

EasySafe Hexam+

I- GENERAL INFORMATION

Trade name: EasySafe Hexam+
INCI name: Pentylene Glycol (and) Water (and) Hexamidine Diisethionate
Minasolve Code: PFS0032
Function: Preservative, skin humectant

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

	Pentylene Glycol	Hexamidine Diisethionate
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 (not as preservative)
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)
Pentylene Glycol	Listed	Listed	NDSL + R-ICL	Listed	Listed	Listed	Listed	Listed
Hexamidine Diisethionate	Listed	Not listed	DSL	Listed	Listed	Not listed	Not 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	70-90	Pentylene Glycol	5343-92-0	226-285-3
2	10-30	Water	7732-18-5	231-791-2
3	3-5	Hexamidine Diisethionate	659-40-5	211-533-5

The above information is accurate to the best of our knowledge. Customers are advised to make their own studies on the usefulness of any ingredient for a particular application. Recommended usage information is only provided as indication, and should not be considered as recommendations to use Minasolve SAS's products in violation of any laws, patents, or official regulations dealing with manufacture, composition, local procedures, product design, or end usage.

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IV- TOXICOLOGICAL DATA

1- Toxicological data

TESTS	Pentylene Glycol	Hexamidine Diisethionate
Acute Toxicity	Oral (OECD 401, rat): LD₅₀ > 5000mg/kg bw Inhalation (OECD 403, rat, 4h): LC₅₀ > 7015 mg/m ³ air Dermal (OECD 402, rat, 24 h): LD₅₀ > 2000 mg/kg	Oral (comparable to OECD 401, rat): LD₅₀ = 650 mg/kg Dermal LD₅₀ (rat) > 4000 mg/kg
Skin penetration	No data available	When the compound was applied as a 0.1 % formulation in cold cream under an occlusive dressing for 96 hours a mean of ca. 0.6 % was absorbed (maximum value 1.4 %).
Irritation eye/skin	Eye (OECD 405): <i>Irritating</i> Skin (OECD 404): <i>Not irritating</i>	Eye (rabbits): No reactions observed in a 0.05% dose group. Slight reactions were observed in eyes not rinsed of for 0.1% dose of Hexamidine Diisethionate at 24, 48, and 72 h, but this observation disappeared after 72 h. No reactions were observed for a dose of 0.1% of Hexamidine Diisethionate in eyes rinsed 2 or 4 s after administration. Skin : In rats, slight irritation observed at 0.2%. In human, a clinical test at 0.1% produced no irritation.
Skin compatibility and sensitization	HRIFT : negative (tested material: undiluted EasySafe Hexam+) Repeated applications of EasySafe Hexam+ under occlusive patch (9 consecutive applications within 30 days, Finn Chamber, 20 µl per patch) on a panel of 101 subjects – 35 of which with sensitive skin – induced no irritation and no allergic skin reaction. In conclusion, EasySafe Hexam+ showed a very good skin compatibility.	
Mutagenicity	AMES test : <i>Negative</i>	AMES test : <i>Negative</i>
Genotoxicity	Chromosome aberration : <i>Negative</i>	Chromosome aberration : <i>Negative</i>
Repeated dose toxicity	Oral (OECD 422, rat): NOAEL = 1000 mg/kg bw/day Dermal (OECD 411, rat): NOAEL = 700 mg/kg bw/day	Oral (rat): NOAEL = 50 mg/kg/ bw/day Dermal (sub-chronic 90 days, rabbit): NOAEL > 16 mg/kg bw/day
Reproductive toxicity	No effects on reproduction No effects on development	No effects on reproduction No effects on development
Phototoxicity	No data available	Hexamidine Diisethionate is not a photosensitizer

2- Ecotoxicological data

TESTS	Pentylene Glycol	Hexamidine Diisethionate
Bioaccumulative potential	Log P = 0.06 at 25°C => Accumulation in organisms is not expected	Log P = 2.0 at 25°C => Accumulation in organisms is not expected
Solubility in water	EasySafe Hexam+ is miscible with water at 25°C	
Acute aquatic ecotoxicity	OECD 203 (96 hours, Zebra fish): LC₅₀ > 1096 mg/L EU Directive 79/831/EWG Appendix V (48 hours, Daphnia magna): EC₅₀ > 500 mg/L	OECD 202 (48 hours, Daphnia magna): EC₅₀ = 1.1 mg/L
Biodegradation	OECD 301E : readily biodegradable (73 % within 28 days), but failing 10-day window	OECD 301 D (Closed Bottle Test) : 1.7 % biodegradation after 28 days → not readily biodegradable.
Mobility in soil	Henrys Law Constant (25 deg C) : Bond Method : 3.06E-007 atm-m3/mole Group Method : 2.62E-010 atm-m3/mole Predicted by software HENRYWIN v3.10)	KOC (pH 5.5) = 1.02 Predicted by software

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