



## COSMETIC PRODUCT SAFETY REPORT

PRODUCT NAME:

**PERFUMED LIQUID HAND SOAP**

RESPONSIBLE PERSON:

**CID Trading LTD**

COMPANY NAME:

**CID Trading LTD**

ADDRESS OF KEEPING THE PIF:

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REFERENCE NUMBER

**NB15007610RD**

DATE:

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## ASSESSMENT CONCLUSION

**PRODUCT NAME:** PERFUMED LIQUID HAND SOAP

**RESPONSIBLE PERSON:** CID Trading LTD

**COMPANY NAME:** CID Trading LTD

**ADDRESS:** Friden House, Unit 1 Clayton Wood Bank, Horsforth, Leeds, LS16 6QZ

The following Safety Assessment is carried out according to the requirements of Annex I of Regulation (EC) 1223/ 2009 and Schedule 34 of the Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (UK Cosmetics Regulation). The product named above is considered:

### **SAFE**

under normal reasonably foreseeable use according to Article 3. A product made to this formulation is unlikely to produce an abnormally high number of adverse reactions

The product has been assessed taking into account:

- the toxicity profile of each raw material used
- the level of exposure of each ingredient
- the microbiological safety
- stability

The formulation meets the requirements as set out in Article 14 and 15 of the applicable regulation.

## PART A: COSMETIC PRODUCT SAFETY INFORMATION

## 1. QUANTITATIVE &amp; QUALITATIVE COMPOSITION OF THE COSMETIC PRODUCT

INCI	Function	CAS #	EC #	Concentration in Formulation % (w/w)
Aqua	Solvent	7732-18-5	231-791-2	85.230528
Sodium Laureth Sulfate	Cleansing Surfactant - Emulsifying Foaming Surfactant - Cleansing	3088-31-1 / 9004-82-4 / 68891-38-3 / 1335-72-4 / 68585-34-2 / 91648- 56-5	221-416-0 / - / 500-234- 8 / - / 500-223-8 / 293- 918-8	8.6528
Cocamide DEA	Surfactant - Emulsifying Emulsion Stabilising Surfactant - Foam Boosting Surfactant - Cleansing Viscosity Controlling	68603-42-9	271-657-0/931-329-6	2.14
Sodium Chloride	Bulking Fragrance Oral Care Viscosity Controlling	7647-14-5	231-598-3	1.6667
Glycol Stearate	Skin Conditioning - Emollient Surfactant - Emulsifying Opacifying Surfactant - Cleansing	111-60-4	203-886-9	1.239972
Cocamidopropyl betaine	Antistatic / Cleansing Foam Boosting / Hair Conditioning / Surfactant Viscosity Controlling	61789-40-0	263-058-8 931-296-8	0.63
Parfum	Perfuming	JUICY PEACH EFF342861 / European Flavours & Fragrances PLC		0.2
Laureth-7	Surfactant - Emulsifying Surfactant - Cleansing	3055-97-8 / 68439-50- 9 / 9002-92-0	221-283-9 / 500-213-3 / 500-002-6	0.14
2-Bromo-2-Nitropropane-1,3-Diol	Preservative	52-51-7	200-143-0	0.1
CI 18050	Colorant	3734-67-6	223-098-9	0.0021

## Fragrance/ Parfum Information

Name of Fragrance: **JUICY PEACH EFF342861 / European Flavours & Fragrances PLC**

## Allergens present in the product

Allergens	Cas Nr.	% in the formula
Amyl Cinnamal	122-40-1	0
Benzyl Alcohol	100-51-6	0
Cinnamyl Alcohol	104-51-6	0

Citral	5392-40-5	0
Eugenol	97-53-0	0.002
Hydroxycitronellal	107-75-5	0
Iso Eugenol	97-54-1	0
Amyl cinnamyl alcohol	101-85-9	0
Benzyl Salicylate	118-58-1	0
Cinnamal (Cinnamic Aldehyde)	104-55-2	0
Coumarin	91-64-5	0
Geraniol	106-24-1	0.02
Hydroxymethyl Pentyl Cyclohexene Carboxaldehyde (Lyral)	31906-04-4	0
Anisyl Alcohol(Anise Alcohol)	105-13-5	0
Benzyl Cinnamate	103-41-3	0
Farnesol	4602-84-0	0
3-(4-Tert-Butylphenyl)-2-Methylpropanal (Lilial)	80-54-6	0
Linalool	78-70-6	0.04
Benzyl Benzoate	120-51-4	0
Citronellol	106-22-9	0.02
Hexyl Cinnamic Aldehyde (Hexylcinnamal)	101-86-0	0.02
Limonene	5989-27-5	0.01
Methyl Heptine Carbonate	111-12-6	0
3-Methyl-4-(2,6,6 Trimethyl-2-Cyclohexine-1-Yl)-3-Buten-2-One	127-51-5	0
Oak Moss Extract (Evernia Prunastri)	90028-68-5	0
Tree Moss Extract (Evernia Furfuracea)	90028-67-4	0
6-Methyl Coumarin	92-48-8	0
Pinus Mugo	90082-72-7	0
Pinus Pumila	97676-05-6	0
Cedrus AtlanticaOil/Extract	92201-55-3	0
Turpentine	8006-64-2	0
Alpha-Terpinene	80-56-8	0
Terpinolene	586-62-9	0
Myroxylon PereiraeOil/Extract	8007-00-9	0
RoseKetones		0
3-Propylideneophthalide	17369-59-4	0
Lippia citriodora absolute	02-12-/8024	0
Methyl Salicylate	119-36-8	0
AcetylCedrene	32388-55-9	0
AmylSalicylate	2050-08-0	0
Anethole	4180-23-8	0

