10800 231st Way NE
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Updated: 23-Aug-2024

Allantoin, USP

Specification Sheet

Description: Allantoin occurs naturally in the roots & leaves of the comfrey plant, but to satisfy market needs allantoin is produced synthetically but nature identical. Synonyms: 5-ureidohydantoin, glyoxyl-diureide, 2,5-dioxo-4-imidazolidinyl-urea. Purity 99-100%. Melting point 230°C (446°F).

CAS: 97-59-6

INCI Name: Allantoin

Composition: Allantoin

Purity Grade: USP grade

Appearance: White crystalline powder, odorless

Benefits:

- USP grade.
- Soothes and alleviates skin-irritations.
- Has moisturizing and hydrating effects.
- Recognized as skin protectant by the FDA (see below for making proper claims)
- Often used to minimize pore size.
- Has anti-aging properties making the skin look younger and rejuvenated

Use: Add to aqueous phase of formulas or after emulsification process. Use levels 0.2-2%. Can crystallize if added at hot temperatures and then rapidly cooled down. For external use only.

Applications: Lotions, creams, sun care & after sun products, shampoos, scalp rinses, shower gels, lip & baby care products.

Solubility: Water-soluble (ca. 1g/200 ml; problematic to dissolve if higher than 0.5%)

Preservation: Preservative-free

Storage: Store light-protected at a cool and dry place.

Country of Origin: China

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Raw material source: Glyoxylic acid and urea.

Manufacture: Synthetically produced by direct condensation of glyoxylic acid and urea.

Animal Testing: Not animal tested.

GMO: GMO-free (does not contain plant-derived components)

Vegan: Does not contain animal-derived components.

HS Code: 2933210010

Regulatory Information: Allantoin is registered as an OTC skin protectant drug with the FDA (Category I; allowed concentration 0.5-2%). This means that if you want to sell a finished product containing allantoin and you make a skin protectant claim (incl. minor cuts, scrapes, burns, chapped skin and lips, poison ivy, poison oak, poison sumac, and insect bites), allantoin must then be listed under 'Active Ingredients' on the label. Also, your facility and your product must be registered with the FDA and you must operate under cGMP guidelines. However, if no skin protectant drug claims are made on the label, allantoin is not considered an OTC drug and no registration is needed.