

93772-NICOTINAMIDE**1. IDENTIFICATION OF THE SUBSTANCE OR PREPARATION****1.1 Identification of the substance or preparation**

Name: Nicotinamide

Bulk code: 93772

Internal code: 401338

Valid from batch: 0131609

1.2 Synonyms

3-pyridinecarbossamide; nicotilamide ; niacinamide ; vitamin PP; vitamin B3

2. DESCRIPTION

Appearance: crystalline powder / crystals

Color: white or almost white / colorless

Odor: odorless or almost odorless

Origin: synthetic

Geographical origin: China

3. COMPOSITION/INFORMATION ON INGREDIENTS

Ingredients: Nicotinamide (99-101%)

Formula: C₆H₆N₂O

CAS: 98-92-0

CE: 202-713-4

Molecular weight: 122.12 g/mol

INCI Name: Niacinamide

4. PHYSICAL-CHEMICAL DATA

For more detailed information, please consult the analysis bulletin.

Solubility: Very soluble in water and alcohol, soluble in glycerin and very slightly soluble in chloroform.**Incompatibilities:** Alkalis , strong acids.**5. PROPERTIES/USES**

Excipient for pharmaceutical use.

Food use.

93772-NICOTINAMIDE

6. DOSAGE

No data available.

7. OBSERVATIONS

The product has been handled in a NON-sterile room, so the product is NOT STERILE.

The documentation corresponding to the regulatory part of the product that is available for it is the one we reflect below.

NUTRITIONAL INFORMATION:

According to our supplier or manufacturer, the approximate nutritional information for this product is as follows:

The following table contains the nutritional values of the aforementioned product, in accordance with Regulation (EU) 1169/2011 of 25 October 2011 on the provision of food information to consumers.

The purpose of this document is to provide the information necessary to complete the nutritional information tables for consumer products.

Energy content total	kJ/100g	0
Energy content total	kcal/100g	0
Content in:		
Fat	g/100g	0
➤ thereof saturated fatty acids	g	0
➤ thereof mono-unsaturated fatty acids	g	0
➤ thereof poly-unsaturated fatty acids	g	0
Carbohydrates	g/100g	0
➤ thereof sugars	g	0
➤ thereof polyols	g	0
➤ thereof starch	g	0
Fibre	g/100g	0
Protein	g/100g	0
Salt (Sodium content x 2.5)	g/100g	0

ALLERGENS:

Food allergens: The product does not contain sucrose, corn, corn products, benzoates, BHA/BHT. According to our supplier or manufacturer, the above-mentioned product does not contain any allergens according to Regulation (EU) No. 1169/2011 , Annex II, and its subsequent amendments. Based on the allergen risk assessment conducted at the manufacturing plant, the presence of these allergens is unlikely. These allergens are:

- Cereals containing gluten (wheat, rye, barley, oats, spelt, kamut (khorasan) or their hybrid strains) and their products

93772-NICOTINAMIDE

- Crustaceans and their products
- Eggs and their products
- Fish and its products
- Peanuts and their products
- Soybeans and their products
- Milk and its products (including lactose)
- Nuts (almonds, hazelnuts, walnuts, cashews, pecans, Brazil nuts, pistachios, macadamia nuts /Queensland) and their products
- Celery and its products
- Mustard and its products
- Sesame seeds and their products
- Sulfur dioxide and sulfites in concentrations greater than 10 mg/kg or 10 mg/liter expressed as SO₂ in the product intended for the final consumer
- Lupins and derived products
- Molluscs (gastropods, bivalves, cephalopods) and derived products

STORAGE:

Store at room temperature in a cool, dry place, protected from light and with the container tightly closed, away from sources of heat and moisture.

SHELF LIFE:

3 years from the date of manufacture. For more detailed information, see the analysis bulletin.

REGULATIONS:

The product complies with:

- Regulation (EC) 1925/2006
- Directive 2002/46/EC
- EU Regulation 609/2013
- Regulation (EC) 852/2004
- Regulation (EC) 853/2004
- Regulation (EC) 178/2002
- Regulation (EC) 931/2011

BSE/TSE:

The product does not present a BSE/TSE risk according to EC Regulation 999/2001.

GMO:

The product is non-GMO in accordance with Regulations 1829/2003/EC and 1830/2003/EC.

93772-NICOTINAMIDE**NANOMATERIALS:**

The product does not contain nanomaterials according to the Reg.(EU) n.1169/2011.

RADIATION:

The product has not been irradiated in accordance with Directive 1999/2/EC and Directive 1999/3/EC.

The product complies with Regulation (Euratom) 2016/52, Regulation (EC) 1158/2020, Regulation (EU) 2021/1533 and Regulation (EU) 2023/1453 for Radioactivity.

ETHYLENE OXIDE:

Ethylene oxide has not been used in accordance with Regulation 231/2012/EC and Regulation 396/2005/EC.

PESTICIDES:

The product complies with Regulation 396/2005/EC.

RESIDUAL SOLVENTS:

According to ICH Q3C, USP and Ph. Eur .

IMPURITIES/CONTAMINANTS:

- The product complies with Regulation (EU) 2023/915:
 - o Mycotoxins
 - o Dioxins
 - o PCBs
 - o PAH (Polycyclic aromatic hydrocarbons)
 - o Erucic acid
 - o Pyrrozylidine alkaloids
 - o Tropane alkaloids
 - o Chlorates and perchlorates
 - o 3-MCPD, 3-MCPD esters and glycerides of esters
 - o Melamine (Absent according to Regulation 2023/915).

- The product complies with Regulation (EU) 2017/2158 for acrylamide.
- The product does not contain sensitizing substances or other constituents.
- The product does not contain phthalates in accordance with Regulation 1935/2004/EC and Regulation 10/2011.

HEAVY METALS:

The product complies with Regulation (EU) 2023/915.

Total heavy metals \leq 20ppm

As \leq 1 ppm

Pb \leq 2 ppm

93772-NICOTINAMIDE

Hg \leq 0.1 ppm

Cd \leq 0.5 ppm

HALAL:

The product has Halal certification .

KOSHER:

Kosher certified .

VEGAN/VEGETARIAN:

The product is suitable for vegan/vegetarian use.

ANIMAL TESTED:

The product has not been tested on animals.

DOPING SUBSTANCES:

The product does not contain any of the substances on the WADA Prohibited List.

REACH:

01-2119968268-22