bulletin VC-936

allantoin and allantoin USP

cosmetic and pharmaceutical skin protectant for healthy skin and mouth

formulator benefits	**formulation benefits**
o skin and oral mucosa protectant o skin conditioning agent o active ingredient in drug products when used according to U.S. FDA monograph	usability (multiple benefits) o promotes healthy skin o soothes skins o gives temporary protection to minor cuts, scrapes, and burns o help relieve symptoms of dryness integrity (high quality) o long history of use in cosmetics, over-the counter topical and oral care products o allantion USP meets current US Pharmacopeia (USP) and European Pharmacopeia (EP) monographs o allantoin USP complies with ICH Q7 Good Manufacturing Practices for Active Pharmaceutical ingredients

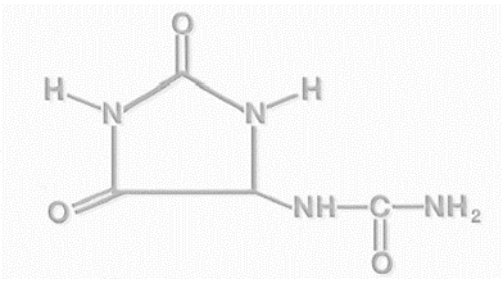
applications

leave-on, rinse-off, oral care, OTC

product forms cream, emulsion, gel, liquid, mousse, ointment, powder, stick, wipes

available formulations from Ashland skin care/ mask

chemistry



description amphoteric compound that is anionic under basic conditions
urea (2,5-dioxo-4-imidazolidinyl), $C_4H_6N_4O_3$
INCI name: allantoin
not preserved

typical properties

appearance.....white crystalline powder
pka @ 25ºC..... 8.96
solubility @ 25ºC (g/100g solvent)
in water.....0.45 g
in ethanol .....<0.1 g
in propylene glycol.....<0.1 g
in 10% HCl .....<0.4 g
in 10% NaOH .....39.0 g

Product specifications are available on request.

formulation guidelines

recommended use levels	0.5 to 2.0%
temperature/mixing conditions	Addition of allantoin at 0.5% or more or at temperatures above 50ºC in aqueous systems can cause recrystallization upon cooling.
compatibility	Allantoin is compatible with most ingredients used in personal care formulations.
when to add	For emulsions: during cooling process after emulsion made.
tips from our technical solvers	To achieve a suitable suspension, good agitation is required to thoroughly disperse the allantoin. Due to low water solubility, it is suggested that the material be suspended in a thick base. When conducting stability testing, care must be taken to look for issues of recrystallization.

safety, handling, and storage

Avoid dust formation. May form combustible dust concentrations in air. Keep dust/air mixtures away from ignition sources. Please read and follow SDS before handling.

A toxicology summary can also be made available, on a confidential basis.

regulatory

CAS No. 97-59-6

The United States (U.S.) Food and Drug Administration (FDA) lists Allantoin as a skin protectant at 0.5% to 2.%. As regulations vary globally, please consult the applicable local regulations in the markets in which your end use product is to be sold.

Ashland maintains a Type II U.S. Drug Master File (DMF) with the U.S. FDA for allantoin USP. Customers may request a DMF Letter of Authorization from Ashland. The U.S. manufacturing plant (Chatham, NJ) is registered with the U.S. FDA.

Other regulatory information available on request.