

# SAFETY DATA SHEET

## Art. No 150100000, NOVAPATCH

### 1. Identification of the substance/preparation and the company

#### 1.1 Identification of the substance or preparation:

Synonyms: None

CAS No. : N.A.  
EC index No. : N.A.  
EINECS No. : N.A.  
RTECS No. : N.A.  
NFPA code : N.D.  
Molecular weight : N.A.  
Formula : N.A.



#### 1.2 Use of the substance or the preparation:

Pharmaceutical product

#### 1.3 Company/undertaking identification:

NOVATIO EUROPE N.V.  
Industrielaan 5D  
B-2250 Olen  
Tel. : +32 14 25 76 40  
Fax : +32 14 22 02 66  
[www.novatio.com](http://www.novatio.com)

#### 1.4 Telephone number for emergency:

+32 14 58 45 45  
Brandweerinformatiecentrum voor gevaarlijke stoffen (B.I.G.)  
Technische Schoolstraat 43 A, B-2440 Geel

### 2. Composition/information on ingredients

Hazardous ingredients	CAS No. EINECS/ELINCS No.	Conc. in %	Hazard symbol	Risks (R-phrases)
cotton	-	85-90	-	-
latex	-	5-10	-	-
D-gluconic acid, compound with N,N''-bis(4- chlorophenyl)-3,12- diimino-2,4,11,13- tetraazatetradecanediami- ne (2:1) (20%)	18472-51-0 242-354-0	0.4-0.5	-	-

### 3. Hazards identification

- No hazard classification in accordance with directives 67/548/EEC and 1999/45/EC

### 4. First aid measures

#### 4.1 Eye contact:

- If irritation persists: consult a doctor/medical service

#### 4.2 Skin contact:

- If irritation persists: consult a doctor/medical service

#### 4.3 After inhalation:

- Not applicable

- 4.4 After ingestion:**  
- Not applicable

## 5. Fire-fighting measures

- 5.1 **Suitable extinguishing media:**
- Water spray
  - Polyvalent foam
  - ABC powder
  - Carbon dioxide
- 5.2 **Unsuitable extinguishing media:**
- No data available
- 5.3 **Special exposure hazards:**
- May burn
  - Upon combustion CO and CO2 are formed
- 5.4 **Instructions:**
- No specific firefighting instructions required
- 5.5 **Special protective equipment for firefighters:**
- Heat/fire exposure: compressed air/oxygen apparatus

## 6. Accidental release measures

- 6.1 **Personal protection/precautions:**  
See heading 8.1/8.3/10.3
- 6.2 **Environmental precautions:**
- Not applicable
- 6.3 **Methods of cleaning up:**
- Pick-up the material

## 7. Handling and storage

- 7.1 **Handling:**
- Observe normal hygiene standards
- 7.2 **Storage:**
- Store in a cool area
  - Store in a dry area
  - Meet the legal requirements
  - Keep away from: heat sources, oxidizing agents

Storage temperature	: N.D.	°C
Quantity limits	: N.D.	kg
Storage life	: N.D.	days
Materials for packaging	: N.D.	

- 7.3 **Specific uses:**
- See information supplied by the manufacturer

## 8. Exposure controls/Personal protection

- 8.1 **Exposure limit values:**
- |             |              |
|-------------|--------------|
| TLV-TWA     | : not listed |
| TLV-STEL    | : not listed |
| TLV-Ceiling | : not listed |
| OES-LTEL    | : not listed |
| OES-STEL    | : not listed |
| MEL-LTEL    | : not listed |
| MEL-STEL    | : not listed |
| MAK         | : not listed |
| TRK         | : not listed |

MAC-TGG 8 h : not listed  
 MAC-TGG 15 min. : not listed  
 MAC-Ceiling : not listed

VME-8 h : not listed  
 VLE-15 min. : not listed

GWBB-8 h : not listed  
 GWK-15 min. : not listed  
 Momentary value : not listed

