MINASOLVE
BIO-INGREDIENTS FOR YOUR APPLICATIONS

Regulatory Data Sheet
April 2019 – V2

EasySafe OC 8

I- GENERAL INFORMATION

Trade name: **EasySafe OC 8**

INCI name: Caprylyl Glycol (and) Phenylpropanol (and) o-Cymen-5-ol

Functions: Skin humectant, aroma, masking agent, preservative

Supplier: Minasolve S.A.S
145, Chemin des Lilas
59310 Beuvry-la-Forêt, France
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II- REGULATORY INFORMATION

1- Regulatory status for cosmetic application

Region	Caprylyl Glycol	Phenylpropanol	o-Cymen-5-ol
EUROPE (European Cosmetic Regulation (EC) No 1223/2009)	Approved	Approved	Approved
U.S.A. (FD&C Act— 21 CFR 700 to 740)	Approved	Approved	Approved
CANADA (Food and Drugs Act and Cosmetic Regulations)	Approved	Approved	Approved
AUSTRALIA (Notification & Assessment Act 1989, as amended—TGA)	Approved	Approved	Approved
JAPAN (Pharmaceutical Affairs Law - regulations for cosmetics)	Approved	Approved	Approved
KOREA (Cosmetics Law - Korea Food & Drug Administration KFDA)	Approved	Approved	Approved
CHINA (IECIC 2015)	Approved	Approved	Approved

2- Regulatory compliance

	EU (EINECS)	USA (TSCA)	CANADA (DSL/NDSL/ R-ICL)	AUSTRALIA (AICS)	CHINA (IECSC)	JAPAN (ENCS)	KOREA (KECI/ECL)	NEW ZEALAND (NZIoC)
Caprylyl Glycol	Listed	Listed	NDSL	Listed	Listed	Listed	Listed	Listed
Phenylpropanol	Listed	Listed	DSL	Listed	Listed	Listed	Listed	Listed
o-Cymen-5-ol	Listed	Not listed	DSL	Listed	Listed	Listed	Listed	Listed

3- REACH requirements

	REACH Status	Registration N°
Caprylyl Glycol	registered	01-2119966905-22
Phenylpropanol	exempted	annual volume < 1 mT
o-Cymen-5-ol	exempted	annual volume < 1 mT

Presence of SVHC: YES ☐ NO ☒

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III- PRODUCT COMPOSITION

1- Composition (%)

Substance	%	INCI name	CAS n°	EC n°
1	50-70	Caprylyl Glycol	1117-86-8	214-254-7
2	10-30	Phenylpropanol	122-97-4	204-587-6
3	5-15	o-Cymen-5-ol	3228-02-2	221-761-7
4	5-15	Water	7732-18-5	231-791-2

2- Impurities

	YES	NO
Phthalates	☐	☒
Glycol Ethers	☐	☒
Residual Monomers	☐	☒
Latex	☐	☒

3- Allergens

CAS n°	Substances (INCI name)	YES	NO	%
122-40-7	Amyl cinnamal	☐	☒	
100-51-6	Benzyl alcohol	☐	☒	
104-54-1	Cinnamyl alcohol	☐	☒	
5392-40-5	Citral	☐	☒	
97-53-0	Eugenol	☐	☒	
107-75-5	Hydroxycitronellal	☐	☒	
97-54-1	Isoeugenol	☐	☒	
101-85-9	Amylcinnamyl alcohol	☐	☒	
118-58-1	Benzyl salicylate	☐	☒	
104-55-2	Cinnamal	☐	☒	
91-64-5	Coumarin	☐	☒	
106-24-1	Geraniol	☐	☒	
31906-04-4	Hydroxyisohexyl 3-cyclohexene carboxaldehyde	☐	☒	
105-13-5	Anise alcohol	☐	☒	
103-41-3	Benzyl cinnamate	☐	☒	
4602-84-0	Farnesol	☐	☒	
80-54-6	Butylphenyl methylpropional	☐	☒	
78-70-6	Linalool	☐	☒	
120-51-4	Benzyl benzoate	☐	☒	
106-22-9	Citronellol	☐	☒	
101-86-0	Hexyl cinnamal	☐	☒	
5989-27-5	Limonene (d-alpha)	☐	☒	
111-12-6	Methyl 2-octynoate	☐	☒	
127-51-5	Alpha-isomethyl ionone	☐	☒	
90028-68-5	Evernia Prunastri (Oakmoss)extract	☐	☒	
90028-67-4	Evernia Furfuracea (Treemoss) extract	☐	☒	

4- VOC

Presence of chemical ingredients which are classified as VOC: YES ☐ NO ☒

5- CMR

Substance classified as CMR: YES ☐ NO ☒

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IV- ORIGIN

1- Vegetal ☐

2- Synthetic ☒

3- Biotechnology ☐
Microorganisms used:

4- Animal ☐
Absence of BSE/TSE:

5- Mineral ☐
Process for obtaining it:
Nanomaterial:

6- Naturalness
Ingredient COSMOS approved: YES ☐ NO ☒
Ingredient compliant with Natrue: YES ☐ NO ☒
Renewable carbon 0 mol-% renewable

Naturality Index (ISO 16128)	**Natural index**	**Natural origin index**	**Organic index**	**Organic origin index**
With/without water	0/0	0/0	0/0	0/0

V- PHYSICO-CHEMICAL DATA

See TDS – Available upon request

VI- MICROBIOLOGICAL DATA

EasySafe OC 8 is self-preserved. Furthermore, the antimicrobial performance of EasySafe OC 8 in cosmetic products has been proven in microbial challenge tests. The presence of living pathogenic germs inside EasySafe OC 8 can therefore be excluded.

