Octiol

I- GENERAL INFORMATION

Trade name: **Octiol**
INCI name: Caprylyl Glycol
Minasolve Code: PFS0009
Function: Skin humectant, 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

EUROPE (European Cosmetic Regulation (EC) No 1223/2009)	Approved
U.S.A. (FD&C Act— 21 CFR 700 to 740)	Approved
CANADA (Food and Drugs Act and Cosmetic Regulations)	Approved
AUSTRALIA (Notification & Assessment Act 1989, as amended—TGA)	Approved
JAPAN (Pharmaceutical Affairs Law - regulations for cosmetics)	Approved
KOREA (Cosmetics Law - Korea Food & Drug Administration KFDA)	Approved
CHINA (IECIC 2015)	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)
Listed	Listed	NDSL	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	100	Caprylyl Glycol	1117-86-8	214-254-7

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IV - TOXICOLOGICAL DATA

1- Toxicological data

TESTS	Caprylyl Glycol
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.
Skin penetration	No data available
Irritation eye/skin	- **Skin irritation**: not irritating. - **Eye irritation** (EU B.5, eye irritation/corrosion, rabbit): Irritating to eyes.
Skin compatibility and sensitization	Formulations in paraffin containing 4.2% or 5.25% octane-1,2-diol (amongst other ingredients) were tested in a human repeated insult patch test [Modified Draize assay]. Reactions to the challenge application were not evident for any of these formulations. In response to induction applications only Grade 1 reactions were seen in a small number of subjects. Since Grade 1 reactions are minimal irritant responses, the tested formulations were judged neither to be significant irritants nor contact sensitizers.
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.
Repeated dose toxicity	**NOAEL** (OECD 408, repeated dose 90-day oral toxicity, rat) = 150 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.
Phototoxicity	No data available

2- Ecotoxicological data

TESTS	Caprylyl Glycol
Bioaccumulative potential	**Log P =** 2.1 at 25°C => Accumulation in organisms is not expected
Solubility in water	7.5 g/L at 20 °C, pH 6.3 (OECD 105 and 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)
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)
Volatization from water	No data available