Prepared 09.07.2015_Ver 1
Prepared 09.09.2015_Ver 2 (updated specifications for raw materials)
Prepared 23.06.2016_Ver 3 (updated specification for final product)

COSMETIC PRODUCT SAFETY REPORT FOR

Trade name: Panthenol Jojoba Spray

Responsible person: Valeant sp. z o.o. sp. j.,
ul. Przemysłowa 2

35-959 Rzeszów

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PART A – COSMETIC PRODUCT SAFETY INFORMATION

1. Qualitative and quantitative composition of the cosmetic product.

1.1. Qualitative composition.

INGREDIENTS: AQUA, PANTHENOL, BUTANE, PROPANE, ETHYLHEXYL LAURATE, CETEARYL ALCOHOL, PARAFFINUM LIQUIDUM, ISOBUTANE, SODIUM CETEARYL SULFATE, SIMMONDSIA CHINENSIS SEED OIL, PARFUM, TOCOPHERYL ACETATE, CITRIC ACID

1.2. The quantitative composition of the cosmetic product, including chemical identity of the substances (INCI, CAS, EINECS/ELINCS, where possible) and their intended function.

CHEMICAL NAME or other for the identification	INCI	%	CAS	EINECS	FUNCTION
water	AQUA	81,027	7732-18-5	231-791-2	base, solvent
Butanamide, 2,4-dihydroxy-N-(3-hydroxypropyl)-3,3-dimethyl-, (2R)-; dl-Panthenol	PANTHENOL	4,607	81-13-0 / 16485-10-2	201-327-3 / 240-540-6	conditioning
Butane	BUTANE	4,100	106-97-8	203-448-7	propellant
Propane	PROPANE	3,500	74-98-6	200-827-9	propellant
2-Ethylhexyl laurate	ETHYLHEXYL LAURATE	2,764	20292-08-4	243-697-9	emollient
Alcohols, C16-18	CETEARYL ALCOHOL	1,6-1,8	67762-27-0 / 8005-44-5	267-008-6 / -	emollient, emulsifier, emulsion stabiliser,foambusting, surfactant, viscosity controlling
Paraffin oils. Liquid hydrocarbons from petroleum	PARAFFINUM LIQUIDUM	1,382	8012-95-1 / 8042-47-5	232-384-2 / 232-455-8	emollient
Isobutane	ISOBUTANE	0,200	75-28-5	200-857-2	propellant
(octadecyloxy)sulfonic acid	SODIUM CETEARYL SULFATE	0,16-0,18	59186-41-3	n.a.	clansing, foaming, surfactant
fixed oil expressed or extracted from seeds of the desert shrub, Jojoba, Simmondsia chinensis, Buxaceae	SIMMONDSIA CHINENSIS SEED OIL	0,299	90045-98-0	289-964-3	emollient, conditioning
mixture	PARFUM	0,147	n.a.	n.a.	fragrance

3,4-Dihydro-2,5,7,8-tetramethyl-2-(4,8,12-trimethyltridecyl)-2H-benzopyran-6-yl acetate	TOCOPHERYL ACETATE	0,100	7695-91-2 / 58-95-7	231-710-0 / 200-405-4	antioxidant, conditioning
2-Hydroxy-1,2,3-propanetricarboxylic acid	CITRIC ACID	0,016	77-92-9 / 5949-29-1	201-069-1	buffering

1.3. Description of the name and code number of the composition and the identity of the supplier.

Name: Just Mild

Code: DC10188/3

Supplier: Symrise AG

Allergens which exceeding 0.001%, which should be listed on the label of the finished product: the composition does not contain allergens.

IFRA classification: 4C (body balm).

The maximum permitted use according to the IFRA certificate: 0.16%

2. Physical/chemical characteristics and stability of the cosmetic product

2.1. Product specification.

PROPERTIES	REQUIREMENTS
appearance	after spraying – foam
color	white
smell	slight, according to used fragrance
ph	4,3 – 6,5
microbiological purity	Total number of aerobic microorganisms, including: mesophilic aerobic bacteria count, yeast and molds 10^3 cfu / g Staphylococcus aureus Pseudomonas aeruginosa Candida albicans Escherichia coli - absent / g

2.2. Safety Data Sheets and Technical Data Sheets for raw materials.

Safety Data Sheets and Technical Data Sheets for raw materials in the File “TDS” (annex).

2.3. The stability of the cosmetics product under reasonably foreseeable storage conditions.

Due to the fact that this is a specific product (a form of foam formed during the application), testing the stability and compatibility of the packaging is not required.

3. Microbiological quality.

3.1. The microbiological specifications of the raw materials.

Summary of raw materials for microbial sensitivity:

The microbiological specifications of the raw materials in separate file.

