1. Product and Company Identification

Product name: Niacinamide USP FCC
Product code: 04 0963 4
Company information:
Enquiries: 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:
- 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 %
### 3. Hazards identification

#### Emergency Overview

<table>
<thead>
<tr>
<th>Property</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Form</td>
<td>crystalline powder</td>
</tr>
<tr>
<td>Color</td>
<td>practically white</td>
</tr>
<tr>
<td>Odor</td>
<td>almost odourless, with bitter taste</td>
</tr>
<tr>
<td>Hazard Overview</td>
<td>- Severe dust explosion hazard</td>
</tr>
<tr>
<td>Potential Health Effects</td>
<td>- Exposure: Inhalation, Ingestion, Skin contact, Eye contact</td>
</tr>
<tr>
<td></td>
<td>- Target Organs: kidneys, gastrointestinal system</td>
</tr>
<tr>
<td></td>
<td>- 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.</td>
</tr>
<tr>
<td></td>
<td>- Chronic Effects: May cause liver necrosis (destruction of liver cells).</td>
</tr>
<tr>
<td></td>
<td>- Carcinogenicity: not listed by NTP, IARC or OSHA</td>
</tr>
<tr>
<td>Additional Health Information</td>
<td>- Conditions Aggravated: Diabetes, liver conditions and/or impaired liver function, high blood pressure, gout, ulcers.</td>
</tr>
</tbody>
</table>

#### 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  
- collect solids (avoid dust formation) and hand over to waste removal  
- rinse with plenty of water

## 7. Handling and storage

### Handling

Technical measures  
- 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  
- stainless steel, aluminium, enamel, glass, polyethylene

### Storage

Storage conditions  
- room temperature  
- protected from light  
- store in a dry place

Validity  
- 36 months, < 25 °C, in the unopened original container, see "best use before" date stated on the label

Packaging materials  
- tightly closing; material: glass, aluminium, food-approved plastics

## 8. Exposure controls/Personal protection

### Engineering Measures

- see 7.

### Monitoring

Threshold value (Roche) air  
- IOEL: 5 mg/m³ (Internal Occupational Exposure Limit)

Analytics  
- sampling on glass fibre filter and gravimetric or chemical determination

### Personal protective equipment

Respiratory protection  
- 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  
- protective gloves

Eye protection  
- safety glasses
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  
C₆H₇N₂O

Density  
1.36 g/cm³ (20 °C)

Bulk density  
~ 0.6 g/cm³

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 %
~ 69'000 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  
- LD₅₀ 3'500 mg/kg (oral, rat)
- LD₅₀ 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

<table>
<thead>
<tr>
<th>Ready biodegradability</th>
<th>- readily biodegradable 96 %, 28 days (Modified OECD Screening Test, OECD No. 301 E)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ecotoxicity</td>
<td>- barely toxic for fish (guppy) ( \text{LC}_{50} (96 \text{ h}) &gt; 1000 \text{ mg/l} )</td>
</tr>
<tr>
<td></td>
<td>- barely toxic for planktonic crustaceans (Daphnia magna) ( \text{EC}_{50} (48 \text{ h}) &gt; 1000 \text{ mg/l} )</td>
</tr>
<tr>
<td></td>
<td>- barely toxic for microorganisms (Vorticella campanula) ( \text{NOEC} 3500 \text{ mg/l} )</td>
</tr>
<tr>
<td></td>
<td>- barely toxic for algae (green algae) ( \text{EbC}_{50} (72 \text{ h}) &gt; 1000 \text{ mg/l} )</td>
</tr>
<tr>
<td>Air pollution</td>
<td>- observe local/national regulations</td>
</tr>
</tbody>
</table>

### 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. |
## 16. Other information

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

*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.