EC : not listed  
 EC-STEL : not listed

**Sampling methods:**

- No data available

**8.2 Exposure controls:**

**8.2.1 Occupational exposure controls:**  
 - No data available

**8.2.2 Environmental exposure controls:** see heading 13

**8.3 Personal protection:**

**8.3.1 respiratory protection:**  
 - Not required for normal conditions of use

**8.3.2 hand protection:**  
 - Not required for normal conditions of use

**8.3.3 eye protection:**  
 - Not required for normal conditions of use

**8.3.4 skin protection:**  
 - Not required for normal conditions of use

**9. Physical and chemical properties**

**9.1 General information:**

Appearance (at 20°C) : Cotton balls  
 Odour : Odourless  
 Colour : Rose or blue

**9.2 Important health, safety and environmental information:**

pH value : N.D.  
 Boiling point/boiling range : N.A. °C  
 Flashpoint : N.D. °C  
 Explosion limits : N.D. Vol% ( °C)  
 Vapour pressure (at 20°C) : N.D. hPa  
 Vapour pressure (at 50°C) : N.D. hPa  
 Relative density (at 20°C) : N.D.  
 Water solubility : Poorly soluble  
 Soluble in : N.D.  
 Relative vapour density : N.D.  
 Viscosity (at 20°C) : N.A. Pa.s  
 Partition coefficient n-octanol/water : N.D.  
 Evaporation rate :  
     ratio to butyl acetate : N.D.  
     ratio to ether : N.D.

**9.3 Other information:**

Melting point/melting range : N.D. °C  
 Auto-ignition point : N.D. °C  
 Saturation concentration : N.D. g/m<sup>3</sup>

## 10. Stability and reactivity

### 10.1 Conditions to avoid/reactivity:

- No data available

### 10.2 Materials to avoid:

- Keep away from: heat sources, oxidizing agents

### 10.3 Hazardous decomposition products:

- Upon combustion CO and CO<sub>2</sub> are formed and formation of small quantities of hydrogen chloride, sulphur oxides

## 11. Toxicological information

### 11.1 Acute toxicity:

LD50 oral rat	: N.D.	mg/kg
LD50 dermal rabbit	: N.D.	mg/kg
LD50 dermal rabbit	: N.D.	mg/kg
LC50 inhalation rat	: N.D.	mg/l/4 h
LC50 inhalation rat	: N.D.	ppm/4 h

### 11.2 Chronic toxicity:

EC carc. cat.	: not listed
EC muta. cat.	: not listed
EC repr. cat.	: not listed

Carcinogenicity (TLV)	: not listed
Carcinogenicity (MAC)	: not listed
Carcinogenicity (VME)	: not listed
Carcinogenicity (GWBB)	: not listed

Carcinogenicity (MAK)	: not listed
Mutagenicity (MAK)	: not listed
Teratogenicity (MAK)	: not listed

IARC classification	: not listed
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### 11.3 Routes of exposure: ingestion, inhalation, eye and skin

### 11.4 Acute effects/symptoms:

- Unlikely to cause harmful effects

### 11.5 Chronic effects:

- May cause sensitization by skin contact

## 12. Ecological information

### 12.1 Ecotoxicity:

- Unlikely to cause harmful effects

### 12.2 Mobility:

- Volatile organic compounds (VOC): N.D. %
- Poorly soluble in water

For other physicochemical properties see section 9

### 12.3 Persistence and degradability:

- Biodegradation BOD <sub>5</sub>	: N.D.	% ThOD
- Water	: N.D.	
- Soil	: T ½ N.D.	days

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### 12.4 Bioaccumulative potential:

- log P<sub>ow</sub> : N.D.
- BCF : N.D.