Raw Material	Microbiological Specification
Dexpanthenol	Purity – Total aerobic microbial count ≤ 2000 CFU / g, Purity – Total combined yeasts and moulds count. ≤ 200 CFU / g, Purity – Total combined aerobic microbial and total combined yeasts and moulds count. ≤ 100 CFU / g
Rofetan 148	no data
Galenol 1618 CSP	Total of aerobic bacteria and fungi <= 100 cfu/g, Gram-negative bacteria <= 10 cfu/g
Pionier 2076	no data
Jojoba oil	Total aerobic microorganisms <100 jtk/g, yeasts mirroorganisms <10 jtk/g, molds microorganisms <10jtk/g
Perfume (Just Mild DC10188/3)	no data
α-Tocopheryl acetate	Total aerobic microbial count ≤ 1000cfu/g, total combined yeasts and moulds count. ≤ 100 cfu/g, Enterobacteriaceae < 10cfu/g, E.coli negative in 10g, Salmonella negative in 25g, Staphylococcus aureus negative in 10g, Pseudomonas aeruginosa neg in 10g.

Citric acid monohydrate	Total Aerobic mesophilic count max. 1000 CFU/g, Yeasts and molds max. 100 CFU/g, Enterobacteriaceae max. 10/g, Escherichia coli negative in 10g, Salmonella negative in 25g, Coagulase positive staphylococcus negative in 10g, Pseudomonas aeruginosa negative in 10g, Listeria monocytogenes negative in 25g, Bacterial endotoxins max. 0,5 IU/mg
Purified water	Total aerobic microbial count <100 jtk/ml, Pseudomonas Aeruginosa absent w 250 ml
5.5 bar Propellant	no data

3.2. The microbiological specifications of the final product.

In accordance with the ISO 29621: 2010 cosmetic classified as low-risk due to the type of packaging (container under pressure, with the use of propellant). Microbiological tests are not mandatory.

3.3. Results of preservation challenge test.

In accordance with the ISO 29621: 2010 cosmetic classified as low-risk due to the type of packaging (container under pressure, with the use of propellant). Preservation challenge test is not mandatory.

4. Impurities, traces, information about the packaging material

4.1. The purity of the raw materials:

Ingredients which are part of the preservative system cannot be considered as traces. Therefore, when present in a mixture, they have to be added to the INCI list.

Any other ingredient listed on the MSDS as impurities may be considered as a trace, as long as its concentration in the raw material is lower than 1%.

The non-intended presence of a small quantity of a prohibited substance, stemming from impurities of natural or synthetic ingredients, the manufacturing process, storage, migration from packaging, which is technically unavoidable in good manufacturing practice, shall be

permitted provided that such presence poses no risk to human health . A detailed document sustaining this unavoidability must be provided to satisfy this requirement.

Raw Material	Impurities
Dexpanthenol	heavy metals < 10 ppm, aminopropanol < 0,1 %, pantoic acid max 0,5%, pantolactone max 1%, dichlorometane max 600 ppm, metanol max 3000ppm
Rofetan 148	no data
Galenol 1618 CSP	aqua 1,9%
Pionier 2076	acc. to Ph.Eu.
Jojoba oil	heavy metals laid down in Regulation (EC) No. 1881/2006 of 19 December 2006 settings maximum levels for certain contaminants in foodstuffs.
Perfume (Just Mild DC10188/3)	no data
α-Tocopheryl acetate	impurity max. 2,5%, free tocopherol max 0,5%, Lead max 2 ppm
Citric acid monohydrate	Heavy metals: max. 1 ppm, Arsenic: max. 1 ppm, Lead: max. 0.5 ppm, Mercury: max. 1 ppm, Copper: max. 1 ppm, Zinc: max. 1 ppm, Iron: max. 1 ppm, Barium: max. 1 ppm, Calcium: max. 10 ppm, Magnesium: max. 1 ppm, Aluminium: max. 0.2 ppm, Chlorides: max. 5 ppm, Sulphates: max. 30 ppm, Oxalates: max. 10 ppm,
Purified water	no data
5.5 bar Propellant	impurities < 0,9%

The current impurities do not affect the safety of cosmetic products. The removal of these contaminants is not possible due to technological reasons the present state of knowledge.

4.2. The relevant characteristics of packaging material, in particular purity and stability.

The packaging material having direct contact with final product are:

Part of packaging	Material
Container	Aluminium 99,7% internal coated. Internal coating intended for contact with food.
Valve	multi-material element
Nozzle head	PP (Polipropylene)
Cap	PP (Polipropylene)

Specifications for particular parts the packaging are attached.

5. Normal and reasonably foreseeable use.

The cosmetic is designed for adults body care . Leave-on product.

6. Exposure to the cosmetic product.

6.1. The site of application

All body

6.2. The surface area of application.

15670 cm^2. (The SCCS'S notes of guidance for the testing of cosmetics ingredients and their safety evaluation. 8^{TH} revision)

6.3. The amount of product applied.

7,82 g. (The SCCS'S notes of guidance for the testing of cosmetics ingredients and their safety evaluation. 8TH revision)

6.4. Calculated relative daily exposure.

A – 123,20 (mg/kg/bw/day) (The SCCS'S notes of guidance for the testing of cosmetics ingredients and their safety evaluation. 8TH revision)

6.5. The duration and frequency of use;

Leave-on product. Twice a day. (The SCCS'S notes of guidance for the testing of cosmetics ingredients and their safety evaluation. 8TH revision)

6.6. The normal and reasonably foreseeable exposure route(s);

Skin. Although the product is extracted from a container by use of the propellant gas does not take into account the inhalation because the application does not form a spray which could get into the lungs.