Benzaldehyde	100-52-7	0
Camphor	76-22-2	0
Beta Caryophyllene	87-44-5	0
Carvone	6485-40-1	0
Dimethyl Phenethyl Acetate	151-05-3	0
Hexadecanolactone	109-29-5	0
Hexamethylindenopyran	1222-05-5	0
Linalyl Acetate	115-95-7	0
Menthol	1490-04-6	0
Trimethyl cyclopentenyl Methyl isopentenol	107898-54-4	0
Salicylaldehyde	90-02-8	0
Santalol	11031-45-1	0
Sclareol	515-03-7	0
Terpineol	98-55-5	0.01
Tetramethyl acetyl octahydro naphthalenes	54464-57-2	0
Trimethylbenzene propanol	103694-68-4	0
Vanillin	1-33-5	0
Cananga Odorata Oil/Extract (Ylang Ylang Oil)	83863-30-3	0
Cinnamomum Cassia Leaf Oil (Chinese Cinnamon Oil)	84961-46-6	0
Cinnamomum Zeylanicum Bark Oil	84649-98-9	0
Citrus Aurantium Flower Oil	8016-38-4	0
Citrus Aurantium Peel Oil	8028-48-6	0
Citrus Aurantium Bergamia Peel Oil	89957-91-5	0
Citrus Limon Peel Oil	84929-31-7	0
Lemongrass Oil	8007.-02.-1	0
Eucalyptus Globulus Oil	8000-48-4	0
Eugenia Caryophyllus Oil	8015-97-2	0
Jasmine Oil/Extract	84776-64-7	0
Juniperus Virginiana Oil	8000-27-9	0
Laurus Nobilis Leaf Oil	8007-48-5	0
Lavandula Oil/Extract	90063-37-9	0
Mentha Piperita Oil	8006-90-4	0
Mentha Viridis Leaf Oil	84696-51-5	0
Narcissus Extract	68917-12-4	0
Pelargonium Graveolens Flower Oil	90082-51-2	0
Pogostemon Cablin Oil	8014.-09.-3	0
Rose Flower Oil/Extract	8007-01-0	0
Santalum Album Oil	8006-87-9	0

Eugenyl Acetate	93-28-7	0
Geranyl Acetate	105-87-3	0
Isoeugenyl Acetate	93-29-8	0
Pinene	80-56-8/127-91-3	0

### Allergens to be declared on the label:

UK Market: Citronellol, Geraniol, Hexylcinnamal, Limonene, Linalool

EU Market: Citronellol, Geraniol, Hexylcinnamal, Limonene, Linalool, Terpineol.

\*The allergens calculations are based on the perfume's provided MSDS

## 2. PHYSICAL/CHEMICAL CHARACTERISTICS & STABILITY OF THE COSMETIC PRODUCT

### 2.1 Physical & Chemical Properties of the cosmetic product.

Physical Description of the product: **non-Viscous Gel**

Scent: **Characteristic of the Fragrance oils**

Colour: **Pink with pearling effect**

pH: **6.5-7.5**

Viscosity: **4000-6000 cp**

Specific Gravity: **1.03 – 1.08**

### 2.2 STABILITY OF THE COSMETIC PRODUCT

The ingredients used in the production of the cosmetic product comply with the relevant legal regulations.

Both the product and constituent ingredients are stable under normal use and warehousing conditions during the entire time of PAO period of 12M

*The physical/chemical stability of the product has been evaluated by Naturally Balmy Ltd, performing Stability Test with Lab reference number: 14429 PLHSP – 25/11/2024*

**CID Trading LTD** confirms that all product stability tests reflect the stability of the product which is to be placed on the market **CID Trading LTD** uses a PAO of 12M based on the results of **CID Trading LTD** stability testing, including shelf-life stability testing.

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## 2.3 MICROBIOLOGICAL QUALITY

### MICROBIOLOGICAL SPECIFICATION OF INGREDIENTS (SUBSTANCES AND MIXTURES).

Based on available information from the ingredient specification (see section 1. Quantitative and qualitative composition– specification of ingredients), the ingredients used can be assessed as microbiologically safe.

### MICROBIOLOGICAL SPECIFICATION OF THE FINISHED PRODUCT.

***The microbiological stability of the finished product has been evaluated with a Challenge test (PET) performed by MELBEC – Reference Number: 84340 – 16/12/2024***

***Conclusion: The test product has met the requirements of criteria A as specified in the standard BS EN ISO 11930:2019.***

The given cosmetic product can be regarded as microbiologically safe for consumers' health under the ISO 29621:2010 standard "Cosmetics -- Microbiology -- Guidelines for the risk assessment and identification of microbiologically low-risk products".

The microbiological harmlessness of the ingredients and the cosmetic product is assessed according to COLIPA: Guideline for Microbiological Quality Management (MQM).

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## 2.4 INFORMATION ABOUT THE PACKAGING MATERIAL

**Container: 5L Jerrycan**

**Container Material: HDPE**

**Airless Container: No**

The packaging material applied is suitable for the given type of cosmetic product and meets the predictable use requirements.

The available research suggests that the concentration of phthalates in the contents of High-Density Poly-Ethylene bottles varies as a function of the contents of the bottle, with phthalates leaching into lower pH products. Temperature also appears to influence the leaching both of phthalates and of antimony from HDPE, with greater leaching at higher temperatures. The evidence also suggests that HDPE bottles may yield endocrine disruptors under conditions of common use, particularly with prolonged storage and elevated temperature. Therefore, it is advisable, in using HDPE containers, to ensure a minimum pH of 4.0 and to store products at cooler temperatures using a shorter BBE period.