See TDS – Available upon request

VII- USE AND STORAGE CONDITIONS

See MSDS, chapters 7 and 8 – Available upon request

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VIII- TOXICOLOGICAL DATA

1- Toxicological data

TESTS	Caprylyl Glycol	Phenylpropanol	o-Cymen-5-ol
Acute Toxicity	**Oral (**OECD 401, acute oral toxicity, rat): **LD_{50}** > 2000 *mg/kg bw* **Dermal** (OECD 402, acute dermal toxicity, rat): **LD_{50}** > *2000 mg/kg*	**Oral** (OECD 401, rat): **LD_{50}** = 2250 mg*/kg bw* **Dermal** (OECD 402, rabbit, 24 h): **LD_{50}** < *5000 mg/kg*	**Oral (**OECD 401, mouse): **LD_{50}** > 2200 *mg/kg bw* **Dermal** (OECD 402, rat): **LD_{50}** > *2000 mg/kg*
Skin penetration	*No data available*	*No data available*	*No data available*
Irritation eye/skin	**EU Method B.5** (eye irritation/corrosion, rabbit); **Result:** *irritating to eyes*	**Skin** (OECD 439): *Irritating* **Eye**: *Irritating (based on results on skin)*	**Skin** (OECD 404, rabbit): not irritating **Eye** (OECD 437): corrosive
Skin compatibility and sensitization	**HRIPT:** negative Repeated applications of EasySafe OC 8 under occlusive patch (9 consecutive applications within 30 days, Finn Chamber, 20 µl per patch), on a panel of 51 subjects - 11 of which with sensitive skin - induced no irritation and no allergic reaction on skin. In conclusion, EasySafe OC 8 shows very good skin compatibility		
Mutagenicity	**AMES test:** *Negative*	**AMES test:** *Negative*	**AMES test:** *Negative*
Genotoxicity	**Chromosome aberration:** *Negative*	**Chromosome aberration:** *Negative*	**Chromosome aberration:** *Negative*
Repeated dose toxicity	**Oral** (OECD 408, repeated dose, 90days, rat): **NOAEL** > *150 - < 300 mg/kg bw/day*	**Oral** (OECD 422, rat): **NOAEL** = *1000 mg/kg bw/day*	**Oral** (OECD 422, rat) **NOAEL** = *1000 mg/kg bw/day (para-Thymol)*
Reproductive toxicity	**OECD 421** (reproduction / developmental toxicity screening test, rat): **NOAEL** ≥ 1 000 mg/kg bw/day (NOAEL = highest dose tested) **OECD 414** (prenatal developmental toxicity study, rat): **NOAEL** = 150 mg/kg bw/day, maternal toxicity **NOAEL** = 300 mg/kg bw/day, developmental tox. **NOAEL** = 1000 mg/kg bw/day, teratogenicity **Summary**: *no teratogenic potential observed.*	**NOAEL** (oral, rat) = *300 mg/kg bw/day*	Combined Repeated Dose Toxicity Study with the Reproduction / Developmental Toxicity Screening Test, rat: **NOAEL** = *1000 mg/kg bw/day (para-Thymol)*
Phototoxicity	*No data available*	*No data available*	*No data available*

2- Ecotoxicological data

TESTS	Caprylyl Glycol	Phenylpropanol	o-Cymen-5-ol
Bioaccumulative potential	**Log P =** 2.1 at 25°C *=> Accumulation in organisms is not expected*	**Log P =** 1.6 at 35°C *=> Accumulation in organisms is not expected*	**Log P =** 3.43 (QSAR) *=> Accumulation in organisms is not expected*
Solubility in water	7.5 g/L at 20°C	8 g/L at 20°C	210 mg/L at 20°C
Acute aquatic ecotoxicity	**OECD 203** (Fish, acute toxicity test, *Brachydanio rerio*, 96 h): **LC_{50}** > 2.2 - < 22 mg/L **OECD 202** (48 hours, Daphnia magna): **EC_{50}** > 100 mg/L **OECD 201** (Freshwater algae, growth inhibition test, *Scenedesmus subspicatus* and *Selenastrum capricornutum*, 72 h): **EC_{50}/LC_{50}** = 35 mg/L	**OECD 203** (96 hours, Zebra fish): **LC_{50}** = 61 mg/L **OECD 202** (48 hours, Daphnia magna): **EC_{50}** = 60.6 mg/L	**OECD 212** (fish, 9d long-term toxicity, *Danio rerio*): **NOEC** = 1.5 mg/L (p-Thymol) **OECD 209** (activated sludge, respiration inhibition test, 3h): **EC_{50}** = 39.6 mg/L
Biodegradation	**Biodegradation in water (OECD 301F, EU C.4-D and OECD 301D, EU C.4-E):** screening tests: aerobic biodegradation 85% and 75% (ThOD) in 28 days. Biodegradation **in water (OECD 311):** screening tests: anaerobic biodegradation 70% (ThIC) in 60 days. **Summary of results:** readily biodegradable	**OECD 301F:** *Readily biodegradable (83 % within 28 days)*	**EU C.4-E:** *Readily biodegradable (83 % within 28 days)*

3- Animal testing

Animal testing performed/subcontracted by Minasolve on this material: YES ☐ NO ☒