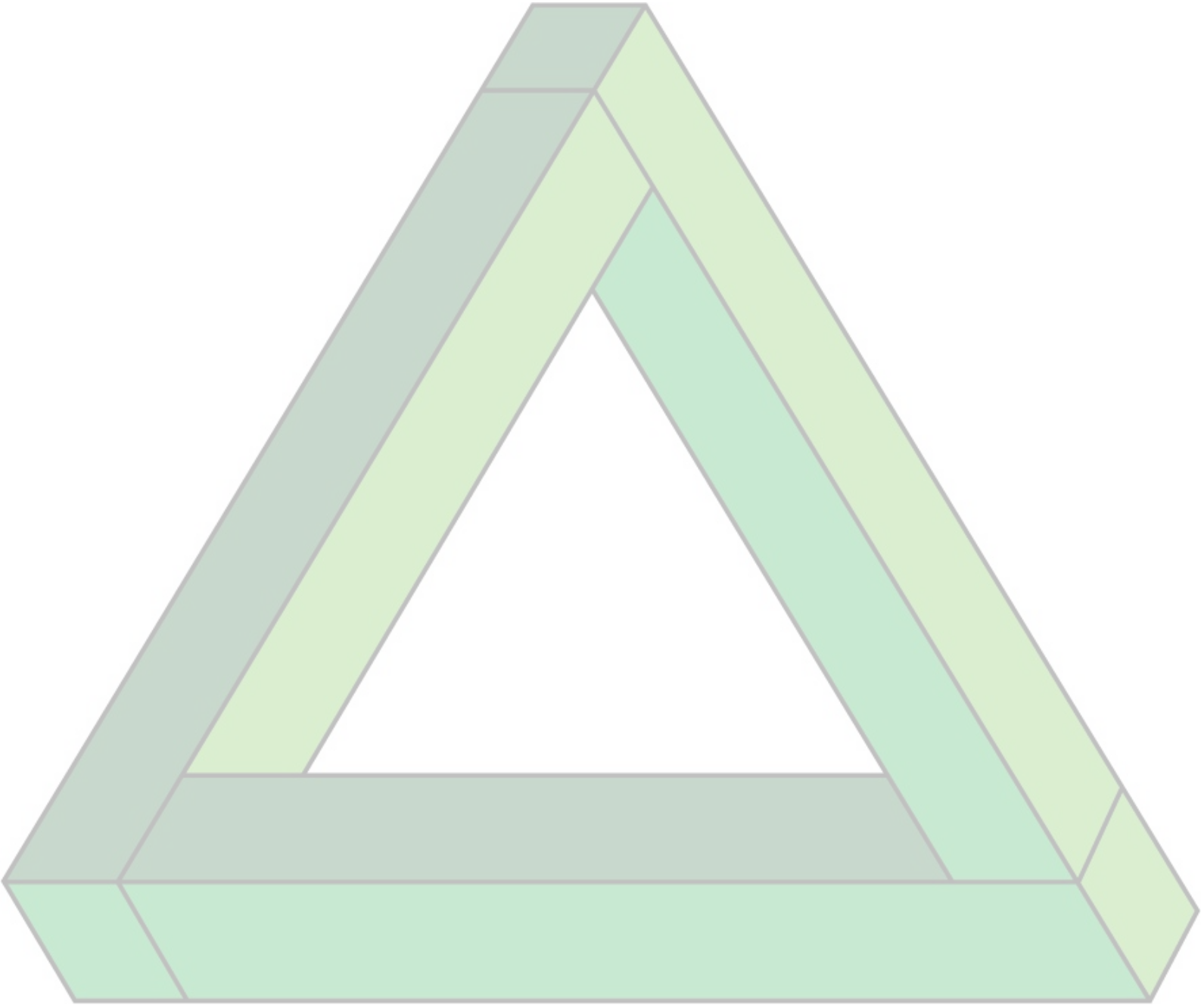
Chemical Inventory: Listed as existing; Ethanol

California Prop 65: Listed if present in alcoholic beverages

FDA OTC Monograph: Controlled
Alcohol 60-95% (v/v) in an aqueous solution denatured according to Bureau of Alcohol, Tobacco and Firearms regulations in 27 CFR

part 20 (eg. SDA-40A or 40B): Eligible active ingredient for use in consumer antiseptic rubs under 84 FR 14847, Publication Date: April 12, 2019

Cosmetic Regulation: Alcohol Denat.
Not Controlled

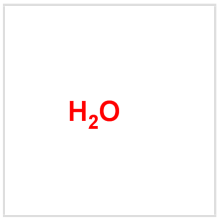


Substance: Aqua

CAS: 7732-18-5

Function: Solvent

Concentration in Product: 40.39%



Regulatory Listings

Europe:

EINECS: 231-791-2

EU GHS Classification: Unclassified

REACh Annex XVII: Not Controlled

REACh SVHC: Not Controlled

EU Cosmetic Regulation: Not Controlled

EU INCI Name: Aqua

EN71 Toy Standards: EN71 - 7 and EN71 - 9 Not Controlled

EU Toy Directive: Not Controlled

EU Biocides Regulation: Not Registered for any Biocidal Uses

EU Detergents Regulation: Not Controlled

United Kingdom

UK Cosmetic Regulation: Not Controlled

UK Toy Legislation: Not Controlled

ANDEAN Community

Cosmetic Regulation: Not Controlled

ASEAN Countries

Cosmetic Regulation: Not Controlled

Australia

AICIS Inventory: Listed

Inventory Obligations: Not Listed

SUSMP: Not Listed

Cosmetic Regulation: Not Controlled

TGA Controls: POTABLE WATER - Listed as an excipient under Therapeutic Goods (Permissible Ingredients) Determination (No. 1) 2020, Volume 5, entry 4053.
PURIFIED WATER - Listed as an excipient under Therapeutic Goods (Permissible Ingredients) Determination (No. 1) 2020, Volume 5, entry 4202.

Canada

DSL: Listed on the Canadian DSL

WHMIS: Listed. Not controlled as Hazardous according to WHMIS

Cosmetic Regulation: Not Controlled

OTC Monographs: Not Controlled

China

IECSC: Listed

Cosmetic Regulation: Not controlled. Reported usage level on the IECIC 2013 at up to 94.78%
Listed on IECIC Ref 06259

Eurasian Economic Community

Cosmetic Regulation: Not controlled

GCC Countries

Cosmetic Regulation: Not Controlled

Hong Kong Not Controlled

Cosmetic Regulation:

India

Cosmetic Regulation: Not controlled

Japan

Chemical Inventory: Listed

Cosmetic Regulation: Not Controlled

Korea

Chemical Inventory: Listed

Cosmetic Regulation: Not Controlled

MERCOSUR

Cosmetic Regulation: Not Controlled

Mexico

Cosmetic Regulation: Not Controlled

Morocco

Cosmetic Regulation: Not controlled

New Zealand

Cosmetic Regulation: Not Controlled

South Africa

Cosmetic Regulation: Not Controlled

Taiwan

Chemical Inventory: Not Controlled

Turkey

Cosmetic Regulation: Not controlled

USA

Chemical Inventory: Listed as existing; Water

California Prop 65: Not Listed

FDA OTC Monograph: Controlled
Active ingredient for OTC Eyewashes according to 21CFR349.20: The product also contains suitable tonicity agents to establish

isotonicity with tears, suitable agents for establishing pH and buffering to achieve the same pH as tears, and a suitable preservative agent.