**CID Trading LTD** confirms that the results of reference sample monitoring show no reaction between the packaging material and the product during the product's stated minimum useable life. During that life, no changes to the physical and chemical properties of the product were noticed that would affect its usability and safety.

The packaging material applied is suitable for the given type of cosmetic product and meets the predictable use requirements.

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## 2.5 PHYSICAL & CHEMICAL PROPERTIES OF THE COSMETIC PRODUCT'S RAW MATERIALS.

### 2.5.1. SODIUM LAURETH SULFATE

Sodium Laureth Sulfate (SLES) is an anionic surfactant and detergent widely used in cosmetics and personal care products. It is known for its excellent foaming, emulsifying, and cleansing properties. SLES is produced by ethoxylating lauryl alcohol, derived from either coconut or palm oils, followed by sulfation and neutralization with sodium hydroxide.

INCI Name: Sodium Laureth Sulfate

CAS Number: 68585-34-2 (main commercial form)

EINECS Number: 209-553-4

Common Synonyms: Sodium Lauryl Ether Sulfate, SLES

Regulatory Status:

Approved for use in cosmetics worldwide, provided levels of ethylene oxide and 1,4-dioxane impurities are controlled.

Concentration is typically restricted in rinse-off products to minimize irritation.

Composition:

A sodium salt of a sulfated ethoxylated lauryl alcohol.

The degree of ethoxylation is typically 2–3 moles of ethylene oxide per molecule.

Contains residual unreacted lauryl alcohol, ethylene oxide, and 1,4-dioxane in trace amounts if not properly purified.

Physical and Chemical Properties:

Appearance: Colourless to light yellow liquid or paste.

Odor: Mild characteristic Odor.

Solubility: Readily soluble in water.

Molecular Weight: ~288–420 g/mol (depending on ethoxylation degree).

pH: 6.0–8.5 (1% aqueous solution).

Surface Tension: Effective at reducing surface tension, enabling foaming and cleansing.

Stability:

Stable at a wide pH range (3.0–10.0).

Sensitive to hard water, which can reduce foaming efficiency.

Toxicological Information:

Acute Toxicity:

Oral LD50 (rat): >2000 mg/kg, indicating low acute oral toxicity.

Dermal LD50 (rabbit): >2000 mg/kg, suggesting low acute dermal toxicity.

Irritation and Sensitization:

Can cause moderate skin and eye irritation, especially at higher concentrations.

Not a known skin sensitizer.

Chronic Toxicity:

Subchronic exposure studies indicate no significant systemic toxicity at typical cosmetic concentrations.

Carcinogenicity:

Not classified as a carcinogen.

Concerns about carcinogenicity arise from potential contamination with 1,4-dioxane, a byproduct of ethoxylation, and ethylene oxide, which are carcinogens at high exposure levels. Proper manufacturing minimizes these impurities.

Reproductive/Developmental Toxicity:

No significant effects on reproduction or fetal development in available studies.

Environmental Impact:

Readily biodegradable under aerobic conditions.

Can be toxic to aquatic organisms at high concentrations.

NOAEL:

Oral NOAEL:

100 mg/kg/day in rats (90-day subchronic study).

Higher doses caused gastrointestinal irritation and slight liver changes.

Dermal NOAEL:

50 mg/kg/day in rabbits (21-day dermal study).

Mild skin irritation noted at higher concentrations.

Inhalation NOAEL:

Limited data available, but SLES is not typically used in aerosolized forms to avoid respiratory irritation.

Applications in Cosmetics:

Commonly used as:

Primary surfactant in shampoos, body washes, and facial cleansers.

Foaming agent to create rich, stable foam in rinse-off products.

Cleansing agent for its ability to emulsify and remove oils, dirt, and residues.

Typical concentrations:

5–15% in shampoos and body washes.

1–5% in facial cleansers and other mild products.

### 2.5.2. COCAMIDE DEA

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Cocamide DEA (Cocamide Diethanolamine) is a non-ionic surfactant and viscosity enhancer commonly used in cosmetics and personal care products. It is derived by reacting coconut oil fatty acids with diethanolamine. Cocamide DEA is known for its ability to improve foam stability, thicken formulations, and provide mild cleansing properties.

INCI Name: Cocamide DEA

CAS Number: 68603-42-9

EINECS Number: 271-657-0

Source: Derived from coconut oil (coconut fatty acids) and diethanolamine.

Regulatory Status:

Approved for use in cosmetics globally, with restrictions in some regions due to concerns about potential nitrosamine formation.

In the EU, its use is restricted under Annex III of the EU Cosmetics Regulation. It must not be used with nitrosating agents, and formulations must be kept free of nitrosamines.

Composition:

A mixture of ethanolamides formed by the reaction of diethanolamine with coconut fatty acids (primarily lauric acid).

Typically contains:

Fatty acid residues (~85–90%).

Free diethanolamine (DEA), often <10% due to processing limitations.

Physical and Chemical Properties:

Appearance: Light yellow viscous liquid or waxy solid.

Solubility: Soluble in water, alcohols, and polar solvents.

Melting Point: ~24–28°C (solidifies at lower temperatures).

Boiling Point: Decomposes before boiling.

pH: Neutral to slightly alkaline (5.0–11.0 depending on formulation).

Stability:

Stable under normal cosmetic formulation conditions.

Sensitive to nitrosating agents, which can form carcinogenic nitrosamines.

Toxicological Information:

Acute Toxicity:

Oral LD50 (rat): >5000 mg/kg, indicating low acute toxicity.

Dermal LD50 (rabbit): >2000 mg/kg, suggesting low toxicity via skin exposure.

Irritation and Sensitization:

Can cause mild to moderate skin and eye irritation, especially at higher concentrations.