### 12.5 Other adverse effects:

- WGK : - (internal classification)
- Effect on the ozone layer : Not dangerous for the ozone layer (1999/45/EC)
- Greenhouse effect : No data available
- Effect on waste water purification : No data available

## 13. Disposal considerations

### 13.1 Provisions relating to waste:

- Waste material code (75/442/EEC, Council Decision 2001/118/EC, O.J. L47 of 16/2/2001): 18 01 04 (wastes whose collection and disposal is not subject to special requirements in order to prevent infection (for example dressings, plaster casts, linen, disposable clothing, diapers))
- Waste material code (Flanders): 604

### 13.2 Disposal methods:

- According to literature: no environmental hazard
- Remove to an authorized waste treatment plant

### 13.3 Packaging:

- No data available

## 14. Transport information

### 14.1 Classification of the substance in compliance with UN Recommendations

UN number :  
CLASS : -  
SUB RISKS :  
PACKING :  
PROPER SHIPPING NAME :

### 14.2 ADR (transport by road)

CLASS : NOT SUBJECT  
PACKING :  
CLASSIFICATION CODE :  
DANGER LABEL TANKS :  
DANGER LABEL PACKAGES :

### 14.3 RID (transport by rail)

CLASS : -  
PACKING :  
CLASSIFICATION CODE :  
DANGER LABEL TANKS :  
DANGER LABEL PACKAGES :

### 14.4 ADNR (transport by inland waterways)

CLASS : NOT SUBJECT  
PACKING :  
CLASSIFICATION CODE :  
DANGER LABEL TANKS :  
DANGER LABEL PACKAGES :

### 14.5 IMDG (maritime transport)

CLASS : NOT SUBJECT  
SUB RISKS :  
PACKING :  
MFAG :  
EMS :  
MARINE POLLUTANT :

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- 14.6 ICAO (air transport)
- |   |   |             |
|---|---|-------------|
| CLASS                                   | : | NOT SUBJECT |
| SUB RISKS                               | : |             |
| PACKING                                 | : |             |
| PACKING INSTRUCTIONS PASSENGER AIRCRAFT | : |             |
| PACKING INSTRUCTIONS CARGO AIRCRAFT     | : |             |
- 14.7 Special precautions in connection with transport : Not restricted for any mode of international transport

## 15. Regulatory information

Labelling in accordance with directives 67/548/EEC and 1999/45/EC

NOT REQUIRED ACCORDING TO AVAILABLE INFORMATION

**16. Other information**

The information provided on this MSDS is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered as a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other material or in any process, unless specified in the text.

**N.A.** = NOT APPLICABLE  
**N.D.** = NOT DETERMINED  
**(\*)** = INTERNAL CLASSIFICATION (NFPA)

**Exposure limits:**

**TLV :** Threshold Limit Value - ACGIH USA 2003  
**OES :** Occupational Exposure Standards - United Kingdom 2003  
**MEL :** Maximum Exposure Limits - United Kingdom 2003  
**MAK :** Maximale Arbeitsplatzkonzentrationen - Germany 2002  
**TRK :** Technische Richtkonzentrationen - Germany 2002  
**MAC :** Maximale aanvaarde concentratie - The Netherlands 2003  
**VME :** Valeurs limites de Moyenne d'Exposition - France 1999  
**VLE :** Valeurs Limites d'Exposition à court terme - France 1999  
**GWBB:** Grenswaarde beroepsmatige blootstelling - Belgium 2002  
**GWK :** Grenswaarde kortstondige blootstelling - Belgium 2002  
**EC :** Indicative occupational exposure limit values - Directive 2000/39/EC

**I :** Inhalable fraction = **T :** Total dust = **E :** Einatembarer Aerosolanteil  
**R :** Respirable fraction = **A :** Alveolengängiger Aerosolanteil/Alveolar dust  
**C :** Ceiling limit

<b>a:</b>	aerosol	<b>r:</b>	rook/Rauch	(fume)
<b>d:</b>	damp (vapour)	<b>st:</b>	stof/Staub	(dust)
<b>du:</b>	dust	<b>ve:</b>	vezel	(fibre)
<b>fa:</b>	Faser (fibre)	<b>va:</b>	vapour	
<b>fi:</b>	fibres	<b>om:</b>	oil mist	
<b>fu:</b>	fume	<b>on:</b>	olienevel/Ölnebel	(oil mist)
<b>p:</b>	poussière (dust)	<b>part:</b>	particles	

**Chronic toxicity:**

**K:** List of the carcinogenic substances and processes - The Netherlands 2003