Cosmetic Regulation: Water
Not Controlled

Substance: Perfume - DRIVE ME NUTS - symrise
CAS: Mixture
Function: Perfuming
Concentration in Product: 2.5%

No Structure Available

Regulatory Listings

Europe:
EINECS: Preparation
EU GHS Classification: H315, H317, H319 and H411

REACh Annex XVII: Not controlled

REACh SVHC: Not controlled

EU Cosmetic Regulation: Ingredient controlled
Any of 26 allergens listed in the regulations must be shown as individual ingredients if present at concentrations >0.01% in a rinse-off or >0.001% in a leave-on cosmetic product
EU INCI Name: Parfum

United Kingdom
UK Cosmetic Regulation: Ingredient controlled
Any of 26 allergens listed in the regulations must be shown as individual ingredients if present at concentrations >0.01% in a rinse-off or >0.001% in a leave-on cosmetic product

ANDEAN Community
Cosmetic Regulation: Not controlled

ASEAN Countries Any of 26 allergens listed in the regulations must be shown as individual ingredients if present at concentrations >0.01% in a rinse-off or >0.001% in a leave-on cosmetic product
Cosmetic Regulation: Ingredient controlled

Australia Any of 26 allergens listed in the regulations must be shown as individual ingredients if present at concentrations >0.01% in a rinse-off or >0.001% in a leave-on cosmetic product
AICIS Inventory: Mixture not listed
Cosmetic Regulation: not controlled

Canada
DSL: Mixture not listed
Cosmetic Regulation: Not controlled

China
IECSC: Mixture not listed
Cosmetic Regulation: Listed in IECIC 2015 as "Fragrance"

Eurasian Economic Community
Cosmetic Regulation: Ingredients controlled

GCC Countries Any of 26 allergens listed in Appendix 2 (Items 67 to 92 inclusive) of Regulations On safety of perfumery cosmetic products, (TR CU 009/2011) must be shown as individual ingredients if present at concentrations >0.01% in a rinse-off or >0.001% in a leave-on cosmetic product.
Cosmetic Regulation: Ingredient controlled

Hong Kong Not controlled
Cosmetic Regulation:

India
Cosmetic Regulation: Not controlled

Japan
Chemical Inventory: Mixture not listed
Cosmetic Regulation: Not controlled

Korea
Chemical Inventory: Mixture not listed
Cosmetic Regulation: Not controlled

MERCOSUR
Cosmetic Regulation: Not controlled

Mexico
Cosmetic Regulation: Not controlled

Morocco
Cosmetic Regulation: Not controlled

New Zealand
Cosmetic Regulation: Ingredients controlled

South Africa
Cosmetic Regulation: Ingredients controlled

Taiwan
Chemical Inventory: Not controlled

Turkey
Cosmetic Regulation: Ingredients controlled

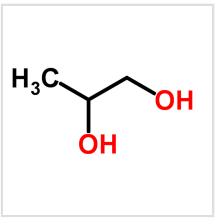
USA
Chemical Inventory: Mixture - Not listed
California Prop 65: Not listed. Some components may potentially require notification. Manufacturers data and IFRA declaration should identify any requirements
Cosmetic Regulation: Fragrance
Not controlled

Substance: Propylene Glycol

CAS: 57-55-6; 4254-14-2

Function: Humectant; Skin Conditionpropylene Glycoling; Solvent; Viscosity Controlling

Concentration in Product: 0.5%



Regulatory Listings

Europe:

EINECS: 200-338-0; 610-038-5

EU GHS Classification: CAS No. 57-55-6:
Not Classified (self-classified, 6420 notifiers with joined entry); H410 (self-classified, 57 notifiers); H319 (self-classified, 40 notifiers); H302 (self-classified, 15 notifiers)
CAS No. 4254-14-2:
H319 (self-classified, 3 notifiers); Not Classified (self-classified, 2 notifiers)

REACh Annex XVII: Not Controlled

REACh SVHC: Not Controlled

EU Cosmetic Regulation: Not Controlled

EU INCI Name: Propylene Glycol

EN71 Toy Standards: EN71 - 7 and EN71 - 9 Not Controlled
EN71-5 permissible in solvent-based paints and lacquers

EU Toy Directive: Not Controlled

EU Biocides Regulation: Not Registered as a Biocide

EU Detergents Regulation: Not a Detergent

United Kingdom

UK Cosmetic Regulation: Not Controlled

UK Toy Legislation: Not Controlled

ANDEAN Community

Cosmetic Regulation: Not Controlled

ASEAN Countries

Cosmetic Regulation: Not Controlled

Australia

AICIS Inventory: Listed as 1,2-Propanediol (CAS No. 57-55-6)

Inventory Obligations: Not considered to pose an unreasonable risk to health based on Tier I IMAP assessment

SUSMP: Appendix B, Part 3 - Substances considered not to require control by scheduling (Reason: Low Toxicity)

Cosmetic Regulation: Not Controlled

TGA Controls: Listed as an active and excipient under Therapeutic and Goods (Permissible Ingredients).

Canada

DSL: Listed

WHMIS: Listed. Uncontrolled. Disclosure at 1,0% according to the ingredient disclosure list.

Cosmetic Regulation: Not Controlled

OTC Monographs: Not Controlled

China

IECSC: Listed

Cosmetic Regulation: Not controlled. Listed in IECIC 2015

Eurasian Economic Community

Cosmetic Regulation: Not Controlled

GCC Countries

Cosmetic Regulation: Not Controlled

Hong Kong Not Controlled

Cosmetic Regulation:

India

Cosmetic Regulation: Not controlled

Japan

Chemical Inventory: Listed

Cosmetic Regulation: Not Controlled

Korea

Chemical Inventory: Listed

Cosmetic Regulation: Not Controlled

MERCOSUR

Cosmetic Regulation: Not Controlled

Mexico

Cosmetic Regulation: Not Controlled

Morocco

Cosmetic Regulation: Not controlled

New Zealand

Cosmetic Regulation: Not Controlled

South Africa

Cosmetic Regulation: Not Controlled

Taiwan

Chemical Inventory: Not Controlled

Turkey

Cosmetic Regulation: Not Controlled

USA

Chemical Inventory: Listed as 57-55-6

California Prop 65: Not listed

FDA OTC Monograph: Controlled
Approved active ingredient, at 0.2 - 1%, for Ophthalmic demulcents according to 21CFR349.12(d)(5)

Cosmetic Regulation: Propylene Glycol
Not Controlled

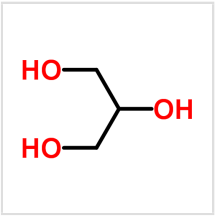
Delphic HSE Solutions Limited
Building B, Riverside Way, Watchmoor Park, Camberley, Surrey, GU15 3YL
Tel: +44 (0)1252 856 700 e-mail: tra@delphichse.com

Substance: Glycerin

CAS: 56-81-5; 8013-25-0

Function: Denaturant; Humectant; Hair Conditioning; Oral Care; Perfuming; Skin Protecting; Viscosity Controlling

Concentration in Product: 0.3%



Regulatory Listings

Europe:

EINECS: 200-289-5

EU GHS Classification: Not Classified (self-classification)

REACh Annex XVII: Not Controlled

REACh SVHC: Not Controlled

EU Cosmetic Regulation: Not Controlled

EU INCI Name: Glycerin

EN71 Toy Standards: Special additive for liquid adhesives for paper and wood as per EN71-5. Ingredient used in the manufacture of finger paints per EN71-7. Not listed in EN71-9.

EU Toy Directive: Not Controlled

EU Biocides Regulation: Not Registered for any Biocidal Uses

EU Detergents Regulation: Not Controlled

United Kingdom

UK Cosmetic Regulation: Not Controlled

UK Toy Legislation: Not Controlled

ANDEAN Community

Cosmetic Regulation: Not Controlled

ASEAN Countries

Cosmetic Regulation: Not Controlled

Australia

AICIS Inventory: Listed as 1,2,3-Propanetriol (CAS No. 56-81-5)

Inventory Obligations: HPV substance identified as low concern to human health by application of expert validated rules

SUSMP: Not Listed

Cosmetic Regulation: Not Controlled

TGA Controls: GLYCEROL - Listed as active ingredient and excipient under Therapeutic Goods (Permissible Ingredients) Determination (No. 1) 2020, Volume 3, entry 2359. When used as an active ingredient, it is only for use in topical medicines for dermal application.

Canada

DSL: Listed on the Canadian DSL

WHMIS: Not Listed as Hazardous according to WHMIS

Cosmetic Regulation: Manufacturers of oral and leave-on products containing glycerin must ensure the raw material used is within the specifications of an accepted pharmacopoeia with respect to diethylene glycol (DEG) impurities (e.g. Glycerin Official Monograph in the most current edition of the USP).

