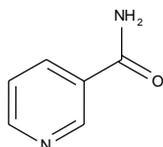


1. Product and Company Identification

Product name	Niacinamide USP FCC	
Product code	04 0963 4	
Company information	Enquiries:	Local representation:
	Roche Vitamins Inc. 45 Waterview Boulevard USA-Parsippany, NJ 07054-1298 United States of America	
	Phone	001-973/257 10 63
	US Emergency phone: (800)-827-6243 US Chemtrec phone: (800)-424-9300	
Roche Nutley Inventory Code	0487147	
Roche number	Ro 01-3854/000	
CAS number	98-92-0	
Synonyms	<ul style="list-style-type: none"> - Niacinamide - Nicotinamide - Niacinamide, Free Flowing (product code 5002141) - Niacinamide (product code 04 8784 8) - 3-Pyridine carboxamide - Vitamin PP 	
Characterization	water soluble B group vitamin	

2. Composition/Information on ingredients

Chemical name	- Pyridine-3-carboxylic acid amide
Percentage	≥ 99 %



Niacinamide USP FCC

3. Hazards identification

Emergency Overview

Form	crystalline powder
Color	practically white
Odor	almost odourless, with bitter taste
Hazard Overview	- Severe dust explosion hazard
Potential Health Effects	- Exposure: Inhalation, Ingestion, Skin contact, Eye contact - Target Organs: kidneys, gastrointestinal system - Acute Effects: May cause eye irritation., May cause skin irritation., May cause gastrointestinal effects., Signs and symptoms may include nausea, vomiting, diarrhea, constipation, cramps, and loss of appetite. - Chronic Effects: May cause liver necrosis (destruction of liver cells). - Carcinogenicity: not listed by NTP, IARC or OSHA
Additional Health Information	- Conditions Aggravated: Diabetes, liver conditions and/or impaired liver function, high blood pressure, gout, ulcers.

4. First-aid measures

Eye contact	- rinse immediately with tap water for 10 minutes - open eyelids forcibly - consult physician
Skin contact	- remove immediately contaminated clothes, wash affected skin with water and soap - do not use any solvents
Inhalation	- remove the casualty to fresh air and keep him/her calm
Note to physician	- treat symptomatically

5. Fire-fighting measures

Suitable extinguishing media	- water spray jet, dry powder, foam, carbon dioxide
Flash point (liquid)	not applicable
Specific hazards	- formation of toxic and corrosive combustion gases (nitrogen oxides (NOx)) possible - consider dust explosion hazard
Protection of fire-fighters	- precipitate gases/vapours/mists with water spray

Niacinamide USP FCC

6. Accidental release measures

- | | |
|-------------------------|---|
| Methods for cleaning up | <ul style="list-style-type: none">- collect solids (avoid dust formation) and hand over to waste removal- rinse with plenty of water |
|-------------------------|---|

7. Handling and storage

Handling

- | | |
|--------------------|--|
| Technical measures | <ul style="list-style-type: none">- processing in closed systems, if possible superposed by inert gas (e.g. nitrogen)- local exhaust ventilation necessary- take precautionary measures against electrostatic charging- avoid dust formation; very high dust explosion hazard |
| Suitable materials | <ul style="list-style-type: none">- stainless steel, aluminium, enamel, glass, polyethylene |

Storage

- | | |
|---------------------|---|
| Storage conditions | <ul style="list-style-type: none">- room temperature- protected from light- store in a dry place |
| Validity | <ul style="list-style-type: none">- 36 months, < 25 °C, in the unopened original container, see "best use before" date stated on the label |
| Packaging materials | <ul style="list-style-type: none">- tightly closing; material: glass, aluminium, food-approved plastics |

8. Exposure controls/Personal protection

- | | |
|----------------------|--|
| Engineering Measures | <ul style="list-style-type: none">- see 7. |
|----------------------|--|

Monitoring

- | | |
|-----------------------------|--|
| Threshold value (Roche) air | <ul style="list-style-type: none">- IOEL: 5 mg/m³ (Internal Occupational Exposure Limit) |
| Analytics | <ul style="list-style-type: none">- sampling on glass fibre filter and gravimetric or chemical determination |

