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TOXICOLOGICAL AND ECO-TOXICOLOGICAL DATA

Product Name	Vitamin B3 (Niacinamide)
Product Code	AL00039
INCI Name	Niacinamide
CAS Number	98-92-0

Toxicological Summary

1. Acute oral toxicity

Oral: LD50-rat (male/female) - > 2500 mg/kg bw
Inhalation: LC50 - rat (male/female) - > 3.8 mg/L air-4h
Dermal: LD50 - rabbit (male/female) - > 2 000 mg/kg bw-24h

2. Skin irritation

EU Method B.4 and OECD Guideline 404 (Acute Dermal Irritation / Corrosion).
A single 4-hour, semi-occluded application of the test material to the intact skin of three rabbits produced no evidence of skin irritation. The test material produced a primary irritation index of 0.0 and was classified as nonirritant to rabbit skin according to the Draize classification scheme. No corrosive effects were noted.

3. Eye irritation

EU Method B.5 and OECD Guideline 405
A single application of the test material to the non-irrigated eye of three rabbits produced a dulling of the normal lustre of the corneal surface, diffuse corneal opacity, iridial inflammation and moderate to severe conjunctival irritation. The test material produced a maximum group mean score of 34.3 and was classified as a moderate irritant (Class 5 on a 1 to 8 scale) to the rabbit eye according to a modified Kay and Calandra classification system.

4. Skin sensitisation

OECD Guideline 406 (Skin Sensitisation)
The sensitisation potential of the test material was assessed in a guinea pig maximisation test. Nine of the twenty animals exposed displayed weak signs of erythema at 24 h, 7 of which persisted for 48 h, while two animals in the control group displayed erythema. This was determined to be non-significant in a statistical analysis. The test item is determined to be non-sensitising.

5. Genotoxicity

EU Method B.12 and OECD Guideline 474(Mammalian Erythrocyte Micronucleus Test)
Groups of six mice were examined 24, 48 and 72 hours following treatment in vitro. According to the criteria of assessment, the test item is considered non-mutagenic in the reported in vivo mouse micronucleus test.
EU Method B.10 and OECD Guideline 473 (In vitro Mammalian Chromosome Aberration Test)
Assess the ability of the test item to induce chromosomal aberrations in human lympho-cytes cultured in vitro. Testes were carried out up to 5000 ug/mL (limit concentration)

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with and without metabolic activation, with cells harvested 21 and 44 hours after initiation of treatment. The test item showed no evidence of clastogenic activity in this in vitro cytogenetic test system.

6. Repeated dose toxicity

EU Method B.7 and OECD Guideline 407 (Repeated Dose 28-Day Oral Toxicity in Rodents)
NOAEL-mat (male/female)-215 mg/kg bw (total dose)
The results of this study indicate the very low toxicity of the test item. Even at a dose of 1000 mg/kg daily administered for 4 weeks the liver as the main target organ is only slightly affected. All changes are reversible after the end of exposure to unphysiologically high levels of test item.

Ecotoxicological Summary

1. Toxicity

Toxicity to fish: LC50 - Poecilia reticulata - > 1 000 mg/L - 96 h. NOEC=1000 mg/L.
Toxicity to daphnia and other aquatic invertebrates: EC50 - Daphnia magna - > 1 000 mg/L - 24 h.
Toxicity to algae: IC50 - Desmodesmus subspicatus (previous name: Scenedesmus subspicatus) - > 1 000 mg/L - 72 h. NOEC=560 mg/L.
Toxicity to microorganisms: NOEC - Pseudomonas putida - 4 235 mg/L-18 h.