OTC Monographs: Not Controlled

China

IECSC: Listed

Cosmetic Regulation: Not controlled.
Listed on IECIC Ref 02421

Eurasian Economic Community

Cosmetic Regulation: Not controlled

GCC Countries

Cosmetic Regulation: Not Controlled

Hong Kong Not controlled as per EU

Cosmetic Regulation:

India

Cosmetic Regulation: Not controlled

Japan

Chemical Inventory: Listed

Cosmetic Regulation: Glycerin mixed with cosmetics should contain diethylene glycol less than 0.1g per 100g glycerin.

Korea

Chemical Inventory: Listed

Cosmetic Regulation: Not Controlled

MERCOSUR

Cosmetic Regulation: Not controlled

Mexico

Cosmetic Regulation: Not controlled

Morocco

Cosmetic Regulation: Not controlled

New Zealand

Cosmetic Regulation: Not Controlled

South Africa

Cosmetic Regulation: Not Controlled

Taiwan

Chemical Inventory: Not Controlled

Turkey

Cosmetic Regulation: Not controlled

USA

Chemical Inventory: Listed as existing; 1,2,3-Propanetriol

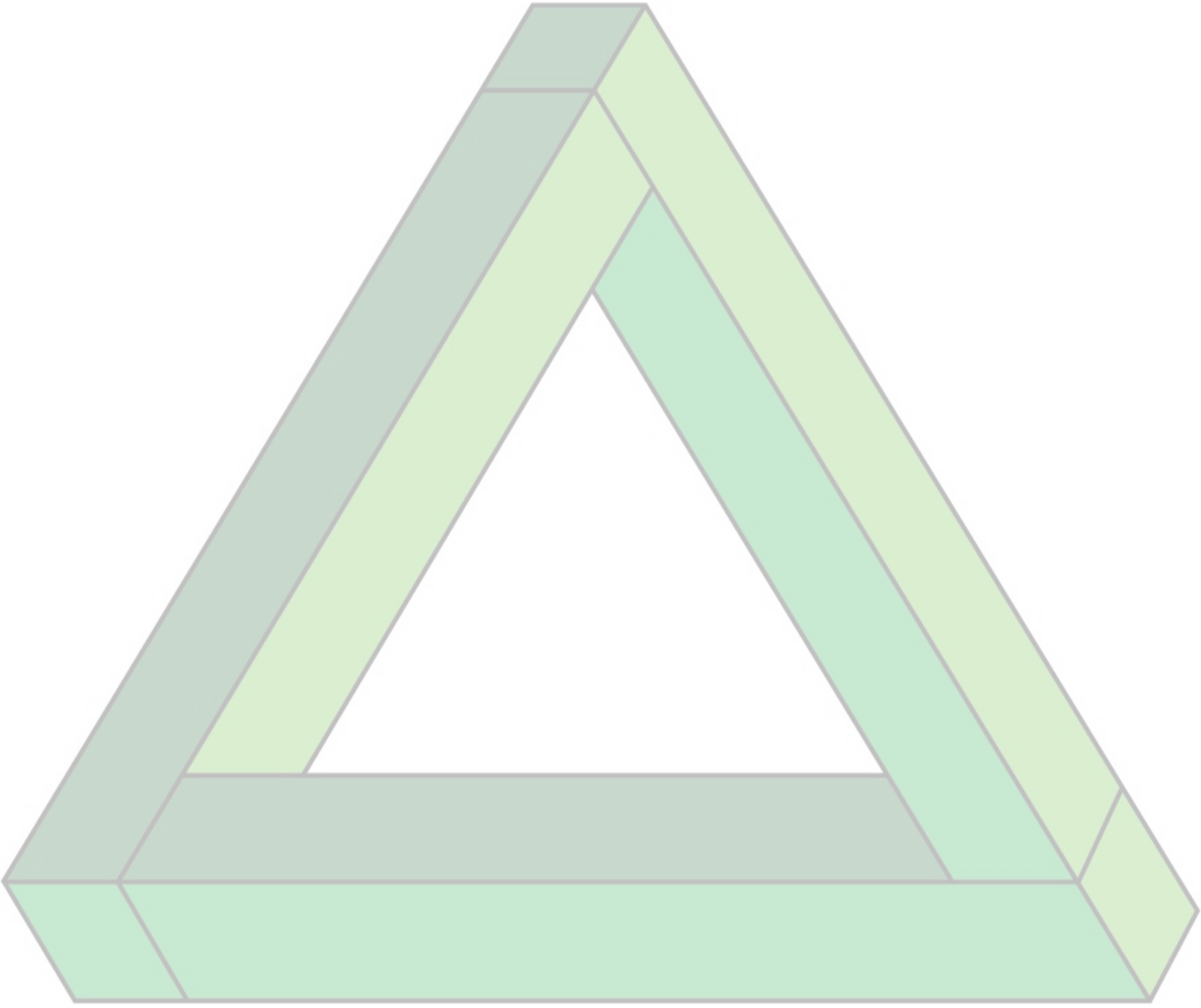
California Prop 65: Not listed

FDA OTC Monograph: Controlled

Active ingredient for anorectal protectant 21CFR346.14; external analgesic of poison ivy/oak/sumac 21CFR310.545; hyperosmotic laxative; Ophthalmic demulcents at 0.2-1% 21CFR349.12; oral health care products; topical otic drugs 51FR28660; skin protectant for

diaper rash and insect bites/stings 21CFR310.545, for fever blister/cold sore; skin protectant at 20-45% 21CFR347.10

Cosmetic Regulation: Glycerin
Not Controlled

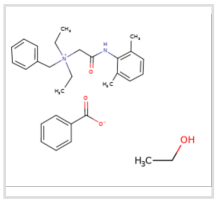


ANNEX II - INGREDIENT DATA

Substance: Alcohol Denat
CAS: 64-17-5
Function: Antifoaming; Antimicrobial; Astringent; Masking; Solvent; Viscosity Controlling

Concentration in Product: 56.31%
Dermal Exposure Level: 0.290239031 mg/cm^2
Daily Body Burden: 15.76680000mg/kg

Chemical Structure



Physical/Chemical Characteristics

Appearance	Colourless Liquid
Boiling Point	78°C
Flammability	Highly Flammable
Flash Point	~13°C
Molecular Mass	46.07
Melting Point	-114°C
Vapour Pressure	78.7hPa @25°C
Water Solubility	789000 mg/L @20°C
Density	784.4kg/m3@25°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:

Alcohol, denatured to make it unpalatable. Used as an antifoaming, antimicrobial, astringent, masking, solvent and viscosity controlling material.

A narcotic substance, that is readily absorbed via the gastrointestinal Tract and Lungs, but which is poorly absorbed across the skin (OECD, SIDS 2004). Due to the poor rates of absorption, skin contact is unlikely to result in significant adverse effects and based on available data it is not a skin irritant or sensitiser. Moreover, most of the substance rapidly evaporates after application. It possesses moderate potential to irritate the eye.

100% Ethyl Alcohol was irritating to rabbit eyes. However, 40% Ethyl Alcohol was not irritating to eyes in a Draize test. Another Draize test showed that Ethyl Alcohol at 25% solution in water is considered a negligible occular irritant and at 50% a mild occular irritant. The ECHA endpoint summary reviewed those eye irritation studies and stated that mixtures of 50% Ethyl Alcohol do not produce levels of eye irritation warranting classification, therefore a cut off for mixtures of 50% is proposed (ECHA).

In a 90-Day oral toxicity study in rats, conducted to OECD test guideline 408, a NOAEL of 1730 mg/kg/day was identified, and can be considered a suitable Point of Departure (PoD).

Negative in both in vivo and in-vitro genotoxicity studies.

A worst-case dermal absorption rate of 21% can be considered, based on available data (ECHA 2000).

The Cosmetic Ingredient Review (CIR) Expert Panel also reported that Alcohol Denat. was used at 0.0008–99% in 821 products (with up to 99% in leave-on products), and concluded that it is safe as cosmetic ingredient in the present practices of use and concentration.