6.7. The targeted (or exposed) population(s)

Adults.

7. Exposure to the substances.

SED (Systemic Exposure Dosage) was calculated.

SED (mg/kg bw/day) = A (mg/kg bw/day) * C (%)/100 * DA (%)/100

with:

A (mg/kg mc/d) – Estimated daily exposure to a cosmetic (“THE SCCS'S NOTES OF GUIDANCE FOR THE TESTING OF COSMETIC SUBSTANCES AND THEIR SAFETY EVALUATION 8TH REVISION”)

C (%) – concentration of the substance under study in the finished cosmetic product

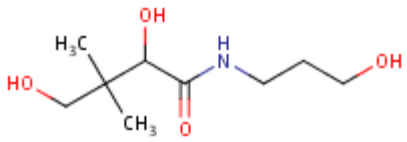
DA (%) – Dermal Absorption expressed as a percentage of the test dose assumed to be applied in real life conditions

INCI	**SED**
AQUA	99,825
PANTHENOL	5,676
BUTANE	5,051
PROPANE	4,312
ETHYLHEXYL LAURATE	3,405
CETEARYL ALCOHOL	2,218
PARAFFINUM LIQUIDUM	1,703
ISOBUTANE	0,246
SODIUM CETEARYL SULFATE	0,222
SIMMONDSIA CHINENSIS SEED OIL	0,368
PARFUM	0,181
TOCOPHERYL ACETATE	0,123
CITRIC ACID	0,020

8. Toxicological profile of the substances

INCI NAME: PANTHENOL

1. **Description** Precursor of vitamin B5 (pantothenic acid), provitamin B5. Panthenol after penetration into the skin is converted into pantothenic acid. Both compounds have the same biological activities. Vitamin B is found in every living cell.
2. **Chemical name:** Butanamide, 2,4-dihydroxy-N-(3-hydroxypropyl)-3,3-dimethyl-, (2R)-; dl-Panthenol
3. **Molecular formula:** $C_9H_{19}NO_4$ (mw 205.25, Log P −0.989)
4. **The structural formula**:



5. **CAS:** 81-13-0 / 16485-10-2
6. **EINECS:** 201-327-3 / 240-540-6
7. **Origin:** synthetic. Is prepared by the combination 3-amino-1-propanolamine with the lactone of 2,4-dihydroxy-3,3-dimethyl butyric acid.
8. **Function**: Active ingredient, moisturizing ingredient,
9. **Phisical and chemical data**: MSDS, point 9
10. **Toxicological data:**

10.1. Acute toxicity oral: rat: LD50 >15 g/kg (Source: CIR report), LD50 10000 mg/kg (source: ECHA base)

10.2. Acute dermal toxicity: LD50 >2000 mg/kg (source: ECHA base)

10.3. Acute inhalation toxicity: one group of 12 rats (6/sex) was exposed for 7 h to a saturated atmosphere of D-Panthenol at 20°C. Animals then were observed for 14 days. No mortality occurred. No clinical signs of toxicity. were observed. No gross pathological findings were reported. (source: ECHA base)

10.4. Skin irritation properties – not irritating (Source: ECHA base)

10.5. Eye irritation properties – not irritating (Source: ECHA base)

10.6. Sensitizing properties – non-sensitizing (or rarely sensitizing) (Source: ECHA report)

10.7. Dermal absorption – no data, (m.w. 205,2521, Log Pow-1.06, water solubility > 509 g / l). D- Panthenol is expected to be systemically absorbed after oral and dermal exposure. No bioaccumulation is expected.

10.8. Chronic toxicity – no toxic effects were associated with the subchronic (90 days) oral administration of D and DL Panthenol (100%), rats (CIR report)
NOAEL 200 mg/kg (source: ECHA base), NOEL 1000 mg/kg bw/d (source : ECHA base)

10.9. Not classified as CMR: Genetic toxicity negative in vitro and in vivo (source: ECHA base

10.10. Research Involving humans – the ocular irritation potential of two mascaras containing 0,1% panthenol was evaluated with 23 famale subjects, during 3 week period. There were no observations of eye irritation that were considered to be test substance related. (source: CIR report)

A skin care preparation containing 0,5% panthenol was applied to 18 subjects a 4 day cumulative skin irritation study, The conclusion: product was “essentially nonirritating” to the skin (source: CIR report)

11. **Legislation (Regulation 1223/2009/WE):** not regulated

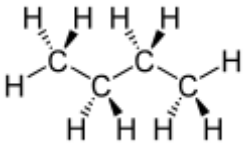
INCI NAME: BUTANE

12. **Description:** Propellant. Is an organic compound. Butane is a gas at room temperature and atmospheric pressure. The term may refer to either of two structural isomers, n-butane or isobutene.

