MinaSolve
Hexam

I- GENERAL INFORMATION

Trade name: **MinaSolve Hexam**
INCI name: Hexamidine Diisethionate
Minasolve Code: PFS0001
Function: Preservative

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 (not as preservative)
KOREA **(Cosmetics Law - Korea Food & Drug Administration KFDA)**	Approved
CHINA **(IECIC 2015)**	Approved

2- Chemical inventory status

EU (EINECS)	USA (TSCA)	CANADA (DSL/NDSL)	AUSTRALIA (AICS)	CHINA (IECSC)	JAPAN (ENCS)	KOREA (KECI/ECL)	NEW ZEALAND (NZIoC)
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	100	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	DATA
Acute toxicity	**Oral** (comparable to OECD 401, rat): **LD_{50}** = *650 mg/kg* **Dermal (rat)** **LD_{50}** > *4000 mg/kg*
Skin penetration	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** (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 sensitization	The authors concluded that Hexamidine Diisethionate did not produce any evidence of delayed contact hypersensitivity **Clinical assessment of safety:** 0.10% Hexamidine Diisethionate did not provoke primary irritation, inflammation, or sensitization in human subjects.
Mutagenicity	**AMES test:** Negative
Genotoxicity	**Chromosome aberration:** *Negative*
Repeated dose toxicity	**Oral** (rat): **NOAEL** = *50 mg/kg/ bw/day*
	Dermal (sub-chronic 90 days, rabbit): **NOAEL** > *16 mg/kg bw/day*
Reproductive toxicity	The Panel concluded that dermal exposures would not likely present a risk of reproductive/ developmental toxicity
Phototoxicity	Hexamidine Diisethionate is *not a photosensitizer*.

2- Ecotoxicological data

TESTS	DATA
Bioaccumulative potential	**Log Kow** = 2.0 at 25 °C (calculation adapted from guideline OECD for the testing of chemicals)
Solubility in water	readily soluble
Acute aquatic ecotoxicity	**OECD 202** (48 hours, Daphnia magna): **EC_{50}** = *1.1 mg/L*
Biodegradation test	**OECD 301 D (Closed Bottle Test):** *1.7 % bio-degradation after 28 days → not readily bio-degradable.*
Mobility in soil	**KOC (pH 5.5)** = *1.02* Predicted by software

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