Overall the use of this material in products where ingestion and inhalation of significant amounts is unlikely, it is not expected to pose any substantial health risk. However, misuse (either intentional or accidental) of products containing this substance can lead to severe adverse effects, including Narcosis and Death. Denaturing makes the product unpalatable.

References:

OECD SIDS (2004). SIDS Initial Assessment Report. Ethanol. CAS No: 64-17-5. UNEP Publications

ECHA registration dossier for ethanol. CAS No. 64-17-5. Available at: https://echa.europa.eu/registration-dossier/-/registered-dossier/16105/7/1 (Last accessed: 26/03/2019)

ECHA registration dossier. Ethanol. CAS number: 64-17-5. Irritation endpoint summary. Available at: https://echa.europa.eu/de/registration-dossier/-/registered-dossier/16105/7/4/1 (Last accessed: 22/09/2020)

CIR (2008). Final Report of the Safety Assessment of Alcohol Denat., Including SD Alcohol 3-A, SD Alcohol 30, SD Alcohol 39, SD Alcohol 39-B, SD Alcohol 39-C, SD Alcohol 40, SD Alcohol 40-B, and SD Alcohol 40-C, and the Denaturants, Quassin, Brucine Sulfate/Brucine, and Denatonium Benzoate. IJT 27(Suppl. 1):1-43, 2008

Margin(s) of Safety

Point of Departure - Animal Study: 1730.0000mg/kg
Exposure from Product 15.76680000mg/kg
Margin of Safety 109.724231

ANNEX II - INGREDIENT DATA

Alcohol Denat

Acute Toxicity Acute Oral Toxicity, Lethality [OECD 401, OECD 423, OECD 425]		LD50 = 10470 mg/kg
Rat	Oral, NOS	
Acute Toxicity Acute Inhalation Toxicity, Lethality [OECD 403, OECD 436]		The LC50 (4hr) was established to be around the 117 -125mg/l and the LC0 around 62mg/l. It is worthy of note that the LD50 is well above the lower explosive limit (LEL).
Rat	Inhalation	
ADME In vitro skin absorption [OECD 428]		Systemic doses of ethanol via skin absorption under practical conditions will be very low. Absorption rates were around 21% (under occlusion conditions) and 1% (under non-occlusive conditions) of applied doses respectively.
Pig	In vitro exposure	
Eye Irritation In vivo Eye Irritation [Other]		[Read-across data] This screening test gave evidence of mild to moderate irritation of the mucous membrane on contact with pure methanol, which was fully reversible within 8 days. Therefore, there was no need for classification as eye irritating.
Rabbit	Instillation	
Eye Irritation Draize, Standard [OECD 405]		1) 40% ethanol - not irritating [GLP, 1975 study] 2) 100% ethanol - category 2 irritant [1998 study] 3) 25% ethanol in water - negligible irritant. 50% ethanol - Mild irritant. [1956 study]
Rabbit	Instillation	
Genotoxicity In vivo genotoxicity assay [Other]		Ethanol is unlikely to be a dominant lethal mutagen.
Mouse	Oral, Gavage	
Genotoxicity Bacterial reverse mutation test (Ames) [OECD 471]		Negative
Bacteria	In vitro exposure	
Genotoxicity Mammalian cell gene mutation test [OECD 476]		Negative
In-vitro culture	In vitro exposure	
Repeated Dose 90-Day Oral Toxicity Study [OECD 408, OECD 409]		NOAEL = 1730 mg/kg/day (10 ml/Kg). 0, 5, 10 or 20 mg/Kg of a mixture containing 16.25% USP ethanol resulted in dose-related increases significant increases in kidney weights in the mid and high dose groups treated.
Rat	Oral, Gavage	
Reproductive Toxicity Two-Generation Reproduction Toxicity [OECD 416]		Ethanol in drinking water at concentrations up to 15% (equivalent to 20.7 g/kg/day) had no demonstrable effect on fertility.
Mouse	Oral, Water	
Reproductive Toxicity Prenatal Development Toxicity Study [OECD 414]		NOAEL 5.2 g/kg/day
Rat	Oral, Feed	
Skin Irritation In vivo skin irritation [Other]		Not irritating [read-across: methanol]
Rabbit	Dermal	
Skin Sensitisation Buehler [OECD 406]		Not sensitising [Read-across: methanol]
Guinea Pig	Dermal	

ANNEX II - INGREDIENT DATA

Substance: Aqua
CAS: 7732-18-5
Function: Solvent

Concentration in Product: 40.39%
Dermal Exposure Level: 0.208182462 mg/cm^2
Daily Body Burden: 53.85333333mg/kg

Chemical Structure

H_2O

Physical/Chemical Characteristics

Boiling Point	100°C
Appearance	Clear colourless liquid
Flammability	Not flammable
Flash Point	not flammable
Molecular Mass	18
Melting Point	0°C
Odour	none
pH	7
Specific Gravity	1

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:

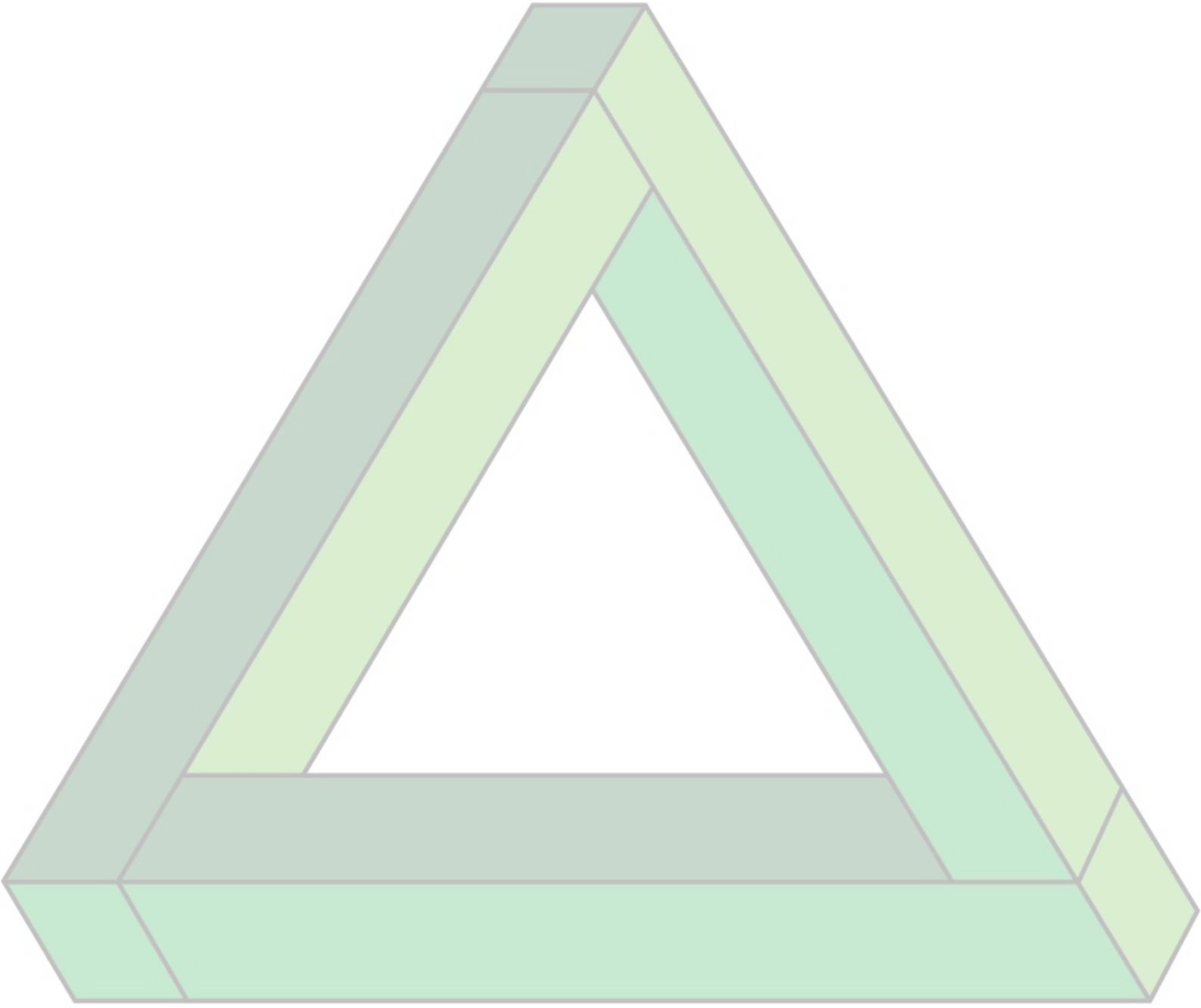
A ubiquitous chemical substance that is the basis for all known forms of life. Use in consumer products is not expected to result in any Acute or Chronic Toxicity following typical exposures.