13. **Chemical name:** Butane

3. **Molecular formula:** C_4H_{10}

4. **Structural formula**:



5. **CAS:** 203-448-7

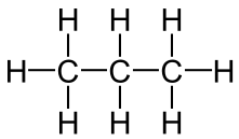
6. **EINECS:** 106-97-8

7. **Origin:** synthetic

8. **Function**: propellant
9. **Physical and chemical data**: point 9 MSDS, (log Pow 1.09, m.w. 58,12 g/mol, woter solubility 61.2 mg/L)
10. **Toxicological data:**
    - 10.1. Acute toxicity oral: no data, not applies.
    - 10.2. Acute inhalation toxicity: 52.04% (520,400 ppm or 1237 mg/l). (source: ECHA base)
    - 10.3. Skin irritation properties – no data, not applies
    - 10.4. Eye irritation properties – no data, not applies
    - 10.5. Sensitizing properties – no data, not applies
    - 10.6. Dermal absorption – no data, not applies
    - 10.7. Chronic toxicity – NOAEC 9000 ppm (odpowiednik 21394 mg/m^3 (mw. 58,12 g/mol). (źródło: baza ECHA)
    - 10.8. Not classified as CMR. Not genotoxic in in vivo and in vitro test. (source: ECHA base)
    - 10.9. Research involving humans – No-threshold effect and/or no dose-response information available
11. **Legislation (Regulation 1223/2009/WE):** not regulated.

INCI NAME: PROPANE

1. **Description:** Propellant. Is an organic compound. Odourless.
2. **Chemical name:** Propane
3. **Molecular formula:** C_3H_8
4. **Structural formula**:

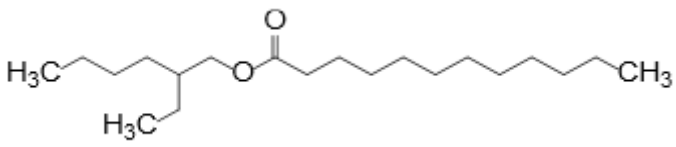


5. **CAS:** 74-98-6
6. **EINECS:** 200-827-9
7. **Origin:** synthetic

8. **Function**: propellant
9. **Physical and chemical data**: point 9 MSDS, (log Pow 1.09, m.w. 44,10 g/mol, water solubility 61.2 mg/L)
10. **Toxicological data:**
    - 10.1. Acute toxicity oral: no data, not applies.
    - 10.2. Acute inhalation toxicity: 52.04% (520,400 ppm or 1237 mg/l). (source: ECHA base)
    - 10.3. Skin irritation properties – no data, not applies
    - 10.4. Eye irritation properties – no data, not applies
    - 10.5. Sensitizing properties – no data, not applies
    - 10.6. Dermal absorption – no data, not applies
    - 10.7. Chronic toxicity – NOAEC 9000 ppm (odpowiednik 21394 mg/m^3 (mw. 58,12 g/mol). (źródło: baza ECHA)
    - 10.8. Not classified as CMR. Not genotoxic in in vivo and in vitro test. (source: ECHA base)
    - 10.9. Research involving humans – No-threshold effect and/or no dose-response information available
11. **Legislation (Regulation 1223/2009/WE):** not regulated.

INCI NAME: ETHYLHEXYL LAURATE

1. **Description:** It is an ester of 2-ethylhexyl alcohol and lauric acid.
2. **Chemical name:** 2-Ethylhexyl laurate
3. **Molecular formula:** $C_{20}H_{40}O_2$ (mw. 312.534 g/mol)
4. **The structural formula**:

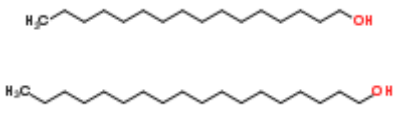


5. **CAS:** 20292-08-4
6. **EINECS:** 243-697-9

7. **Origin:** vegetable and synthetic.
8. **Function**: emollient
9. **Phisical and chemical data**: MSDS, point 9, (mw. 312.534 g/mol, water solubility 1 mg/l (20°C), Log Pow 8,781)
10. **Toxicological data:**
    - 10.1. Acute toxicity oral: LD50>2000 mg/kg (Source: ECHA report)
    - 10.2. Acute inhalation toxicity: LC50> 230 ppm (source: CIR, ECHA)
    - 10.3. Skin irritation properties – non-irritating (Source: ECHA report)
    - 10.4. Eye irritation properties – non-irritating (Source: ECHA report)
    - 10.5. Sensitizing properties – non-sensitizing (Source: ECHA report)
    - 10.6. Dermal absorption – no data
    - 10.7. Chronic toxicity – NOAEL 1000 mg/kg bw/d (28-day research) (source: CIR)
    - 10.8. Not classified as CMR. Not genotoxic in vivo and in vitro researches. (source: ECHA base)
    - 10.9. Research Involving humans – not irritant or very slight irritant (undiluted) (source: CIR report)
11. **Legislation (Regulation 1223/2009/WE):** not regulated

INCI NAME: CETEARYL ALCOHOL

1. **Description:** Mixture of cetyl alcohol and stearyl alcohol
2. **Chemical name:** Alcohols, C16-18
3. **Molecular formula:** $C_{34}H_{72}O_2$ ($C_{18}H_{38}O.C_{16}H_{34}O$)
4. **The structural formula**:



5. **CAS:** 67762-27-0
6. **EINECS:** 267-008-6

7. **Origin:**
8. **Function**: emollient, emulsifying, emulsion stabilising, opacifying, surfactant, viscosity controlling
9. **Phisical and chemical data**: MSDS, point 9
10. **Toxicological data:**
    - 10.1. Acute oral toxicity: LD50 > 1000 mg/kg bw (Source: IUCLID)
    - 10.2. Skin irritation properties – not irritate (Source: IUCLID)
    - 10.3. Eye irritation properties: not irritate (Source: IUCLID)
    - 10.4. Sensitizing properties – not sensitize (Source: IUCLID)
    - 10.5. Dermal absorption – no data
    - 10.6. Chronic toxicity – NOAEL > 1000 mg/kg/day (source: IUCLID)
    - 10.7. Not classified as CMR
    - 10.8. Research Involving humans – five published cases of allergic reactions (nex to reactions on other components) (Source: PubMed)
11. **Legislation (Regulation 1223/2009/WE):** not regulated.

INCI NAME: PARAFFINUM LIQUIDUM

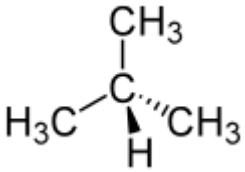
1. **Description:** White mineral oil (petroleum) a highly refined petroleum mineral oil consisting of a complex combination of hydrocarbons obtained from the intensive treatment of a petroleum fraction with sulfuric acid and oleum, or by hydrogenation, or by a combination of hydrogenation and acid treatment. Additional washing and treating steps may be included in the processing operation. It consists of saturated hydrocarbons having carbon numbers predominantly in the range of C15 through C50. Mineral oil (US)
2. **Chemical name:** Liquid hydrocarbons from petroleum
3. **Molecular formula:** n.a.
4. **The structural formula**:

   n.a.

5. **CAS:** 8012-95-1 / 8042-47-5
6. **EINECS:** 232-384-2 / 232-455-8
7. **Origin:** synthetic
8. **Function**: emollient, solvent
9. **Physical and chemical data**: MSDS, point 9
10. **Toxicological data:**
    - 10.1. Acute toxicity: - LD50 – 5000 mg/kg (Source: IUCLID)
    - 10.2. Skin irritation properties – non-irritating (Source: IUCLID)
    - 10.3. Eye irritation properties – non-irritating (Source: IUCLID)
    - 10.4. Sensitizing properties – non-sensitizing (Source: IUCLID)
    - 10.5. Dermal absorption – negligible
    - 10.6. Chronic toxicity – NOAEL - 1800 mg/kg/day (Source: IUCLID)
    - 10.7. Not classified as CMR
    - 10.8. Research involving humans – a lot of reports (Source: HSDB)
11. **Legislation (Regulation 1223/2009/WE):** not regulated

INCI NAME: ISOBUTANE

1. **Description:** Propellant. Is an organic compound. Butane is a gas at room temperature and atmospheric pressure. The term may refer to either of two structural isomers, n-butane or isobutene.
2. **Chemical name:** Butane
3. **Molecular formula:** C_4H_{10}
4. **Structural formula**:

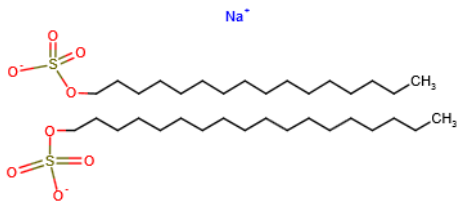


5. **CAS:** 203-448-7
6. **EINECS:** 106-97-8
7. **Origin:** synthetic

8. **Function**: propellant
9. **Physical and chemical data**: point 9 MSDS, (log Pow 1.09, m.w. 58,12 g/mol, water solubility 61.2 mg/L)
10. **Toxicological data:**
    - 10.1. Acute toxicity oral: no data, not applies.
    - 10.2. Acute inhalation toxicity: 52.04% (520,400 ppm or 1237 mg/l). (source: ECHA base)
    - 10.3. Skin irritation properties – no data, not applies
    - 10.4. Eye irritation properties – no data, not applies
    - 10.5. Sensitizing properties – no data, not applies
    - 10.6. Dermal absorption – no data, not applies
    - 10.7. Chronic toxicity – NOAEC 9000 ppm (odpowiednik 21394 mg/m^3 (mw. 58,12 g/mol). (źródło: baza ECHA)
    - 10.8. Not classified as CMR. Not genotoxic in in vivo and in vitro test. (source: ECHA base)
    - 10.9. Research involving humans – No-threshold effect and/or no dose-response information available
11. **Legislation (Regulation 1223/2009/WE):** not regulated.

