MINASOLVE®
BIO-INGREDIENTS FOR YOUR APPLICATIONS

Regulatory Data Sheet
March 2019 – V7

Fresh'in

I- GENERAL INFORMATION

Trade name: Fresh'in

INCI name: Methyl Diisopropyl Propionamide

Function: Cooling agent

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

II- REGULATORY INFORMATION

1- Regulatory status for cosmetic application

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- Regulatory compliance

EU (EINECS)	USA (TSCA)	CANADA (DSL/NDSL/ R-ICL)	AUSTRALIA (AICS)	CHINA (IECSC)	JAPAN (ENCS)	KOREA (KECI/ECL)	NEW ZEALAND (NZIoC)
Listed	Not listed	NDSL + R-ICL	Not listed	Listed	Not listed	Not listed	Not listed

3- REACH requirements

Component	REACH Status	Registration N°
Methyl Diisopropyl Propionamide	Registered	01-2120760168-51

Presence of SVHC: YES ☐ NO ☒

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III PRODUCT COMPOSITION

1- Composition (%)

Substance	%	INCI name	CAS n°	EC n°
1	100	Methyl Diisopropyl Propionamide	51115-67-4	256-974-4

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 ☐
Plant's usual name:
Plant part used:
GMO presence: YES ☐ NO ☐

2- Synthetic ☒

3- Biotechnology ☐
Microorganisms used:

4- Animal ☐
Absence of BSE/TSE:

5- Mineral ☐
Process for obtaining it:
Nanomaterial:

6- Naturalness
Ingredient Ecocert certified: YES ☐ NO ☒
Ingredient COSMOS approved: YES ☐ NO ☒
Ingredient compliant with Natrue: YES ☐ NO ☒

Naturalilty 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
TAMC (Total Aerobic Microbial Count): 0 CFU/g
TYMC (Total combined Yeasts/Mould Count): 0 CFU/g
Specific microorganisms:
Staphylococcus aureus: absent
Escherichia coli: absent
Pseudomonas aeruginosa: absent
Bile tolerant gram negative bacteria: absent

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	DATA
Acute Toxicity	**Oral: LD_{50}** = *500-1000 mg/kg bw* (rat, OECD 423)
Skin penetration	*No data available*
Irritation eye/skin	**Eye** (OECD 405, rabbits): *Not irritating (0.1% Fresh'in in 1% ethanol)* **Skin** (rabbits): *Not irritating (0.1% Fresh'in in 1% ethanol)*
Skin sensitization	**HRIPT** (tested material: Fresh'in, applied as 40 wt.-% solution in Pentylene Glycol). Repeated applications under occlusive patch (9 consecutive applications within 30 days, Finn Chamber, 20 µl per patch) on a panel of 50 subjects – 18 of which with sensitive skin – induced no irritative and no allergic skin reaction. Conclusion: very good skin compatibility was demonstrated.
Mutagenicity	**AMES test**: *Negative*
Genotoxicity	**Forward Mutation Mouse lymphoma (L5178Y cells):** at concentration of 0.01 to 1,000 µg/ml: *Negative*
Repeated dose toxicity	**The NOEL** was *5 mg/kg bw/day*, on the basis of histopathological lesions in the kidneys of male rats in the 14-week study.
Reproductive toxicity	A study of **reproductive and teratogenic toxicity** in rats at a dose of 0, 10, 50 or 100 mg/kg bw showed *no reproductive effects or fetal abnormalities.*
Phototoxicity	*No data available*

2- Ecotoxicological data

TESTS	DATA
Bioaccumulative potential	**log P** = 2.7 *=> Not expected to bio-accumulate in the environment*
Solubility in water	7.0 g/L at 20 °C
Acute aquatic ecotoxicity	**Acute Toxicity to Fish** (96 hours): **LC_{50}** = 35 mg/L **Acute Toxicity to Daphnia Magna** (48 hours, OECD 202): **EC_{50}/LC_{50}** > 100 mg/L
Biodegradation	**OECD 301 B:** *20 % degradation after 28 days*
Volatization from water	**Henry LC:** 1.78E-007 atm-m3/mole (estimated by Bond SAR Method) **Half-Life from Model River:** 4306 hours (179.4 days) **Half-Life from Model Lake:** 4.709E+004 hours (1962 days) *Predicted by software*
Mobility in soil	**Soil Adsorption Coefficient:** (PCKOCWIN v1.66) **Koc=** 348.7 **Log Koc=** 0<2,542<5 *=> Expected to be mobile in soil* *Predicted by software*

3- Animal testing

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

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