Margin(s) of Safety

ANNEX II - INGREDIENT DATA

Aqua

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



ANNEX II - INGREDIENT DATA

Substance: Perfume - DRIVE ME NUTS - symrise
CAS: Mixture
Function: Perfuming

Concentration in Product: 2.5%
Dermal Exposure Level: 0.012885768 mg/cm^2
Daily Body Burden: 3.33333333mg/kg

Chemical Structure

No Structure Available

Physical/Chemical Characteristics

Water Solubility	Insoluble
Appearance	Liquid

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:

The supplied fragrance is classified H315, H317, H319 and H411 according to manufacturer's MSDS. When used in a leave-on cosmetic product at a concentration of up to 2% the concentration of each potential allergen will be at least 10 x lower than the concentration shown not to cause allergy in human trials.

It should be noted that the full composition of the fragrance has not been disclosed and therefore the manufacture must ensure that the fragrance does not contain any materials which are prohibited for the intended use.

This substance contains Ocean Propanal, self classified as H361 (Suspected of damaging fertility or the unborn child) at a maximum concentration of 1%

While the fragrance material at or below a concentration of 2% is not expected to result in adverse effects in the majority of users, it must be noted that individuals with a pre-existing allergy to one or more of the components may react adversely at levels lower than this.

Stated to be compliant with IFRA Guidelines and to be safe for use in (Class 2) at a concentration of 5.59%.

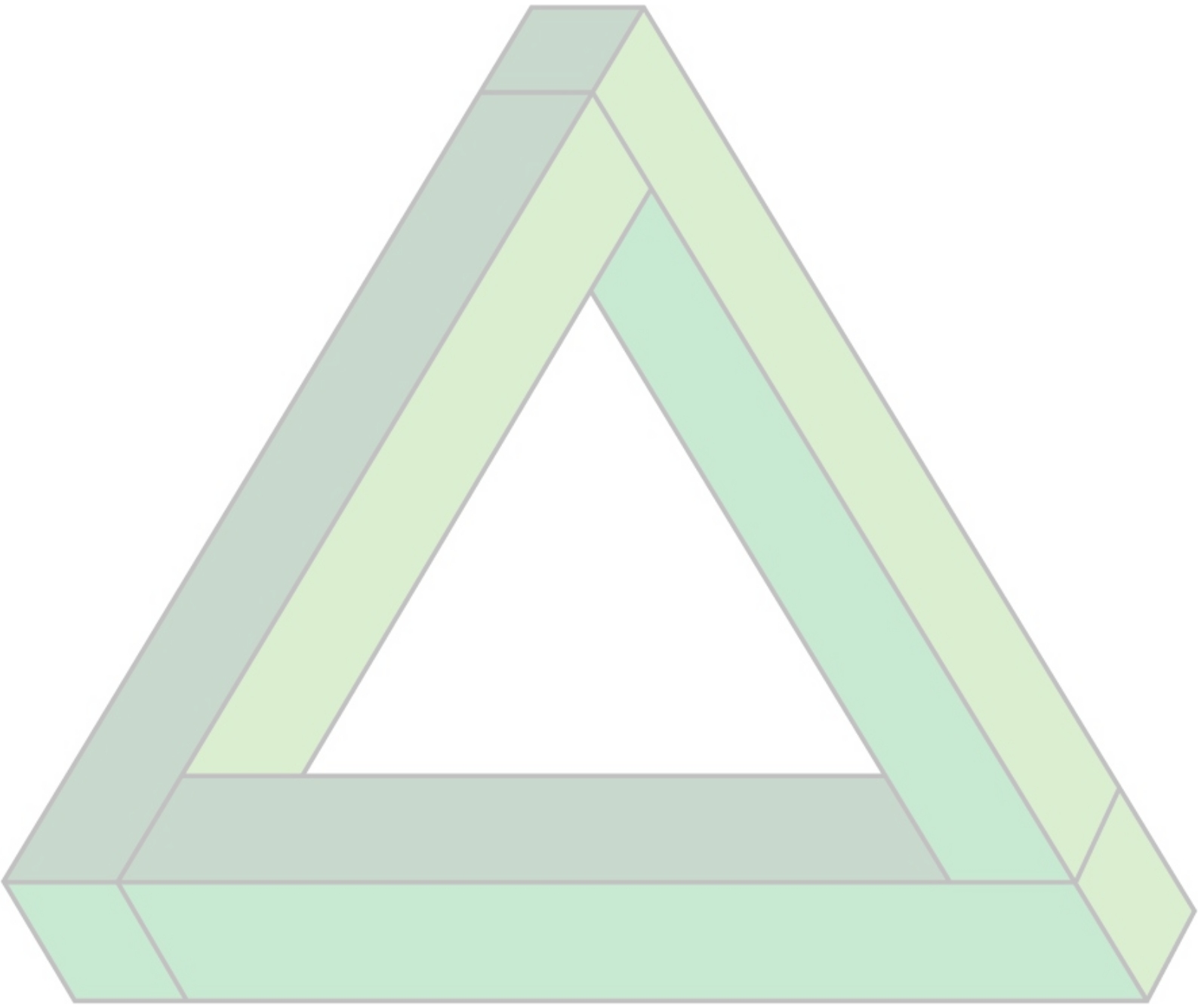
Margin(s) of Safety

Maximum Recommended Exposure 2.0000%
Exposure from Product 2.50000000%
Margin of Exposure 0.80

ANNEX II - INGREDIENT DATA

Perfume - DRIVE ME NUTS - symrise

Details on specific toxicological studies related to endpoints of concern are not available for Perfume - DRIVE ME NUTS - symrise, please see the previous page for a justification of safety based on history of use &/or weight of evidence.

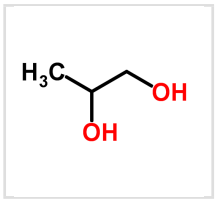


ANNEX II - INGREDIENT DATA

Substance: Propylene Glycol
CAS: 57-55-6; 4254-14-2
Function: Humectant; Skin Conditionpropylene Glycoling; Solvent; Viscosity Controlling

Concentration in Product: 0.5%
Dermal Exposure Level: 0.002577154 mg/cm^2
Daily Body Burden: 0.66666667mg/kg

Chemical Structure



Physical/Chemical Characteristics

Melting Point	-60°C
Boiling Point	187.6°C
Log Kow	0.92
Water Solubility	1000000 mg/L
Vapour Pressure	0..129 mm Hg at 25 °C

Molecular Mass	76.0942
Density	0.785 g/ ml
Appearance	Colourless liquid
Boiling Point	189C

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:

Propylene Glycol is a widely used solvent in consumer products such as Cosmetics and foodstuffs. As a food additive it is referred to as E1520.

Mild irritant to the human skin at 25% in the patch test. Negative in eye irritation Draize test. Found to be non-sensitising in a local lymph node assay and showed low potential for sensitisation in a Human Repeat Insult Patch Tests (HRIPT) study. Propylene Glycol has low oral and dermal acute toxicity with high oral and dermal LD50 of greater than 18350 mg/kg bw and 2000 mg/kg bw, respectively. Non-mutagenic in in vitro and in-vivo genetic toxicity studies.

Propylene Glycol did not show carcinogenic activity in rats up to 50000 ppm in diet per day. Additionally, no adverse effects on reproductive or developmental toxicity was observed up to the highest tested doses in the respective studies. However, the maternal NOAEL from the developmental toxicity study was set at 520 mg/kg bw/day due to increased water consumption at higher doses. No other effects were observed. This value is not considered significant as a point of departure due to the duration of the study.