INCI NAME: SODIUM CETEARYL SULFATE

1. **Description**: Sulfuric acid, mixed cetyl and stearyl esters, sodium salts
2. **Chemical name:** sodium cetearyl sulfate
3. **Molecular formula:** $C_{18}H_{38}O_4S.C_{16}H_{34}O_4S.2Na$ (mw 694.041)
4. **The structural formula**:



5. **CAS:** 59186-41-3
6. **EINECS:** n.a.

7. **Origin:**
8. **Function**: cleansing, foaming, surfactant
9. **Phisical and chemical data**: MSDS, point 9
10. **Toxicological data:**
    - 10.1. Acute toxicity: - LD50 > 10000 mg/kg (Source: TOXLINE)
    - 10.2. Skin irritation properties – Aqueous SCS was not a skin or eye irritant when tested in rabbits at a concentration of 20.0% (Source: TOXLINE)
    - 10.3. Eye irritation properties – Aqueous SCS was not a skin or eye irritant when tested in rabbits at a concentration of 20.0% (Source: TOXLINE)
    - 10.4. Sensitizing properties – did not induce skin sensitization in guinea-pigs at 1.0 and 25% (Source: TOXLINE)
    - 10.5. Dermal absorption – no data
    - 10.6. Chronic toxicity – not toxic (2-year research, without toxic effects) (source: CIR report)
    - 10.7. Not classified as CMR
    - 10.8. Research Involving humans – Because sufficient toxicological data were not available to evaluate SCS, data from a previous assessment of sodium-lauryl-sulfate (151213) (SLS) were reviewed. SLS did not cause skin irritation or irritation when tested in human volunteers.
11. **Legislation (Regulation 1223/2009/WE:** not regulated

INCI NAME: SIMMONDSIA CHINENSIS SEED OIL

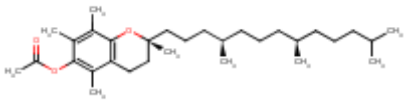
1. **Description:** Simmondsia Chinensis Seed Oil is the fixed oil expressed or extracted from seeds of the desert shrub, Jojoba, Simmondsia chinensis, Buxaceae
2. **Chemical name:** Simmondsia Chinensis (Jojoba) Seed Oil is composed almost completely (97%) of wax esters of monounsaturated, straight-chain acids and alcohols with high-molecular weights (C16-C26). These wax esters exist principally (83%) as combinations of C20 and C22 unsaturated fatty acids and alcohols (McKeown 1983). The long aliphatic chains of both the acids and alcohols make Simmondsia Chinensis (Jojoba) Seed Oil a highly lipophilic chemical (source: CIR report). Fatty acid composition: C18:1 Oleic 5 - 15 %, C20:1 Gadoleic 65 - 80%, C22:1 Erucic 10 - 20 %.
3. **Molecular formula:** n.a.

4. **The structural formula**: n.a.
5. **CAS:** 90045-98-0
6. **EINECS:** 289-964-3
7. **Origin:** plant
8. **Function**: emollient
9. **Phisical and chemical data**: MSDS, point 9
10. **Toxicological data:**
    - 10.1. Acute toxicity: - LD50 – 21.5 ml/kg (rat) (Source: Toxnet)
    - 10.2. Skin irritation properties – non-irritating (Source: Journal of the American College of Toxicology, Vol. 11, No. 1 pages 57-74, 40 references, 1992)
    - 10.3. Eye irritation properties – may cause slight irritation (Source: Journal of the American College of Toxicology, Vol. 11, No. 1 pages 57-74, 40 references, 1992)
    - 10.4. Sensitizing properties – non-sensitizing (Source: Journal of the American College of Toxicology, Vol. 11, No. 1 pages 57-74, 40 references, 1992)
    - 10.5. Dermal absorption – no data
    - 10.6. Chronic toxicity – no data
    - 10.7. Not classified as CMR
    - 10.8. Research Involving humans – A topical product containing 0.5% jojoba-oil and a lip balm containing 20.0% jojoba-oil did not cause skin irritation or sensitization in human volunteers. Refined and crude jojoba-oil caused a low incidence of skin irritation in patients with histories of eczema or dermatitis (Źródło: Journal of the American College of Toxicology, Vol. 11, No. 1 pages 57-74, 40 references, 1992)
11. **Legislation (Regulation 1223/2009/WE):** not regulated.

INCI NAME: TOCOPHERYL ACETATE

1. **Description:** Vitamine E. Tocopherol, or vitamin E, a fat-soluble vitamin is a naturally occuring antioxidant which can be isolated from vegetable oil.
2. **Chemical name:** 3,4-Dihydro-2,5,7,8-tetramethyl-2-(4,8,12-trimethyltridecyl)-2H-benzopyran-6-yl acetate

3. **Molecular formula:** $C_{31}H_{52}O_3$
4. **The structural formula**:

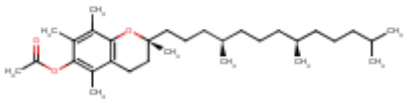


5. **CAS:** 7695-91-2
6. **EINECS:** 231-710-0
7. **Origin:** DL-α-Tocopherol is prepared synthetically by condensation of trimethylhydroquinone and isophytol. The crude product is purified by distillation in vacuo.
8. **Function**: active ingredient
9. **Phisical and chemical data**: MSDS, point 9
10. **Toxicological data:**
    - 10.1. Acute toxicity: - >10000 (Source: ECHA)
    - 10.2. Skin irritation properties – non-irritating (Source: ECHA)
    - 10.3. Eye irritation properties – non-irritating (Source: ECHA)
    - 10.4. Sensitizing properties – non-sensitizing (Source: ECHA)
    - 10.5. Dermal absorption – Max 4,2 % (OECD 428) (Source: ECHA)
    - 10.6. Chronic toxicity– NOAEL 2000 mg/kg bw/day (Source: ECHA)
    - 10.7. Not classified as CMR
    - 10.8. Research Involving humans – no data
11. **Legislation (Regulation 1223/2009/WE):** not regulated

INCI NAME: TOCOPHERYL ACETATE

1. **Description:** Vitamine E. Tocopherol, or vitamin E, a fat-soluble vitamin is a naturally occuring antioxidant which can be isolated from vegetable oil.

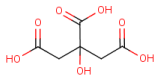
2. **Chemical name:** 3,4-Dihydro-2,5,7,8-tetramethyl-2-(4,8,12-trimethyltridecyl)-2H-benzopyran-6-yl acetate
3. **Molecular formula:** $C_{31}H_{52}O_3$
4. **The structural formula**:



5. **CAS:** 7695-91-2
6. **EINECS:** 231-710-0
7. **Origin:** DL-α-Tocopherol is prepared synthetically by condensation of trimethylhydroquinone and isophytol. The crude product is purified by distillation in vacuo.
8. **Function**: active ingredient
9. **Phisical and chemical data**: MSDS, point 9
10. **Toxicological data:**
    - 10.1. Acute oral toxicity: LD50>10000 (Source: ECHA)
    - 10.2. Skin irritation properties – non-irritating (Source: ECHA)
    - 10.3. Eye irritation properties – non-irritating (Source: ECHA)
    - 10.4. Sensitizing properties – non-sensitizing (Source: ECHA)
    - 10.5. Dermal absorption – Max 4,2 % (OECD 428) (Source: ECHA)
    - 10.6. Chronic toxicity– NOAEL 2000 mg/kg bw/day (Source: ECHA)
    - 10.7. Not classified as CMR
    - 10.8. Research Involving humans – no data
11. **Legislation (Regulation 1223/2009/WE):** not regulated

INCI NAME: CITRIC ACID

12. **Description:** Citric Acid are on the Food and Drug Administration's (FDA) list of direct food substances affirmed as Generally Recognized as Safe (GRAS). Citric Acid is an organic acid that is widely distributed in plants and animals.
13. **Chemical name:** 2-Hydroxy-1,2,3-propanetricarboxylic acid
3. **Molecular formula:** $C_6H_8O_7$ (mw 192.122, logP -1,64)
4. **Structural formula**:



5. **CAS:** 77-92-9 / 5949-29-1
6. **EINECS:** 201-069-1
7. **Origin:**
8. **Function**: buffering, chelating, masking
9. **Phisical and chemical data**: MSDS, point 9
10. **Toxicological data:**
    - 10.1. Acute toxicity: - LD50 5,4 g/kg (source: ECHA base)
    - 10.2. Skin irritation properties: Citric Acid and its salts and esters were not eye irritants, nor did they result in skin irritation or sensitization. (source: CIR report)
    - 10.3. Eye irritation properties – as above
    - 10.4. Sensitizing properties – as above
    - 10.5. Dermal absorption – no data
    - 10.6. Chronic toxicity – no data, no expected (source: SIDS report), NOAEL 4000 mg/kg bw/day (source: ECHA base)
    - 10.7. Not classified as CMR
    - 10.8. Research Involving humans – used in food , several clinical tests, may irritate, non-sensitizing (source: report CIR)
11. **Legislation (Regulation 1223/2009/WE):** not regulated.

Summary:

MoS (Marigin of Safety) was calculated according to “THE SCCS'S NOTES OF GUIDANCE FOR THE TESTING OF COSMETIC SUBSTANCES AND THEIR SAFETY EVALUATION 8TH REVISION”).

MoS = NOAEL / SED

with:

NOAEL – (No Observed Adverse Effect Level) It is the highest dosage for which no (adverse) effects can be observed.

INCI	%	DA	A	SED	NOAEL	MoS
AQUA	81,0270	100	123,2	99,825	n.a.	n.a.
PANTHENOL	4,6070	100	123,2	5,676	NOEL -1000	176
BUTANE	4,1000	100	123,2	5,051	n.a.	n.a.
PROPANE	3,5000	100	123,2	4,312	n.a.	n.a.
ETHYLHEXYL LAURATE	2,7640	100	123,2	3,405	1000	294
CETEARYL ALCOHOL	1,8000	100	123,2	2,218	1000	451
PARAFFINUM LIQUIDUM	1,3820	100	123,2	1,703	1800	1057
ISOBUTANE	0,2000	100	123,2	0,246	n.a.	n.a.
SODIUM CETEARYL SULFATE	0,1800	100	123,2	0,222	n.a.	n.a.
SIMMONDSIA CHINENSIS SEED OIL	0,2990	100	123,2	0,368	n.a.	n.a.
PARFUM	0,1470	100	123,2	0,181	n.a.	n.a.
TOCOPHERYL ACETATE	0,1000	100	123,2	0,123	2000	16234
CITRIC ACID	0,0160	100	123,2	0,020	8000	405844

9. Undesirable effects and serious undesirable effects.

Does not provide any reports of adverse reactions to cosmetic products.

