



## Safety Data Sheet

Product: **Xeomin / NT201**

### 01 IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

#### 1.1. Product identifier

Trade name Xeomin / NT201

#### 1.2. Relevant identified uses of the substance or mixture and uses advised against

Powder for the production of an injection solution - in vials

#### 1.3. Details of the supplier of the safety data sheet

Merz Pharmaceuticals GmbH  
Eckenheimer Landstrasse 100  
D-60318 Frankfurt am Main  
Telephone: ++49 (0) 69 1503-0  
Contact: Klinische Forschung und Entwicklung ZNS

Merz North America, Inc.  
6501 Six Forks Road  
Raleigh, NC 27615

☎ Phone 844-469-6379

1.4. Emergency telephone number Hazmat Service Emergency Number: 800-373-7542  
International Shipments: +1-484-951-2432

### 02 HAZARDS IDENTIFICATION

#### 2.1. Classification of the substance or mixture

This product is not classified as hazardous according to GHS.

#### 2.2. Label elements

Labeling according to GHS Warning labels not required.

#### 2.3. Other hazards

Carcinogenicity NTP: No IARC: No OSHA: No

OSHA Classification This product is not considered to be hazardous per the Occupational Safety & Health Administration's (OSHA's) Hazard Communication Standard 29CFR1910.1200

GHS Hazard Classification This product does not require classification and labeling according to GHS

### 03 COMPOSITION / INFORMATION ON INGREDIENTS

3.1. Substances This product is not classified as hazardous according to GHS.  
See also: Section 2 Hazards Identification

#### Chemical characterization

Mixture: **Pharmaceutical product in powder form.**



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### 04 FIRST AID MEASURES

#### 4.1. Description of first aid measures

<b>General information</b>	Seek medical assistance if discomfort occurs.
<b>After inhalation</b>	Take affected person into fresh air. Get immediate medical attention if any breathing difficulties do occur.
<b>After contact with skin</b>	Wash immediately with soap and water. Remove contaminated clothing and shoes. Get medical attention if symptoms occur.
<b>After contact with eyes</b>	Wash eyes immediately with large amounts of water for several minutes, especially under the eyelids. Consult an eye specialist if irritation occurs.
<b>After ingestion</b>	Rinse mouth with water and get immediate medical attention or call Poison Control Center immediately. Never give anything by mouth to an unconscious person.

#### 4.2. Most important symptoms and effects, both acute and delayed

No information is available

#### 4.3. Indication of any immediate medical attention needed

Show this SDS to the treating physician

### 05 FIRE AND EXPLOSION DATA

<b>5.1. Suitable extinguishing media</b>	Any extinguishing means and measures are acceptable. Alcohol resistant foam, carbon dioxide, dry chemical.
<b>5.2. Special hazards arising from the substance or mixture</b>	None known.
<b>5.3. Advice for firefighters</b>	Contain fire run-off to protect the environment. Keep fire exposed containers cool by spraying with water.
<b>Further advice</b>	Use self-contained breathing apparatus and full protective clothing to prevent contact with skin and eyes.

### 06 ACCIDENTAL RELEASE MEASURES

#### 6.1. Personal precautions, protective equipment and emergency procedures

Clear area. Avoid contact with skin, eyes and clothing. Wear suitable protective clothing and equipment.

#### 6.2. Environmental precautions

Do not release into drains or surface waters.

#### 6.3. Methods and material for containment and cleaning up

Take up mechanically and collect in suitable container for disposal. Sodium hypochlorite in concentrations of 0.5% or higher will denature the toxin within 5 minutes.  
Small Quantities (splashes): decontamination of surfaces with 0.1 molar sodium hydroxide solution.  
Large quantities: 1 molar sodium hydroxide solution in ratio 1:1 with contaminated solution.

#### 6.4. Reference to other sections

Refer to protective measures under Sections 7 and 8.



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### 07 HANDLING AND STORAGE

#### 7.1. Precautions for safe handling

**Advise on safe handling** Avoid contact with skin and eyes. Handle in accordance with good industrial hygiene and safety practice. Do not ingest. Wash thoroughly after handling.

**Advise on protection against fire and explosion** No special fire protection measures are necessary.

#### 7.2. Conditions for safe storage including any incompatibilities

**Requirements for storage areas and containers** Keep container closed when not in use.

**Further information on storage conditions** Keep only in original container and away from food, drink and animal feeding stuffs. Avoid temperatures above 25°C (77°F).

**7.3. Specific end use(s)** For pharmaceutical use only.

### 08 EXPOSURE CONTROLS / PERSONAL PROTECTION

#### 8.1. Control parameters

**Exposure limit values** Ensure adequate local exhaust ventilation.

#### 8.2. Exposure controls

**General protective measures** Observe the standard drug production guidelines for cleanliness and proper hygiene.

**Respiratory protection** Not required under normal use. Use NIOSH approved respirator for exposure to dust.

**Hand protection** Protective gloves recommended.

**Eye protection** Safety glasses or splash goggles recommended if risk of eye contact.

**Body protection** Observe the usual guidelines for cleanliness and proper hygiene. Wash thoroughly after handling. Immediately remove soiled and contaminated clothing. Wash before re-use. Do not eat or drink when handling.