A no-observed-adverse-effect-level (NOAEL) of 2500 mg/kg bw/day is selected from a 2 year rat carcinogenicity study as the point of departure. A human acceptable daily intake (ADI) of 25 mg/kg bw has also been established by Joint FAO/WHO Expert Committee on Food Additives (JECFA, 2002).

An OECD 414 prenatal developmental toxicity study was performed in CD-1 mice by oral gavage (GD 6 to 15) with 30 females per dose group (0.5, 5 and 10 ml/kg bw/day). This study produced a maternal NOAEL of 520 mg/kg bw/day; based on water consumption, and foetal NOAEL of 1040 mg/kg bw/day; based on the top dose (the highest dose tested). A further two-generation reproductive toxicity study was performed also in CD-1 mice (male and female) by ingestion of drinking water with 20/sex/dose in each dose group (0, 1.82, 4.80 and 10.10 g/kg bw/day). This study produced a reproductive NOAEL of 10,100 mg/kg bw/day; also based on no effects occurring at the top dose.

Dermal absorption of propylene glycol is highly variable. In the earliest study radiolabelled propylene glycol did not penetrate the human skin biopsy sample after 1 hour (McGee et al. 1945). In more recent in-vitro studies, the relative dermal absorption of the applied dose was estimated to be 23% (0.96%/h) for monopropylene glycol (Fasano 2011) after indefinite, 24-hour application to human abdominal skin under occlusion. In another, similar study 0.65% (+- 0.35 S.D.) of monopropylene glycol was in the receptor fluid after 24 hours (Trottet 2004). In the same paper it was demonstrated that the skin penetration of PG is largely dependant on the formulation it is found in, and on the amount of product applied to the skin. Two formulations were tested – a gel and a cream, where PG was present at 12, 15 or 40%. The formulations were applied at 10 or 40 mg/cm2 for 24 hrs under occlusion. The skin penetration varied between 29.9% (+/-8.5 S.D.) to 45.4% (+/-5.4 S.D.) - the penetration rates were dependent on the formulation and on the amount applied (there was a positive relationship between the latter and the level of absorption), but it was not dependent on the % inclusion of PG in the formulation. Dermal absorption of 50% is conservatively taken for margin of safety calculations. However, 100% dermal absorption will be used for risk assessment of oral care products.

Propylene glycol was shown to be a penetration enhancer for other substances, in particular for hydrophilic compounds (Carrer et al. 2019). This property of propylene glycol is possibly due to its ability to disorder the lipidic order of the bilayer in dermis and epidermis (Carrer et al. 2019).

The Cosmetic Ingredient Review (CIR) Expert Panel reported Propylene Glycol was used at 0.0008-99% in 9747 products (with up to 73% in leave-on products) as of 2009, and concluded that it is safe as cosmetic ingredient in the present practices of use and concentration when formulated to be nonirritating (CIR 2012).

Overall the use of this material at typical levels would not be expected to pose an undue risk of significant adverse effects.

References

JECFA, (2002). Evaluation of Certain Food Additives. TRS 913-JECFA 59/112

https://echa.europa.eu/substance-information/-/substanceinfo/100.000.307

MacKee GM, Sulzeberger MB, Herrmann F, Baer RL. (1945). Histologic studies on percutaneous penetration with special reference to the effect of vehicles. J Ingest Dermatol, 6, 43–61 [cited in NTP NCRHR, 2004].

Fasano, W. J., Wil, F., Banton, M. I., Heneweer, M., & Moore, N. P. (2011). Dermal penetration of propylene glycols: Measured absorption across human abdominal skin in vitro and comparison with a QSAR model. Toxicology in Vitro, 25(8), 1664-1670.

Trottet, L., Merly, C., Mirza, M., Hadgraft, J., & Davis, A. F. (2004). Effect of finite doses of propylene glycol on enhancement of in vitro percutaneous permeation of loperamide hydrochloride. International journal of pharmaceutics, 274(1-2), 213-219.

Carrer, V., Alonso, C., Pont, M., Zanuy, M., Córdoba, M., Espinosa, S., ... & Coderch, L. (2019). Effect of propylene glycol on the skin penetration of drugs. Archives of Dermatological Research, 1-16.

CIR (2012). Safety Assessment of Propylene Glycol, Tripropylene Glycol, and PPGs as Used in Cosmetics. International Journal of Toxicology 31(Supplement 2) 245S-260S.

Margin(s) of Safety

Point of Departure - Animal Study:	2500.0000mg/kg	**Exposure from Product**	0.66666667mg/kg	**Margin of Safety**	3750
Point of Departure - Human Data:	25.0000mg/kg	**Exposure from Product**	0.66666667mg/kg	**Margin of Safety**	37.5

ANNEX II - INGREDIENT DATA

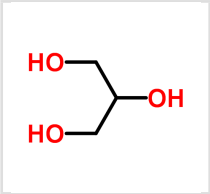
Propylene Glycol

Acute Toxicity Acute Toxicity, Lethality [Other]		LD50: 22000 mg/kg bw /day [1st experiment (serie A): 15, 17.5, 20, 22.5 and 25 ml/kg bw; 2nd experiment (serie B): 17.6, 18,6, 20.0, 21.4 and 22.6 ml/kg bw]
Rat	Oral, Gavage	
Acute Toxicity Acute Toxicity, Lethality [Other]		LD50: >2000 mg/kg bw [Dose: 2000 mg/kg bw]
Rabbit	Dermal	
ADME In vitro skin absorption [OECD 428]		dermal absorption of monopropylene glycol was 23% (0.96%/h) after 24 hours [indefinite dose of monopropylene glycol applied under occlusion]
Human	Dermal	
ADME In vitro skin absorption [OECD 428]		After 24 hours, percentage of propylene glycol (PG) in the receptor fluid was: -in the PG in water as 50/50 solution (occluded, infinite conditions) condition 0.65% (+/- 0.35 S.D.) -in the 12%, 15% or 40% PG in gel or cream formulation (occluded, 10mg/cm2 or 40mg/cm2 applied) from 29.9% (+/- 8.5 S.D.) to 45.5% (+/- 5.4 S.D.)
Human	Dermal	
Carcinogenicity Carcinogenicity studies [Other]		NOAEL: 2500 mg/kg bw /day Dose: 0, 6250, 12500, 25000 and 50000 ppm in diet Duration: 2 years; No. of animal: 30/sex/dose
Rat	Oral, Feed	
Eye Irritation Draize, Standard [OECD 405]		cornea opacity score 0/4; iris score 0.1/2; conjunctivae score 0.4/3; chemosis score 0/4
Rabbit	Instillation	
Genotoxicity Bacterial reverse mutation test (Ames) [OECD 471]		Negative Ames Test +/- S9 activation
Bacteria	In vitro exposure	
Genotoxicity Mammalian chromosome aberration test [OECD 473]		Negative chromosomal aberration (human lymphocytes) +/- S9 activation
In-vitro culture	In vitro exposure	
Genotoxicity Mammalian erythrocyte micronucleus test [OECD 474]		Propylene glycol produced no detectable increase in micronucleated polychromatic erythrocytes when administered by ip injection to mice at doses up to 15000 mg/kg.
Mouse	Intraperitoneal	
Repeated Dose Repeat Dose Oral Toxicity Study [Other]		NOAEL: 50000 ppm (1700 mg/kg bw/day for male; 2 100 mg/kg bw/day for female) [Dose: 0, 6250, 12500, 25000 and 50000 ppm in diet, Exposure: 2 years; No. of animal: 30/sex/dose]
Rat	Oral, Feed	
Repeated Dose Repeat Dose Inhalation Toxicity Study [Other]		Systemic NOAEC: 1000 mg/m³ air for female (bw changed only); 2200 mg/m³ air for male (no effect on males) Local LOAEC: 160 mg/m3 (effect on nose: nasal haemorrhaging) [Dose: 0, 160, 1000, 2200 mg/m³ air / 0, 0.16 ± 0.04, 1.01 ± 0.11 and 2.18 ± 0.31 mg/l, Exposure: 90 days, 6 hours/day, 5 days/week, 19/sex/dose]
Rat	Inhalation	
Reproductive Toxicity NTP Reproductive Assessment by Continuous Breeding (RACB)		NOAEL for toxicity/ fertility/ developmental effects: 10100 mg/kg bw/day [Dose: 0, 1.82, 4.80 and 10.10 g/kg bw/day, two generation study, No of animal: Main study: 20/sex/dose in each treatment group; 40/sex/dose in the control group; Second generation animals: 20/sex/dose]
Mouse	Oral, Water	
Reproductive Toxicity Prenatal Development Toxicity Study [OECD 414]		NOAEL (maternal animals): 520 mg/kg bw/day (water consumption) NOAEL (fetuses): 1040 mg/kg bw/day (highest tested dose) [Dose: 0.5, 5 & 10 ml/kgb w/day; Exposure: On gestation days 6 through 15, No .of animal: 30 females/dose]
Mouse	Oral, Gavage	
Skin Irritation Patch Test, 24hr [Other]		0.2 ml 25% propylene glycol applied to 30 female and 3 male subjects. The tested substance exhibited mild irritation compared to that of the positive control.
Human	Dermal	
Skin Sensitisation Local Lymph Node Assay [OECD 429, OECD 442A, OECD 442B]		Non-sensitiser Dose: 50% and 100% Result: For 50% solution, 1.2; For 100% test substance, 1.6
Mouse	Dermal	
Skin Sensitisation Repeat Insult Patch Test (RIPT) [Other]		Approximately 0.2 ml of the test material was applied to 113 volunteers (as a neat substance for subjects 1-47 only, and as a 50% aqueous solution for the rest of the panel). One subject was observed to be hypersensitive in an irritant manner, throughout the induction and challenge phases of the study.
Human	Dermal	