Personal protective equipment

- | | |
|------------------------|---|
| Respiratory protection | <ul style="list-style-type: none">- Respiratory protection is recommended as a precaution to minimize exposure. Effective engineering controls are considered to be the primary means to control worker exposure. Respiratory protection should not substitute for feasible engineering controls.- in case of open handling or accidental release: particle mask or respirator with independent air supply |
| Hand protection | <ul style="list-style-type: none">- protective gloves |
| Eye protection | <ul style="list-style-type: none">- safety glasses |

Niacinamide USP FCC

9. Physical and chemical properties

Color	practically white
Form	crystalline powder
Odor	almost odourless, with bitter taste
Molecular mass	122.13 g/mol
Empirical formula	C ₆ H ₆ N ₂ O
Density	1.36 g/cm ³ (20 °C)
Bulk density	~ 0.6 g/cm ³
Solubility	~ 10'000 mg/l, diethyl ether ~ 16'000 mg/l, n-octanol ~ 77'000 mg/l, ethanol absolute ~ 100'000 mg/l, glycerine ~ 660'000 mg/l, ethanol 96 % 691'000 mg/l, water (20 °C)
Partition coefficient	log P _{ow} -0.38 (octanol/water 20 °C) (Shake Flask Method, OECD No. 107)
pH value	6.0 to 7.5 (5 % aqueous solution)
Melting temperature	128 to 131 °C
Boiling temperature	224 °C (20 mbar)

10. Stability and reactivity

Stability	- stable under the conditions mentioned in chapter 7
Conditions to avoid	- light - humidity
Materials to avoid	- acids, bases (hydrolysis)
Note	- drying operations at the lowest temperatures possible

11. Toxicological information

Acute toxicity	- LD ₅₀ 3'500 mg/kg (oral, rat) - LD ₅₀ 2'500 mg/kg (oral, mouse)
Local effects	- skin: non-irritant (guinea pig) - eye: strongly irritant (rabbit; OECD No. 405)
Mutagenicity	- not mutagenic
Carcinogenicity	- not carcinogenic
Note	- therapeutic daily dose (adults): 300-1000 mg - long exposure or overingestion may cause vasodilation, skin dryness, skin rashes, abdominal cramps, diarrhoea, nausea, vomiting, liver problems and excessive pigmentation

Niacinamide USP FCC

- RDA (recommended daily dietary allowance; adults): 15 mg
- GRAS (generally recognized as safe for human consumption)

12. Ecological information

- Ready biodegradability
- readily biodegradable
96 %, 28 days
(Modified OECD Screening Test, OECD No. 301 E)
- Ecotoxicity
- barely toxic for fish (guppy)
LC₅₀ (96 h) > 1000 mg/l
 - barely toxic for planktonic crustaceans (Daphnia magna)
EC₅₀ (48 h) > 1000 mg/l
 - barely toxic for microorganisms (Vorticella campanula)
NOEC 3500 mg/l
 - barely toxic for algae (green algae)
EbC₅₀ (72 h) > 1000 mg/l
- Air pollution
- observe local/national regulations

13. Disposal considerations

- Waste from residues
- incinerate in qualified installation with flue gas scrubbing
 - observe local/national regulations regarding waste disposal
- RCRA waste
- not regulated under RCRA

14. Transport information

- Note
- not classified by transport regulations, proper shipping name non-regulated

15. Regulatory information

- US Regulations
- Law: hazardous chemical reporting: community right-to know
 - Ident_No: 40CFR370
 - Common name: SARA title 312
 - Agency: Environmental Protection Agency EPA
 - Authority: USA
 - Criteria met: fire
- TSCA Status
- On TSCA inventory
- Reporting Requirements
- The United States Environmental Protection Agency (USEPA) has not established a Reportable Quantity (RQ) for releases of this material.
 - In New Jersey, report all releases which are likely to endanger the public health, harm the environment or cause a complaint to the NJDEPE Hotline (1-609-292-5560) and to local officials.
 - State and local regulations vary and may impose additional reporting requirements.

Niacinamide USP FCC

16. Other information

Use	- pharmaceutical active substance in vitamin preparations - food and feed additive
Biological activity	- 1 N.E. (Niacin Equivalent) corresponds to 1 mg niacin (as either nicotinic acid or nicotinamide) or 60 mg dietary tryptophan *1
Safety-lab number	- BS-4916 - BS-7069
Edition documentation	- changes from previous version in sections 2
*1 referring to:	Niacin

The information in this safety data sheet is based on current scientific knowledge. It should not be taken as expressing or implying any warranty concerning product characteristics.