Not considered a significant sensitizer in humans or animals.

Chronic Toxicity:

Long-term studies suggest low systemic toxicity, but concerns exist regarding free DEA content and nitrosamine formation during storage or application.

Carcinogenicity:

Concerns arise when Cocamide DEA is exposed to nitrosating agents, as it can form nitrosodiethanolamine (NDEA), a known carcinogen.

The International Agency for Research on Cancer (IARC) has classified DEA and its derivatives, including Cocamide DEA, as Group 2B (possibly carcinogenic to humans) due to NDEA formation under certain conditions.

Genotoxicity and Mutagenicity:

Negative results in standard genotoxicity assays (e.g., Ames test). However, its nitrosamine derivatives are genotoxic.

Environmental Impact:

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Biodegradable, but its decomposition products may pose environmental risks.

Toxic to aquatic organisms at high concentrations.

NOAEL:

Oral NOAEL:

150 mg/kg/day in rats (subchronic studies).

Based on observations of liver and kidney changes at higher doses.

Dermal NOAEL:

50 mg/kg/day in rabbits over 21 days.

Mild irritation observed at higher concentrations.

Inhalation NOAEL:

Limited data available, as inhalation exposure is not a typical route of application for Cocamide DEA.

Applications in Cosmetics:

Commonly used as:

A foam booster and stabilizer in shampoos and body washes.

A thickening agent in liquid soaps, conditioners, and hand washes.

A mild emulsifier in creams and lotions.

Typical concentrations range from 1% to 5% in formulations, depending on product type and purpose.

### 2.5.3. SODIUM CHLORIDE

Sodium Chloride, commonly known as table salt, is an inorganic compound widely used in cosmetics and personal care products. It serves multiple functions, including as a viscosity modifier, exfoliant, and bulking agent. Sodium Chloride is highly stable and non-toxic, making it a versatile and widely accepted ingredient in various formulations.

#### General Information

- INCI Name: Sodium Chloride
- CAS Number: 7647-14-5
- Chemical Formula: NaCl
- Molecular Weight: 58.44 g/mol
- Primary Functions: Viscosity adjuster, thickening agent, abrasive, exfoliant, and bulking agent.
- Source: Naturally occurring mineral (halite) or produced synthetically by evaporating seawater or brine.

#### Physical and Chemical Properties

Property	Details
Appearance	White crystalline powder or granules
Odor	Odourless
Solubility	Highly soluble in water (~359 g/L at 25 °C); insoluble in most organic solvents
Melting Point	801 °C
Boiling Point	1413 °C
Density	~2.16 g/cm <sup>3</sup>
pH (1% solution)	Neutral (~7)
Stability	Chemically stable; hygroscopic under high humidity.

#### Toxicological Information

##### Dermal Irritation and Sensitization

Non-irritating and non-sensitizing in cosmetic formulations.

May cause mild irritation in high concentrations, especially on broken or damaged skin.

##### Oral Toxicity

Acute oral LD50 (rats): ~3000 mg/kg, indicating low acute toxicity.

Essential for physiological processes in the body but excessive ingestion can lead to hypernatremia.

##### Ocular Irritation

May cause mild irritation to eyes in concentrated or crystalline form; minimal risk when dissolved in formulations.

##### Chronic and Sub chronic Toxicity

Well-tolerated at typical exposure levels in cosmetics.

Chronic ingestion of excessive amounts can cause systemic issues (e.g., hypertension), but these risks are not relevant to cosmetic use.

#### Carcinogenicity and Mutagenicity

No evidence of carcinogenic or mutagenic effects.

#### Environmental Impact

Naturally occurring and readily soluble in water; minimal ecological impact at cosmetic concentrations.

#### NOAEL (No Observed Adverse Effect Level)

Dermal NOAEL: Sodium Chloride is considered non-toxic for dermal use; no specific NOAEL is reported, but cosmetic formulations use it at concentrations up to 2-5% for viscosity control without adverse effects.

Oral NOAEL: Based on human dietary studies, an oral NOAEL of 240 mg/kg body weight/day is generally accepted for sodium chloride. This is derived from its role as an essential nutrient rather than a toxicant.

#### 2.5.4. GLYCOL STEARATE

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Glycol Stearate is a cosmetic ingredient primarily used as an opacifier, emulsifier, and thickening agent in personal care formulations. It is an ester of ethylene glycol and stearic acid, typically derived from plant-based sources such as palm or coconut oils. It also provides a pearlescent effect in products, enhancing visual appeal.

INCI Name: Glycol Stearate

CAS Number: 111-60-4

EINECS Number: 203-886-9

Common Synonyms: Ethylene Glycol Monostearate

#### Regulatory Status:

Approved for use in cosmetics globally with no specific concentration limits, subject to general safety regulations.

#### Composition

An ester formed from ethylene glycol and stearic acid (C18 fatty acid).

Commercial grades may include small amounts of other glycol esters, depending on purity.

Typically contains a mix of mono- and di-stearate forms.

#### Physical and Chemical Properties

Appearance: White to off-white waxy flakes or powder.

Odor: Mild, characteristic fatty odor.

Melting Point: 55–60°C.

Solubility: Insoluble in water but dispersible; soluble in alcohol and oils.

Molecular Weight: ~284.5 g/mol (monoester).

pH: Neutral in water-based formulations.

#### Stability:

Stable in acidic to neutral pH ranges.

May hydrolyze in strongly alkaline conditions.

#### Toxicological Information

##### Acute Toxicity:

Oral LD50 (rat): >2000 mg/kg, indicating low acute toxicity.

Dermal LD50 (rabbit): >2000 mg/kg, suggesting low dermal toxicity.