ANNEX II - INGREDIENT DATA

Substance:	Glycerin	**Concentration in Product:**	0.3%	
CAS:	56-81-5; 8013-25-0	**Dermal Exposure Level:**	0.001546292	mg/cm^2
Function:	Denaturant; Humectant; Hair Conditioning; Oral Care; Perfuming; Skin Protecting; Viscosity Controlling	**Daily Body Burden:**	0.40000000mg/kg	

Chemical Structure



Physical/Chemical Characteristics

Appearance	Colourless syrup	Log Kow	1.76
Boiling Point	290˚C	Molecular Mass	92.11
Explosive Properties	Non-explosive	Melting Point	18.2˚C
Flammability	400C	Odour	Sweet
Flash Point	177˚C (Open Cup)		

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:

Glycerin is a trihydroxy sugar alcohol that is commonly used as a solvent, emollient, as well as cosmetic functions of denaturant, hair conditioning, humectant, oral care, perfuming, skin protecting and viscosity controlling (SDA, 1990). Glycerin constitutes around 10% of the Fat found in a typical Human Diet and is readily metabolised on ingestion, and has generally recognised as safe (GRAS) status in the US. (FDA, 21CFR§182.1320).

Test results in rabbits shows the substance has minimal irritancy properties in both the skin and eye. Clinical evaluations have also concluded the substance has no dermal irritation and sensitising potentials. The compound's structure does not contain conjugated double bonds, therefore, it will not absorb UV light which is a prerequisite for phototoxicity.

When given orally at 20% in the diet over 2 years showed no adverse effects in rats. Has a high Oral LD50 (>10g/kg in Rats). However ingestion of large amounts of this material can cause an osmotic effect in the gastrointestinal tract leading to dehydration, nausea and headaches. Glycerine has also been determined to be non-toxic via dermal application (LD50 >10g/kg in Rabbits) and inhalation of saturated vapours (4h LC50 >2.75 mg/L).

A no-observed-adverse-effect-level (NOAEL) of 8000-10000 mg/kg bw was determined based on the absence of treatment-related effects in rats from the 2-year diet study. The lower of these values of 8000 mg/kg bw is conservatively chosen as the point of departure.
The inhalation NOAEC was considered as 167mg/m3 from nose-only aerosol exposure to rats, due to local lung irritation effects at higher concentrations.

Glycerine showed no genotoxicity potential in the Ames assay, and the 2 year dietary study in rats also found no increase in the rates of tumour formation compared to control animals. There was no effect noted on growth, fertility and reproductive performance in rats through two generations, and no developmental toxicity of offspring was observed.

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%.

Given the low toxicity profile of this substance, and the fact it is a constituent of a typical human diet, its use in Consumer Products is not expected to produce significant localised or systemic toxicity. The Cosmetic Ingredients Review (CIR Expert Panel on glycerine reports that glycerine is used in leave-on products at up to 79.2% and in baby products in the range of 0.23-21% (CIR, 2015).

References:

CIR, 2015. Safety Assessment of Glycerin as Used in Cosmetics. Release Date: Jan 14, 2015.

GRAS Listing, [Glycerin]. FDA, 21 CFR. §182.1320 (Last accessed 21/03/2019).

The Soap and Detergent Association (SDA), 1990. Glycerine: an overview. Glycerine & Oleochemical Division. New York.

ECHA registration dossier, Glycerol, CAS: 56-81-5.

Margin(s) of Safety

Point of Departure - Animal Study:	8000.0000mg/kg	**Exposure from Product**	0.40000000mg/kg	**Margin of Safety**	20000

ANNEX II - INGREDIENT DATA

Glycerin

Acute Toxicity Acute Toxicity, Lethality [Other]		LD50 = 27.2g/kg
Rat	Oral, Gavage	
Acute Toxicity Acute Toxicity, Non-Lethal [Other]		TDLo oral 1428mg/kg Behavioural: headache Gastrointestinal: nausea or vomiting
Human	Oral, NOS	
Acute Toxicity Acute Toxicity, Lethality [Other]		LD50 = 56.75g/kg [Occlusive bandage in contact with skin for 4 days.]
Guinea Pig	Dermal	
Acute Toxicity Acute Toxicity, Lethality [Other]		A calculated 4 hour LC50 value based on nominal concentration would be >2.75 mg/L The L(Ct)50 for Glycerine was 4655 mg minute/litre.
Rat	Inhalation	
Carcinogenicity Carcinogenicity studies [Other]		Non-carcinogenic [Dietary exposure over 2 years.]
Rat	Oral, Feed	
Eye Irritation In vivo Eye Irritation [Other]		Glycerin was considered to be non irritating in 19 laboratories and of questionable irritation in one laboratory.
Rabbit	Instillation	
Genotoxicity Bacterial reverse mutation test (Ames) [OECD 471]		Negative with and without metabolic activation [S. typhimurium TA1535, TA1537, TA98, TA100. Up to 10,000µg/plate.]
Bacteria	In vitro exposure	
Repeated Dose Chronic Toxicity Studies in Rodents [OECD 452]		NOAEL = 8000-10,000 mg/kg bw/day Doses:5, 10, 20% in diet (males 2000, 4000 and 8000 mg/kg bw, females 2500, 5000 and 10000 mg/kg bw); 2-year exposure.
Rat	Oral, Feed	
Repeated Dose 90-day Inhalation Toxicity Study [OECD 413]		The NOAEC was 167 mg/m3 based on local irritant effects on the upper respiratory tract, from a viscous liquid aerosol generator by nose-only exposure.
Rat	Inhalation	
Repeated Dose Repeat Dose Dermal Toxicity Study [Other]		There were no effects noted in rabbits dosed 8 hours/day, 5 days/week for 45 weeks with dose levels as high as 4.0 ml/kg.
Rabbit	Dermal	
Reproductive Toxicity Two-Generation Reproduction Toxicity [OECD 416]		Glycerin was administered by oral gavage to groups of male and female rats through two generations. There was no effect noted on growth, fertility and reproductive performance through two generations at a dose level of ~2000 mg/kg/day.
Rat	Oral, Gavage	
Reproductive Toxicity Prenatal Development Toxicity Study [OECD 414]		No Effects Up To 1,310 mg/kg/day (highest tested dose) [Dosing on days 6 to 15 of gestation.]
Rat	Oral, Gavage	
Skin Irritation In vivo skin irritation [Other]		Glycerin was considered to be non irritating to the skin in rabbit irritation studies in 14 testing laboratories.
Rabbit	Dermal	
Skin Irritation In vivo skin irritation [Other]		The dermal irritation potential was examined in 33 humans, 30 female and 3 male. Under the conditions of the study, Glycerine USP (25% concentration) exhibited no clinical irritation when tested in humans.
Human	Dermal	
Skin Sensitisation Repeat Insult Patch Test (RIPT) [Other]		In a study of 420 patients with eczema, 419 showed no irritation or sensitization when tested with a 50% solution in water. A result from one patient was questionable.
Human	Dermal	