10. Information on the cosmetic product

Examination of the finished product which have been performed:

10.1. Microbiological test.

Not performed. The product of low microbiological risk

10.2. Challenge test.

Not performed. The product of low microbiological risk.

10.3. Dermatological test.

The study was conducted (test report No B - 44125/10105/15) to determine the dermal irritation and sensitization potential according to Cosmetics Europe Guideline: “Product Test Guidelines for the Assessment of Human Skin Compatibility, 1997”. In the group of tested 40 persons, including 33 people with a positive history of atopy, 6 with documented contact allergy, there was no positive response, which proves that the product does not show any irritating or sensitizing properties. The product meets the requirements of the compliance test for atopic and very sensitive skin, and meets the requirements for cosmetics products declared as hypoallergenic.

10.4. Stability test.

Due to the physical form of the product (foam is formed during application) stability test are not required.

PART B – COSMETIC PRODUCT SAFETY ASSESSMENT

1. Reasoning.

- The available data are sufficient to assess the safety of the product.
- In the case of components for which there are no data for chronic toxicity (NOAEL) takes into account the local toxicity, acute toxicity data or data on the history of safe use that allow to accept the substance as safe in the product at the given concentrations and conditions of use.
- In the case of raw materials which the results of chronic toxicity were available (NOAEL) margin of safety (MoS) was calculated. All value are > 100, recommended as safe.
- Analysis of the toxicological data of raw materials used in the product indicates no threat to human health.
- The microbiological and challenge test not required – low risk product.
- The results of dermatological tests showed no evidence of skin irritation and sensitization in a group of subjects.
- Contamination of raw materials do not affect the safety of the finished product.
- There were no incompatibility in recipe.
- Purity and stability of packaging material is satisfactory
- The stability tests - not required due to specific form of product (foam is formed during application)

2. Assessment conclusion

After the analysis of information and data about the product

Panthenol Jojoba Spray

with chemical composition declared by the manufacturer, when used for the intended purpose and method of use is not a reasonably foreseeable risk to human health and life, concerning:

- quantitative and qualitative composition,
- chemical, physical and microbiological data of all ingredients,
- chemical, physical and microbiological data of final cosmetic product,
- toxicological profile of the ingredients,
- exposure to the product,
- information about internal packaging,
- appearance,
- production method

the product is – based on the current knowledge – regarded as safe.

The product complies with the requirements of Regulation 1223/2009/WE and with the foreseen use it will not be likely to harm the consumer or bring danger to the user`s health.

NOTE:

- Any change in chemical composition, scope and manner of use or trade name of the product should be re-examined by an safety assessor.
- The opinion does not apply to people who are allergic to any ingredient in this product.

3. Labelled warnings and instructions of use.

No comments regarding the label content.

4. Proof of qualification of safety assessor.

- Since 10.2014 – specialization Toxicology in areas of application in health care (Medical University of Lodz)
- Master of Science (biotechnologist, SGGW 2002)
- Since 2008 – NUCO E. i G. Kosyl s.j. – Safety Assessor
- Since 2010 – Member of working groups (Safety assessment group and Legislation group) in The Polish Union of Cosmetic Industry
- Safety Assessment of Cosmetics in the EU. Training Course – Vrije Universiteit Brussel. (4.02 – 9.02.2013)
- 20-21.11.2014 – Course for Safety Assessors, part 4 of 7 - “Carcinogenicity and Mutagenicity” (IKW / DEUTSCHE GESELLSCHAFT FÜR WISSENSCHAFTLICHE UND ANGEWANDTEKOSMETIK E.V.
- 09-10.04.2014 – Course for Safety Assessors, part 3 of 7 “Microbiological Safety of Cosmetics Products” (IKW / DEUTSCHE GESELLSCHAFT FÜR WISSENSCHAFTLICHE UND ANGEWANDTEKOSMETIK E.V.
- 24-25.10.2013 – Course for Safety Assessors, part 2 of 7 “Metabolism, kinetics and structure-activity relationships (SAR)” (IKW / DEUTSCHE GESELLSCHAFT FÜR WISSENSCHAFTLICHE UND ANGEWANDTEKOSMETIK E.V.
- 25-26.04.2013 – Course for Safety Assessors, part 1 of 7 “Exposure of cosmetics products / percutaneous penetration” (IKW / DEUTSCHE GESELLSCHAFT FÜR WISSENSCHAFTLICHE UND ANGEWANDTEKOSMETIK E.V.

Wołomin 23.06.2016

Agnieszka Litwin,
Safety Assessor
Geodetow 4 Wolomin