##### Irritation and Sensitization:

Non-irritating to mildly irritating to the skin and eyes, depending on concentration.

Not a known skin sensitizer.

##### Chronic Toxicity:

No systemic toxicity observed in repeated exposure studies at typical cosmetic concentrations.

##### Carcinogenicity:

Not classified as a carcinogen.

Free from impurities such as 1,4-dioxane or other carcinogenic byproducts under proper manufacturing conditions.

##### Reproductive/Developmental Toxicity:

No evidence of reproductive or developmental toxicity in available studies.

##### Environmental Impact:

Biodegradable under aerobic conditions.

Low aquatic toxicity, though high concentrations can form surface films that may affect oxygen exchange.

#### NOAEL

##### Oral NOAEL:

100 mg/kg/day in rats based on subchronic toxicity studies.

No adverse effects observed at lower doses.

##### Dermal NOAEL:

200 mg/kg/day in rabbits from 21-day repeated dermal exposure studies.

##### Inhalation NOAEL:

Limited data available, as Glycol Stearate is not typically used in aerosolized formulations.

Applications in Cosmetics

Emulsifier: Enhances the stability of oil-in-water emulsions in lotions, creams, and conditioners.

Opacifier: Imparts a pearlescent or creamy appearance in shampoos, body washes, and facial cleansers.

Thickener: Adds viscosity and texture to formulations.

Typical use concentrations:

0.5–5%, depending on the product type and desired functionality.

### 2.5.5. COCAMIDOPROPYL BETAINE (CAPB)

Cocamidopropyl Betaine (CAPB) is a widely used, mild amphoteric surfactant commonly found in personal care and household products. Derived from coconut oil, it is used for its gentle cleansing, foaming, and viscosity-building properties and is particularly valued for reducing the irritancy of other surfactants when blended into formulations.

General Information:

INCI Name: Cocamidopropyl Betaine

CAS Number: 61789-40-0

Molecular Formula: C<sub>19</sub>H<sub>38</sub>N<sub>2</sub>O<sub>3</sub>

Molecular Weight: Approximately 342.52 g/mol

Origin: Derived from coconut oil (fatty acids) and dimethylaminopropylamine

Common Uses: Shampoos, body washes, facial cleansers, bubble baths, and hand soaps

Physical and Chemical Properties:

Appearance: Clear to pale yellow liquid

Odor: Mild, characteristic

Solubility: Soluble in water, forming stable solutions and suitable for a wide pH range

pH: 5–7 in a 10% solution, which is generally compatible with skin-friendly formulations

Density: Approximately 1.05 g/cm<sup>3</sup> at 20°C

Foaming Ability: High foaming, even in hard water

Viscosity: Varies depending on concentration but generally around 200-700 cp at 20°C

Toxicological Information:

Skin Irritation: Generally mild; CAPB is commonly used in products for sensitive skin due to its low irritancy profile. However, some reports of irritation can occur due to impurities like amidoamine or dimethylaminopropylamine.

Eye Irritation: Low to moderate; some irritation potential in concentrated form but generally well-tolerated in diluted product formulations.

Allergic Reactions: Cases of contact dermatitis have been reported, but this is often due to impurities rather than CAPB itself.

Mutagenicity and Carcinogenicity: No evidence of mutagenic or carcinogenic properties based on available research.

NOAEL (No Observed Adverse Effect Level):

Specific NOAEL values for Cocamidopropyl Betaine in human studies are limited. However, for similar amphoteric surfactants, a NOAEL around 1000 mg/kg body weight/day has been reported in animal studies, which serves as a conservative estimate for safe exposure levels in personal care formulations. This value is based on comparable mild surfactants used in rinse-off and leave-on applications.

### 2.5.6. PARFUM

The scent of the product is determined from the oils below:

- JUICY PEACH EFF342861 / European Flavours & Fragrances PLC

It contains among others:

- Dipropylene Glycol – estimated amount in the FINAL PRODUCT 0.04% - NOAEL = 1000 mg/kg\*bw/day, SED = 0.000666 mg/kg\*bw/day, **MoS = 1,501,501.5 - SAFE**
- Propylene Glycol – estimated amount in the FINAL PRODUCT 0.01%. – NOAEL = 2000 mg/kg\*bw/day, SED = 0.0001665 mg/kg\*bw/day, **MoS = 12,012,012.0 – SAFE**

### 2.5.7. LAURETH-7

Laureth-7 is a non-ionic surfactant and emulsifier widely used in cosmetics and personal care products. It is part of the polyoxyethylene lauryl ether family, created by ethoxylating lauryl alcohol. Laureth-7 is valued for its solubilizing, emulsifying, and stabilizing properties, particularly in oil-in-water emulsions and water-based formulations.

INCI Name: Laureth-7

CAS Number: 3055-97-8

EINECS Number: 221-280-2

Regulatory Status: Approved globally for use in cosmetics, with no strict concentration limits, though it must comply with general safety regulations.

In the EU, it must adhere to the general safety requirements under the EU Cosmetics Regulation.

**Composition:**

A mixture of polyethylene glycol (PEG) ethers of lauryl alcohol.

Typically represented as  $C_{12}H_{26}O \cdot (C_2H_4O)_n$ , where  $n = 7$ , indicating an average of 7 ethylene oxide units.

Composition includes unreacted lauryl alcohol and varying lengths of ethoxylated chains.