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**09 PHYSICAL AND CHEMICAL PROPERTIES**

**9.1. Information on basic physical and chemical properties**

<b>Physical state</b>	powder
<b>Color</b>	white
<b>Odor</b>	odorless
<b>(Odor) Threshold</b>	Not applicable
<b>pH-value (at 20°C)</b>	5.0 - 7.0
<b>Flash point</b>	Not applicable
<b>Melting point</b>	Not determined
<b>Freezing point</b>	Not determined
<b>Boiling point</b>	Not applicable
<b>Evaporation rate</b>	Not determined
<b>Flammability</b>	Not applicable
<b>Lower explosion limit</b>	Not applicable
<b>Upper explosion limit</b>	Not applicable
<b>Vapor pressure</b>	Not determined
<b>Ignition temperature</b>	Not available
<b>Solubility in water (20°C)</b>	Easily soluble
<b>Partition coefficient</b>	Not determined
<b>Decomposition temperature</b>	Not determined
<b>Density (20°C)</b>	0.997 g/ml
<b>Viscosity</b>	Not determined

**9.2. Other information**

<b>Solids content</b>	100%
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**10 STABILITY AND REACTIVITY**

<b>10.1. Reactivity</b>	Product is stable and no hazardous reactions are expected.
<b>10.2. Chemical stability</b>	Stable at room temperature
<b>10.3. Possibility of hazardous reactions</b>	Product is stable and no hazardous reactions are expected.
<b>10.4. Conditions to avoid</b>	Stability and biological activity of the toxin is influenced by factors such as heat (>28°C / 82°F), acids, bases, organic solvents, photo-oxidation and irradiation.
<b>10.5. Incompatible materials</b>	Avoid high temperatures.
<b>10.6. Hazardous decomposition products</b>	No decomposition if stored and applied as directed. Carbon monoxide and carbon dioxide under fire conditions.



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### 11 TOXICOLOGICAL INFORMATION

#### 11.1. Information on toxicological effects

<b>Acute toxicity</b>	This product is intended for pharmaceutical use only. May be harmful by ingestion.
<b>Irritant effect</b>	Avoid contact with eyes. May cause irritation.
<b>Sensitization</b>	No data available.
<b>Specific target organ toxicity (STOT) - single exposure</b>	No data available.
<b>Specific target organ toxicity (STOT) - repeated exposure</b>	Based on the available data, the hazard criteria are not met.
<b>Aspiration hazard</b>	Based on the available data, the hazard criteria are not met.
<b>General remarks</b>	No harmful health effects are known or expected when handled as directed. If irritation or harmful effects occur, immediately discontinue use and consult a doctor.

### 12 ECOLOGICAL INFORMATION

<b>12.1. Toxicity</b>	Ecological information not available.
<b>12.2. Persistence and degradability</b>	No information available.
<b>12.3. Bioaccumulative potential</b>	No information available.
<b>12.4. Mobility in soil</b>	Not determined
<b>12.5. Results of PBT and vPvB assessment</b>	Not determined
<b>12.6. Other adverse effects</b>	No information available
<b>Additional remarks</b>	Do not flush into surface water or sanitary sewer system.

### 13 DISPOSAL CONSIDERATIONS

<b>13.1 Waste treatment methods</b>	Empty containers or liners may retain some product residues. This material and its products must be disposed of in a safe way. Dispose in accordance with federal, state or local regulations. Empty packaging can be disposed via recyclable waste collectors.
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### 14 TRANSPORT INFORMATION

<b>DOT</b>	Not regulated
<b>IATA</b>	Not regulated
<b>IMDG</b>	Not regulated



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### 15 REGULATORY INFORMATION

#### 15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

##### Other regulations

<b>TSCA inventory:</b>	All ingredients are listed on the TSCA inventory or exempt.
<b>DSL inventory</b>	All components are listed on the DSL.
<b>SARA 304 Extremely Hazardous Substances Reportable Quantity</b>	This material does not contain any components with a section 304 EHS RQ.
<b>SARA 311/312 Hazards</b>	No known SARA hazards
<b>SARA Title III</b>	To the best of our knowledge this product contains no toxic chemicals subject to the supplier notification requirements of Section 313 of the Superfund Amendments and Reauthorization Act (SARA/EPCRA) and the requirements of 40 CFR Part 372.
<b>California Proposition 65</b>	Not listed for this form
<b>Massachusetts, New Jersey and Pennsylvania RTK</b>	None
<b>Canada WHMIS</b>	Not regulated

### 16 OTHER INFORMATION

**HAZCOM** No GHS label required.

**Revision Date:** 03 JUN 2016

To the best of our knowledge, the information contained in this SDS is accurate. It is intended to assist the user in his evaluation of the product's hazards, and safety precautions to be taken in its use. The data on this SDS relate only to the specific material designated herein. We do not assume any liability for the use of, or reliance on this information, nor do we guarantee its accuracy or completeness.

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