ANNEX III - ALLERGENS

Allergen Name	% in Product
1,2,3,5,6,7,8,8-octahydro-2,3,8,8-tetramethyl-2-	0.250000
Hexamethylindanopyran (1222-05-5)	0.250000
(E)-Ethyl Linalool (10339-55-6)	0.250000
Vanillin (121-33-5)	0.125000
Linalyl Acetate (115-95-7)	0.125000
(Ethoxymethoxy)cyclododecane (58567-11-6)	0.125000
2-(Isobutyl)-4-hydroxy-4-methyl tetrahydropyran	0.125000
Ethyl Vanillin (121-32-4)	0.125000
5-(2,2,3-Trimethyl-3-cyclopentenyl)-3-	0.125000
Linalool (78-70-6)	0.089350
Benzyl Salicylate	0.071325
Hydroxycitronellal (107-75-5)	0.053550
Coumarin	0.037500
Ionone (79-77-6)	0.025000
Ligustral (68039-49-6)	0.025000
Cyclamen Aldehyde (103-95-7)	0.025000
Ocean Propanal (1205-17-0)	0.025000
(Z)-3-hexenyl salicylate (65405-77-8)	0.025000
2,5,10-trimethyl-2,5,9-cyclododecatrien-1-yl Methyl	0.025000
Pentadecan-15-olide	0.025000
Undecan-4-olide	0.025000
(+/-) trans-3,3-dimethyl-5-(2,2,3-trimethyl-	0.025000
Geraniol	0.005350

<Unrelated Table>

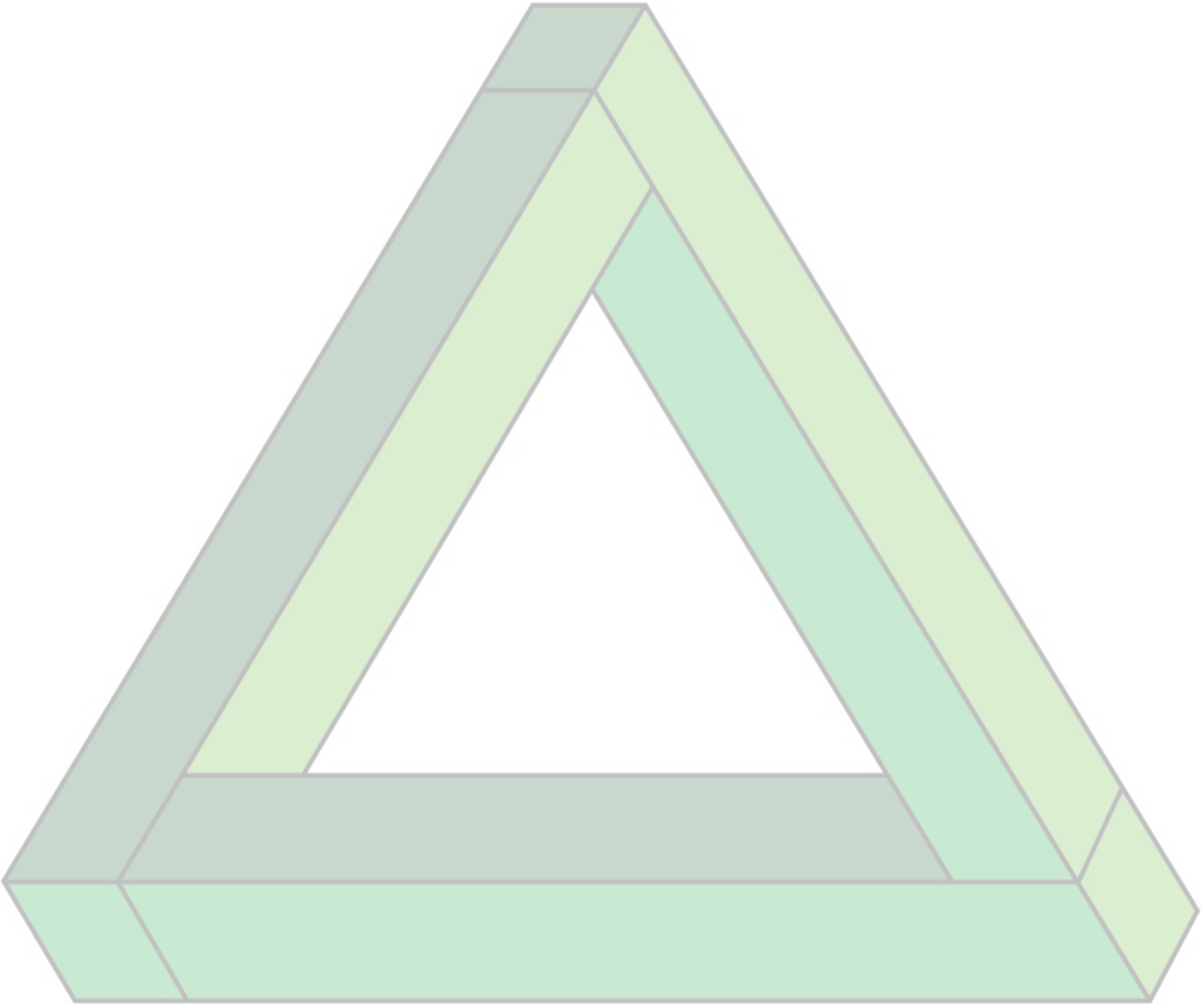
ANNEX III - ALLERGENS

Allergen Name	% in Product
Alpha-Isomethyl Ionone (127-51-5 ; 1335-46-2)	0.003200
Citronellol	0.000250
Isoeugenol (97-54-1, 5932-68-3)	0.000175
Benzyl Alcohol	0.000075
Citral	0.000025
d-Limonene (5989-27-5 ; 7705-14-8)	0.000025

<Unrelated Table>

ANNEX IV - ADDITIONAL REASONABLY FORESEEABLE EXPOSURES

Facial Mist / Spritz



ANNEX V - RAW MATERIAL SPECIFICATIONS

Substance: Alcohol Denat
CAS: 64-17-5

Specification

Alcohol Denat 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:

TSDA class 1 for Skin preparations (perfumes, toiletries, cosmetics and external medical applications such as medicated creams and oitments):
99.9% Ethanol; 0.1% Tertiary Butyl Alcohol; Denatonium benzoate is added to the resulting mixture in the proportion of 10 micrograms per millilitre.

TSDA class 5 for Perfumes/toiletries:
95% Ethanol; 5% Benzyl benzoate

≤ 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: Aqua
CAS: 7732-18-5

Specification

There are no minimum legal purity specifications for water used in the manufacture of cosmetics.

It should ensure that the grade of water used in the manufacture of this product is of a suitably safe specification, following criteria such as those of laid out in GMP standards like ISO 22716.

Substance: Perfume - DRIVE ME NUTS - symrise
CAS: Mixture

Specification

Maximum levels of declared allergens (identified as such by either the EU Cosmetic Regulation or the EU CLP Regulation) as outlined in Annex I as part of the fragrance safety assessment.

< 0.1% additional 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 ≤ 1000 cfu/g, absence of specific pathogens

Substance: Propylene Glycol
CAS: 57-55-6; 4254-14-2

Specification

Propylene Glycol 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:

Minimum purity of 97.5 percent by weight.
≤ 0.2% water,
≤ 0.07% Sulfated Ash
≤ 0.02% Propylene Oxide
≤ 5ppm Lead
≤ 3ppm Arsenic

< 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)

Substance: Glycerin
CAS: 56-81-5; 8013-25-0

Specification

Glycerin 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