**Physical and Chemical Properties:**

**Appearance:** Clear to slightly hazy liquid or waxy solid (depending on storage temperature).

**Solubility:** Soluble in water, alcohols, and glycols; forms stable micelles in water.

**Melting Point:** ~10–25°C (varies with ethoxylation degree).

**Boiling Point:** Decomposes before boiling.

**Molecular Weight:** ~400 g/mol (varies depending on exact ethoxylation).

**pH:** Neutral to slightly acidic (5.0–7.0 in aqueous solution).

**Stability:**

Stable in acidic and neutral pH conditions.

May degrade under strongly alkaline or high-temperature conditions.

**Toxicological Information:**

**Acute Toxicity:**

Oral LD50 (rat): >2000 mg/kg, indicating low acute toxicity.

Dermal LD50 (rabbit): >2000 mg/kg, also considered low toxicity through skin contact.

**Irritation and Sensitization:**

Generally mild on skin and eyes at typical cosmetic concentrations.

May cause slight irritation in sensitive individuals at high concentrations.

Not a significant sensitizer based on available data.

**Chronic Toxicity:**

Repeated exposure studies show no systemic toxicity at typical cosmetic use levels.

**Carcinogenicity:**

No evidence of carcinogenicity in available studies.

Concerns about ethoxylated compounds often stem from potential contamination with 1,4-dioxane, a byproduct of ethoxylation, which is a suspected carcinogen. Proper purification during production minimizes this risk.

**Reproductive/Developmental Toxicity:**

No significant effects on reproduction or development reported at tested concentrations.

**Environmental Impact:**

Biodegradable under aerobic conditions.

May pose risks to aquatic environments in high concentrations due to surfactant activity.

**NOAEL:**

**Oral NOAEL:**

50 mg/kg/day in rats (90-day subchronic toxicity study).

Higher doses showed slight liver effects, considered adaptive rather than toxic.

**Dermal NOAEL:**

100 mg/kg/day in rabbits (21-day dermal toxicity study).

Minimal irritation observed at this dose.

**Inhalation NOAEL:**

Limited data available, as Laureth-7 is not typically used in aerosolized forms.

**Applications in Cosmetics:**

**Commonly used as:**

**Emulsifier:** Stabilizes oil-in-water emulsions in creams, lotions, and serums.

**Solubilizer:** Helps dissolve oil-based ingredients in water-based systems, such as in cleansers and micellar waters.

**Foam Booster:** Enhances foam stability in shampoos and body washes.

**Viscosity Modifier:** Adjusts texture and consistency of formulations.

Typical concentrations range from 1% to 5%, depending on product type and functionality.

### 2.5.9. BRONOPOL

Bronopol, also known as 2-Bromo-2-nitropropane-1,3-diol, is a synthetic antimicrobial preservative used in cosmetics, personal care products, pharmaceuticals, and industrial formulations. It is effective against bacteria, particularly Gram-negative species, making it a versatile preservative for water-based formulations.

INCI Name: Bronopol

CAS Number: 52-51-7

EINECS Number: 200-143-0

Regulatory Status:

Approved for use as a preservative in cosmetics under strict concentration limits.

In the EU, allowed at a maximum concentration of 0.1% (1,000 ppm) in finished products (Annex V, EU Cosmetics Regulation).

In the USA, regulated as a cosmetic ingredient and antimicrobial agent.

Composition:

Chemical Name: 2-Bromo-2-nitropropane-1,3-diol

Molecular Formula: C<sub>3</sub>H<sub>6</sub>BrNO<sub>4</sub>

Molecular Weight: 199.99 g/mol

Contains bromine and nitro functional groups that contribute to its antimicrobial activity.

Physical and Chemical Properties:

Appearance: White crystalline powder

Solubility: Soluble in water, alcohol, and glycols

Melting Point: ~130°C (with decomposition)

Boiling Point: Decomposes before boiling

pH Stability: Stable in acidic to neutral pH (pH 4-7); unstable at higher pH due to hydrolysis.

Odor: Slightly antiseptic odour

Stability:

Sensitive to heat, light, and alkaline conditions.

Can decompose to release formaldehyde and nitrosamines under certain conditions.

Toxicological Information:

Acute Toxicity:

Oral LD50 (rat): ~180 mg/kg

Dermal LD50 (rabbit): >1600 mg/kg

Indicates moderate oral toxicity and low dermal toxicity.

Dermal Absorption:

Bronopol has limited dermal penetration, reducing systemic exposure risks through the skin.

Irritation and Sensitization:

Can cause skin and eye irritation at higher concentrations.

May act as a weak sensitizer in some individuals.

Subchronic Toxicity:

Studies show no significant systemic toxicity at low concentrations.

Toxicity increases with prolonged exposure at higher concentrations.

Genotoxicity and Mutagenicity:

Negative in bacterial reverse mutation assays (Ames test).

Some studies suggest potential genotoxic effects under extreme conditions (e.g., at high doses or in the presence of reactive metabolites).

Carcinogenicity:

No direct evidence of carcinogenicity, but concerns arise due to potential formaldehyde release and nitrosamine formation during decomposition.

Environmental Impact:

Highly toxic to aquatic organisms.

Biodegradable under appropriate conditions, but its decomposition byproducts can contribute to environmental risks.

NOAEL:

Oral NOAEL:

20 mg/kg/day (rat, 90-day study)

Based on subchronic toxicity studies, with liver and kidney changes observed at higher doses.

Dermal NOAEL:

30 mg/kg/day (rabbit, 21-day dermal study)

Minimal irritation at this dose.

Inhalation NOAEL:

Limited data available; inhalation exposure is typically avoided due to the risk of irritation.

Applications in Cosmetics:

Used as a preservative in water-based formulations, including:

Shampoos

Conditioners

Lotions

Creams

Cleansers

Particularly effective in formulations prone to bacterial contamination.

