EasySafe GC 8

I- GENERAL INFORMATION

Trade name: **EasySafe GC 8**
INCI name: Caprylyl Glycol (and) Glyceryl Caprylate/Caprate (and) Glycerin
Minasolve Code: PFS0045
Functions: Moisturizer, Emollient, Re-fatting agent, Antimicrobial protection agent

Supplier: Minasolve S.A.S
145, Chemin des Lilas
59310 Beuvry-la-Forêt, France
Tel. +33 3 20 64 3001

II- REGULATORY INFORMATION

1- Compliance with cosmetic regulation

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

2- Chemical inventory status

	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
Glyceryl Caprylate/Caprate	Listed	Not listed	R-ICL	Listed	Listed	Listed	Listed	Listed

3- Natural certification status

Ingredient ECOCERT certified: YES ☐ NO ☒
Ingredient COSMOS approved: YES ☐ NO ☒
Ingredient compliant with Natrue: YES ☐ NO ☒
USDA certified bio-based product: YES ☐ NO ☒

III- PRODUCT COMPOSITION

Substance	%	INCI name	CAS n°	EC n°
1	30-50	Caprylyl Glycol	1117-86-8	214-254-7
2	30-50	Glyceryl Caprylate/Caprate	85537-06-8	287-488-0
3	10-30	Glycerin	56-81-5	200-289-5

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IV- TOXICOLOGICAL DATA

1- Toxicological data

TESTS	Caprylyl Glycol	Glyceryl Caprylate/Caprate
Acute Toxicity	**- Oral** (OECD 401, EU B.1, acute oral toxicity, rat): **LD_{50}** > 2000 mg/kg bw **- Dermal** (acute dermal toxicity): Waiving, as this study was considered to be scientifically unjustified.	**- Oral** (OECD 401, mouse): **LD_{50}** > 23 625 mg/kg bw **- Dermal** (OECD 402, rat, 24 h): **LD_{50}** > 2 000 mg/kg bw **- Inhalation** (OECD 403, rat, 6h): **LC_{50}** > 1.860 mg/L air
Skin penetration	No data available	No data available
Irritation eye/skin	- **Skin irritation**: not irritating. - **Eye irritation** (EU B.5, eye irritation/corrosion, rabbit): Irritating to eyes.	**- Skin** (EPA OPP 81-5, rabbit): Not irritating - **Eye** (EPA OPP 81-4, rabbit): Not irritating
Skin compatibility and sensitization	**HRIPT:** negative Repeated applications of EasySafe GC 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 GC 8 shows very good skin compatibility.	
Genetic toxicity	The genotoxic potential of octane-1,2-diol was tested in three **in vitro Ames** (OECD 471 or other adequate references), one **in vitro Chromosome aberration** (Notification 1604 MHW Japan 1999, similar to OECD 473) and one **in vitro gene mutation** (OECD 476) tests, each with and without metabolic activation (+/- S9 mix). In each of these studies, consistent, reproducible and toxicologically relevant indications of genotoxicity were not evident.	Mutagenicity in bacteria, clastogenic effects in mammalian cells, mutagenicity in mammalian cells: No adverse effect observed (negative).
Repeated dose toxicity	**NOAEL** (OECD 408, repeated dose 90-day oral toxicity, rat) = 150 mg/kg bw/day	**Oral** (OECD 407, rat): **NOAEL** = 1000 mg/kg bw/day
Reproductive toxicity	In the developmental toxicity study at the high dose level of 1000 mg/kg body weight/day reduced foetus weights were observed. However, at this dose level in repeat dose studies significant effects on body weight gain of adult rats were observed that might be due to disruption of the gut microbiota by the antimicrobial activity of octane-1,2-diol leading to imbalanced nutrition. Thus, the effect observed in the developmental toxicity study very likely is a secondary non-specific consequence of maternal malnutrition. With regard to classification of octane-1,2-diol the situation is considered inconclusive.	**-** No effects on reproduction (OECD Guideline 422). - No effect on intrauterine development (OECD Guideline 426).
Phototoxicity	No data available	No data available

2- Ecotoxicological data

TESTS	Caprylyl Glycol	Glyceryl Caprylate/Caprate
Bioaccumulative potential	**Log P =** 2.1 at 25°C => Accumulation in organisms is not expected	Low potential to bioaccumulate in terrestrial ecosystems
Solubility in water	7.5 g/L at 20 °C, pH 6.3 (OECD 105 and EU A.6)	46 mg/L at 20°C, pH = 5.99-6.65 (EU A.6)
Acute aquatic ecotoxicity	**LC_{50}** (Fish, 96 h, Brachydanio rerio) = 2.2-22 mg/L (OECD TG 203) **EC_{50}** (Daphnia magna, 48h) > 100 mg/L (OECD TG 202) **ErC_{50}** (Freshwater algae, 72 h, Pseudokirchneriella subcapitata) = 35 mg/L (OECD 201)	- Short-term toxicity to fish and aquatic invertebrates: no toxicity up to the limit of water solubility (WS 46 mg/L). - Toxicity to aquatic algae and cyanobacteria: **ErL_{50}** (72h, nominal, loading rate) = 49 mg/L **NOErLR** (72h, nominal, loading rate) = 20.7 mg/L **NOEC** (72h, measured concentration) = 1.19 mg/L - Toxicity to microorganisms: **NOEC** = 46.9 mg/L (from ready biodegradation test, 81.1% biodegradation in toxicity control within 14 days).
Biodegradation	Readily biodegradable. Biodegradation in water, screening tests: - Aerobic biodegradation 85% and 75% (ThOD) in 28 days (OECD 301F, EU C.4-D and OECD 301D, EU C.4-E) - Anaerobic biodegradation 70% (ThIC) in 60 days (OECD 311)	Readily biodegradable: 82.6% within 28 days (OECD 301B)

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