

Niacinamide



Chemical name:	Pyridine-3-carboxamide
CAS No.:	98-92-0
EINECS No.:	202-713-4
INN:	Nicotinamide
INCI:	Nicotinamide
Ph.Eur.:	nicotinamidum
IUPAC:	Nicotinamid
CN code:	29362900
Synonyms:	antipellagra vitamin, vitamin PP (pellagra preventive), PP-factor, pyridin-3-carboniacidamide, nicotinamide, nicotinic acid amide, sometimes niacin

Producer: JUBILANT ORGANOSYS Ltd., India

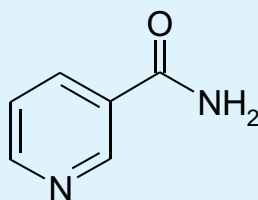


Kyowa Hakko Europe GmbH
Daiichi Fine Chemical Division

SPECIFICATION*

Chemical Name: Pyridine-3-carboxamide

Chemical Structure:



Empirical formula: $C_6H_6N_2O$ Molecular weight: 122.1

Characters: A white crystalline powder or colourless crystals, freely soluble in water and in ethanol

Identification: Melting point 128° to 131° C

- A: Examine by infrared absorption spectrophotometry
- B: Boil 0.1 g with 1 ml of dilute sodium hydroxide solution. Ammonia is evolved which is recognisable by its odour
- C: Dilute 2 ml of solution to 100 ml with water. To 2 ml of solution, add 2 ml of cyanogen bromide solution and 3 ml of a 25 g/l solution of aniline and shake. A yellow colour develops.
- D:

Appearance of solution: Clear and not more intensely coloured than reference solution

pH-value of solution: 6.0 to 7.5

Related substances: thin-layer chromatography (TLC silica gel GF 254 plate): Any spot in the chromatogram obtained with the test solution, apart from the principal spot, is not more intense than the spot in the chromatogram obtained with the reference solution.

Heavy metals: Not more than 30 ppm

Loss on drying: Not more than 0.5 %

Sulphated ash: Not more than 0.1 %

Assay: 99.0 - 101.0 %
calculated with reference to the dried substance

*meets the requirements of the current Ph. Eur. Monograph for Nicotinamide

Other properties

Particle size: Fine granular: min. 98% through 20 mesh (ASTM)
max. 10% through 140 mesh (ASTM)

Free flow: max. 5% granulation BSS+ #100

Powder: min. 90% through 60 mesh

Origin: Synthetic

Odour: Almost odourless

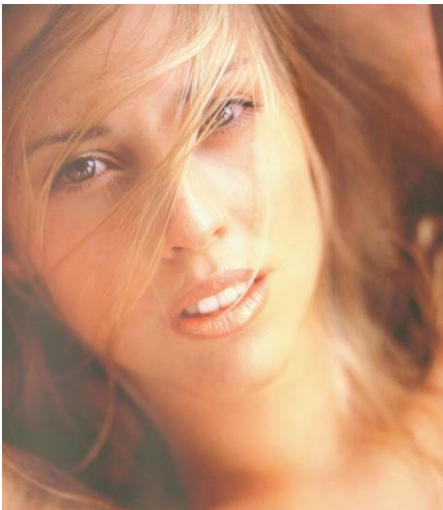
Storage & Packaging

Storage:	Keep closed when not in use. Store in a dry, protected area.
Standard packaging:	20 kg net carton boxes
Expiry date:	5 years after production date in unopened, original packaging at adequate storage conditions

Formulating

Stability:	Stable towards oxygen, light, heavy metals, and at a pH range of 3 to 7.5. Do not heat to more than 85°C. In acidic and alkali solutions it is hydrolysed to nicotinic acid
Solubility:	Soluble in water and alcohol. 1 g dissolves in about 1 ml water, 1.5 ml alcohol, 10 ml glycerol. May form crystal salt with acids
Microorganisms:	Total plate count: not more than 1000 CFU/g Mold and yeast: not more than 10 CFU/g E.coli, pseudomonas aeruginosa, staphylococcus aureus absent in 10g
Safety:	Oral LD ₅₀ rat:3500 mg/kg S.C. LD ₅₀ rat:1680 mg/kg Oral overdose of niacinamide is not reported in the literature. In normal doses, nicotinamide is not toxic. Chronic administration at doses of 3g daily for periods greater than three months may cause nausea, headaches, heartburn, fatigue, sore throat and blurred vision

General functions



Niacinamide, which is also called nicotinamide, is a member of the B-vitamin family. It is also called vitamin B3. Another form of vitamin B3 is nicotinic acid. Since both forms are effective as this one vitamin the term *niacin* is often used as group name despite some authors using the term *niacin* synonymously only with nicotinic acid. Another synonym for them is Anti-Pellagra-Vitamin or PP (Pellagra-Preventive)-Factor.

This term describes a deficiency symptom which occurred in the past frequently with niacin deficient diets. Pellagra, Italian for *pelle agra* means rough or burning skin. The skin becomes rough, hyperpigmented, scaly and inflammated at areas exposed to the sun. Other early signs of deficiency comprise weight loss, weakness and the inability to concentrate. The severe deficiency state is characterized by dementia and diarrhoea.

Niacinamide forms the essential part of the coenzyme nicotinamide adenine dinucleotide (NAD) and nicotinamide adenine dinucleotide phosphate (NADP) that are used to generate energy inside the cells. These coenzymes participate in many metabolic processes including glycolysis, tissue respiration, lipid, amino and purine metabolism. More than 40 biochemical reactions have been identified and are of paramount importance for normal tissue integrity, particularly for the skin, the gastrointestinal tract and the nervous system.

The requirements of niacin are the sum of amounts of niacinamide and nicotinic acid. Niacin is also obtained in the body from the amino acid tryptophan. The conversion of tryptophan is to some extent under hormonal control. Generally, 60 mg of tryptophan are considered to be equivalent to 1 mg of niacin, thus this is the amount indicating 1 niacin equivalent.

Requirements

Dietary recommendations for niacinamide range from 13 to 17 mg niacin equivalent per day for adults.

Literature:

PDR for Nutritional Supplements, 1st ed., Montvale: Medical Economics Company Inc., 2001
Pamela Mason: Dietary Supplements, second ed., London: Pharmaceutical Press, 2001
Bässler K.-H. Et al.: Vitamin Lexikon, 2nd ed. Frankfurt: Gustav Fischer, 1997

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