### 2.5.10. CI 18050

CI 18050, also known as Acid Red 1, is a synthetic monoazo dye with the chemical formula  $C_{18}H_{13}N_3Na_2O_8S_2$  and a molar mass of 509.42 g/mol.

Physical and Chemical Properties:

Appearance: Red powder or granules.

Density: 1.37–1.774 g/cm<sup>3</sup> at 20°C.

Melting Point: Not specified; dye content approximately 60%.

Boiling Point: 794.21°C at 101,325 Pa.

Water Solubility: 131.97 g/L at 20°C; slightly soluble in ethanol and cellosolve.

Vapor Pressure: Negligible at 25°C.

Stability: Light-sensitive; should be stored in amber vials under refrigeration.

Toxicological Data:

CI 18050 is generally considered to have low toxicity. It is classified as not hazardous according to Regulation (EC) No 1272/2008.

Safety data sheets indicate that it does not pose significant acute toxicity, skin corrosion, or irritation hazards.

DC FINE CHEMICALS

The Environmental Working Group (EWG) assigns CI 18050 a low hazard score, indicating minimal concerns regarding cancer, allergies, immunotoxicity, and developmental or reproductive toxicity.

ENVIRONMENTAL WORKING GROUP

However, as with many chemical substances, it is advisable to handle CI 18050 with care to avoid inhalation of dust and contact with skin and eyes. Safety measures such as using appropriate personal protective equipment are recommended during handling.

Safe up to 0.03% in rinse-off and 0.02% leave-on products.

## 2.6 IMPURITIES AND TRACE AMOUNTS OF FORBIDDEN SUBSTANCES

According to specifications (see section 1. Quantitative and qualitative composition – specification of ingredients) submitted by ingredient suppliers, the ingredients contain the impurities below:

1. Methylchloroisothiazolinone/methylisothiazolinone – H319 / H314 / H317

Estimated amount 0.000028% or 0.28ppm in the final product.

Due to EU cosmetics regulation MCI/MI allowed up to 0.0015% (15 ppm) in rinse-off products only. This restriction reflects concerns over contact allergies and dermal sensitization.

NOAEL = 0.83 mg/kg\*bw/day SED=0.0000004662 MoS= NOAEL/SED = 1780351.78 >100 SAFE

## 3. NORMAL & REASONABLY FORESEEABLE USE

### 3.1 DESCRIPTION OF INTENDED APPLICATION & DIRECTIONS FOR USE:

**Wet Skin:** Begin by thoroughly wetting your hands with warm or cold water.

**Apply:** Put an amount of hand liquid soap in your palms and apply it evenly on your wet skin. Massage gently to lather.

**Lathering:** Gently massage the lathered hand liquid soap onto your hands using circular motions, covering all areas you wish to cleanse.

**Rinse:** Rinse off the lather thoroughly with warm water. Ensure that all hand wash residues are washed away to prevent any potential dryness or irritation.

**Dry:** Dry your hands using a dry tower.

## 4. TOXICOLOGICAL PROFILE OF THE COSMETIC PRODUCT AND SUBSTANCES

### 4.1 EXPOSURE TO THE COSMETIC PRODUCT

Site of Application area: **Hands area**

Surface Area of Application (cm<sup>2</sup>): **860**

Amount Applied (g) per day: **18.67 g**

Duration: **Rinse-off**

Frequency: **10 /day**

Retention Factor: **0.01**

Exposure Routes: **Dermal (incidental ocular and oral)**

Target Population: **Adult 60kg**

Calculated relative daily exposure (mg/kg bw/day): **3.33**

*Typical consumer use of the product is taken from the SCCS's Notes of Guidance and the EPA Exposure Factors Handbook.*

### 4.2 EXPOSURE TO THE SUBSTANCE

INCI	Calculated Relative Daily Exposure mg/kg bw/day	Concentration % (w/w)	Dermal Absorption %	Systemic Exposure Dosage mg/kg bw/day
Aqua	3.33	85.230528	50	1.4191
Sodium Laureth Sulfate		8.6528	50	0.1441
Cocamide DEA		2.14	50	0.0356
Sodium Chloride		1.6667	50	0.0278
Glycol Stearate		1.239972	50	0.0206
Cocamidopropyl betaine		0.63	50	0.0105
Parfum		0.2	50	0.0033
Laureth-7		0.14	50	0.0023
2-Bromo-2-Nitropropane-1,3-Diol		0.1	50	0.0017
CI 18050		0.0021	50	0.000034965

### 4.3 TOXICOLOGICAL PARAMETERS OF THE SUBSTANCES

## 4.3.1 LOCAL TOXICITY

INCI	Eye Irritant	Skin Irritant	Skin Sensitiser	Photosensitiser
Aqua	no	no	no	no
Sodium Laureth Sulfate	H318	H315	no	no
Cocamide DEA	H318	H315	no	no
Sodium Chloride	H320	no	no	no
Glycol Stearate	H320	H316	no	no
Cocamidopropyl betaine	H318	no	no	no
Parfum	H319	H315	H317	no
Laureth-7	H319	no	no	no
2-Bromo-2-Nitropropane-1,3-Diol	H319	H315	H317	no
CI 18050	no	no	H317	no

## 4.3.2 MARGIN OF SAFETY AND COMMENTS

INCI	Margin of Safety (MOS)	NOAEL (mg/kg*bw/day)	SED (mg/kg*bw/day)
Aqua			1.4191
Sodium Laureth Sulfate	347.0556355	50	0.1441
Cocamide DEA	467.7668323	16.667	0.0356
Sodium Chloride	8648.475679	240	0.0278
Glycol Stearate	9687.325207	200	0.0206
Cocamidopropyl betaine	95333.42867	1000	0.0105
Parfum	<b>Safe</b> according to IFRA documentation		0.02441
Laureth-7	429000.429	1000	0.0023
2-Bromo-2-Nitropropane-1,3-Diol	6006.006006	10	0.0017
CI 18050	<b>Safe</b> according to CD 2008/128/EC		0.000034965

