Form: TDS-001
Root Reference: M-1107

Effective date: 04.2019

TECHNICAL DATA SHEET

Allantoin

INFORMATION ON SUBSTANCE / MIXTURE

INCI	Allantoin
Origin	No material of animal origin, synthetic
Manufacturing process	-
Raw material category	Skin protectant, keratolytic, soothing, vulnerary agent.

TECHNICAL DATA

Physical and chemical parameters

Appearance	Solid, powder
Color	White
Odor	Odorless
Assay	Min 99.0 %
Solubility	Soluble in water

Biological parameters

Total viable count	max. 100 cfu/g
Pathogens (Enterobacteriaceae, Pseudomonas, Enterococci, Candida albicans, Staphylococci)	absent/g

Contaminants

Heavy metals	10 ppm max.
Additives	Contain no preservatives, antioxidants or further additives.

TRANSPORT, STORAGE and SHELF LIFE

Storage conditions	Keep in tightly closed containers in a cool and dry place, protected from light. Stable at usual storage and use conditions.
Shelf Life	36 months under good storage conditions
Custom Tariff	-

Form: TDS-001
Root Reference: M-1107

TECHNICAL DATA SHEET

Allantoin

Effective date: 04.2019

LEGISLATION

Animal testing	Not tested on animals.
BSE/TSE	Contains no animal derived materials and no TSE (Transmissible Spongiform Encephalopathies) and BSE (Bovine Spongiform Encephalopathy) related material
GMO	Absence of Genetically Modified organisms
Halal status	Meets the Halal requirements, although not formally certified. Contains no ethyl alcohol or any ingredients of animal origin..
Gluten	Absent.
CMR substances	No substances classified as Carcinogenic, Mutagenic or Toxic to Reproduction (CMR) of category CMR 1A,1B, 2 under the Regulation (EC) 1272/2008 (Classification, Labelling & Packaging) are contained.
SVHC	None of the Substances of Very High Concern (SVHC), as described in the current list published by the European Chemicals Agency (http://echa.europa.eu/candidate-list-table) are contained.
NOAEL & LOAEL	Data and QSAR predictions (for molecules in the domain) indicate that repeated dose toxicity tests showed no effects for most endpoints at the highest dose tests (>450 mg/kg/day). The following LOELs were predicted for Allantoin: 989 mg/kg/day read across value for rat and mouse; 1743 mg/kg/day trend analysis for rat; 1000 mg/kg/day read-across for rat. (source: ECHA)
Residual solvents	Manufactured without the use of any solvents of Class 1, 2 and 3 listed in the Impurities Guidelines for Residual Solvents (CPMP/ICH/283/95) or California Proposition 65. Based on the knowledge of the process these solvents are not contained in the final product.
Process impurities	Urea 0.5% max. No substances listed in the Annex II of EU Cosmetic Regulation (EC) 1223/2009 are used in the manufacturing process or contained.
Toxicological data	CIR Final report of the safety assessment of allantoin and its related complexes. International Journal of Toxicology, 29, 3 suppl. 84S-97S (2010)
Nanomaterials	No nanomaterials as described in the Cosmetic Regulation (EC) 1223/2009 or products arising from nanotechnology are contained
Irradiation	Not exposed to any irradiation treatment.
Others	Contains no lactose, pesticides, 1,4-dioxane, phthalates, nitrosamines, BHT, musk xylene, formaldehyde, chloro-organic compounds, glycol ethers or other glycols.
Allergens	No allergens listed in the Annex III of the Cosmetic Directive 76/768/EEC, in its subsequent amendments and in the new Cosmetics Regulation (EC) 1223/2009.
EINECS	202-592-8
CAS	97-59-6

TECHNICAL DATA SHEET

Allantoin

REACH pre-registration no.	05-2117043803-48-0000

DISCLAIMER

All warranty claims in respect to the conformity of our product are subject to our General Terms and Conditions of Sale and Delivery. The data listed above reflects the results of the manufacturer or our supplier quality tests. We do not hereby make any express or implied warranty, whether for specific properties or for fitness for any particular application or purpose. All values are valid for the product when dispatched from the works. We recommend you perform your own quality and or identification checks on receipt.