## 5. UNDESIRABLE EFFECTS &amp; SERIOUS UNDESIRABLE EFFECT

The application of the raw materials used in cosmetic products has been described and tested for a long time. When used as intended, the raw materials show good skin and mucous membrane compatibility in the concentrations used. Due to the toxicological profile of the raw materials as well as the combination of the raw materials in the proportional compositions in the product, no adverse effects are to be expected when used as intended. Interactions of the ingredients are not to be expected due to the chemical nature. At the time of the preparation of the safety report, there were no reports of adverse reactions according to Annex I, Part A 9. When health-related complaints are received, the cases are subjected under the responsibility of the responsible person, the results of which are then considered in the safety assessment.

## 6. REFERENCES

- THE SCCS'S NOTES OF GUIDANCE FOR THE TESTING OF COSMETIC SUBSTANCES AND THEIR SAFETY EVALUATION 8TH REVISION

<http://eurlex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:342:0059:0209:en:PDF>

- MSDS of ingredients

- Commission Implementing Decision of 25th November 2013 Guidelines on Annex I to Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products

- <https://chem.echa.europa.eu/>

- <https://www.inchem.org/>

- <https://www.cir-safety.org/>

- <https://infocus.nlm.nih.gov/2015/11/04/toxnet-the-nlm-toxicology-databases/>

- SCCS – Opinions

[http://ec.europa.eu/health/scientific\\_committees/consumer\\_safety/opinions/index\\_en.htm](http://ec.europa.eu/health/scientific_committees/consumer_safety/opinions/index_en.htm)

- CosIng: the European Commission database on cosmetic substances

<http://ec.europa.eu/consumers/cosmetics/cosing/index.cfm?fuseaction=search.simple>

- REGULATION 1223/2009 ANNEXES

[http://ec.europa.eu/consumers/cosmetics/cosing/index.cfm?fuseaction=ref\\_data.annexes\\_v2](http://ec.europa.eu/consumers/cosmetics/cosing/index.cfm?fuseaction=ref_data.annexes_v2)

## PART B: ASSESSMENT CONCLUSION & REASONING

### 1. ASSESSMENT CONCLUSION

Based on the information supplied, the cosmetic product detailed in this report is safe for human health when used in common or reasonably predictable conditions in compliance with the instructions provided for the consumer.

This conclusion is only applicable to this cosmetic product with the composition, properties, purpose, and method of use of which are detailed in this documentation, and laboratory tests attached to this assessment, including the detailed production, and labelling which has been assessed as meeting the requirements of Cosmetic Regulation (EC) No. 1223/2009 effective on the date this report was issued.

### 2. LABELLED WARNINGS AND INSTRUCTIONS OF USE

The label of this cosmetic product should include this special note regarding its use, in compliance with Article 19 of Cosmetic Regulation (EC) No. 1223/2009:

Keep out of reach of children, Avoid Contact with Eyes, For External Use Only.

No additional wording required.

**Allergens** declared on the label:

UK Market: **Citronellol, Geraniol, Hexylcinnamal, Limonene, Linalool**

EU Market: **Citronellol, Geraniol, Hexylcinnamal, Limonene, Linalool, Terpineol.**

\*The allergens calculations are based on the perfume's provided MSDS

\* The presence of these allergens must be indicated in the list of ingredients when their concentration exceeds: 0.001% in leave-on products or 0.01% in rinse-off products. Only the allergen, not the estimated amount, is required on the label.

### 3. REASONING

Based on the formulation of this cosmetic product, its qualitative and quantitative composition according to its INCI ingredients, basic physical and chemical characteristics, and microbiology, Preservation Challenge Test performed – if applicable, classification of the cosmetic product type, including its purpose and method of application, and available toxicological information and safety sheets of the ingredients used; the cosmetic product safety has been assessed for the consumer by assessing the toxicological profile of all ingredients, their chemical structure, exposure level and Margin of Safety (MoS) depending on the purpose of use in this cosmetic product.

This cosmetic product contains only the allowed ingredients in the allowed concentrations. For ingredients with safety limits as specified in Annexes to Cosmetic Regulation (EC) No. 1223/2009, no ingredient exceeds the allowable safety limit, therefore:

is a **SAFE** concentration in this cosmetic product.

The evaluation of the entire composition and applied ingredient concentrations indicate that the composition of this cosmetic product complies with the requirements of Cosmetic Regulation (EC) No. 1223/2009 of the European Parliament and of the Council.

This assessment is based on information supplied by the client, raw material manufacturers, and published information in recognised authoritative sources. Whilst best endeavours have been used to check the accuracy of this information, the undersigned cannot be held responsible for any erroneous information supplied and used for preparing this assessment.

#### 4. ASSESSOR'S CREDENTIALS

Safety Assessor: *On behalf of Naturally Balmy Ltd.*

Vasileios Karamalakis

Experience and qualifications:

- MSci in Chemical Engineering, Aristotle University of Thessaloniki.
- SCS-U.K. Diploma in Cosmetics Science
- Certified Safety Assessor from the “In Vitro Toxicology and DermatoCosmetology” department of Vrije Universiteit Brussel.
- +18 years of experience in cosmetic product development including but not limited to Formulation, Safety, Testing, Claim substantiation, Efficacy evaluation.
- Full member “A” of the Society of Cosmetic Scientists (SCS) UNITED KINGDOM - Nr 5736.