



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

General information	Seek medical assistance if discomfort occurs.
After inhalation	Take affected person into fresh air. Get immediate medical attention if any breathing difficulties do occur.
After contact with skin	Wash immediately with soap and water. Remove contaminated clothing and shoes. Get medical attention if symptoms occur.
After contact with eyes	Wash eyes immediately with large amounts of water for several minutes, especially under the eyelids. Consult an eye specialist if irritation occurs.
After ingestion	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

5.1. Suitable extinguishing media	Any extinguishing means and measures are acceptable. Alcohol resistant foam, carbon dioxide, dry chemical.
5.2. Special hazards arising from the substance or mixture	None known.
5.3. Advice for firefighters	Contain fire run-off to protect the environment. Keep fire exposed containers cool by spraying with water.
Further advice	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

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

9.2. Other information

Solids content	100%
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10 STABILITY AND REACTIVITY

10.1. Reactivity	Product is stable and no hazardous reactions are expected.
10.2. Chemical stability	Stable at room temperature
10.3. Possibility of hazardous reactions	Product is stable and no hazardous reactions are expected.
10.4. Conditions to avoid	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.
10.5. Incompatible materials	Avoid high temperatures.
10.6. Hazardous decomposition products	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

Acute toxicity	This product is intended for pharmaceutical use only. May be harmful by ingestion.
Irritant effect	Avoid contact with eyes. May cause irritation.
Sensitization	No data available.
Specific target organ toxicity (STOT) - single exposure	No data available.
Specific target organ toxicity (STOT) - repeated exposure	Based on the available data, the hazard criteria are not met.
Aspiration hazard	Based on the available data, the hazard criteria are not met.
General remarks	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

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

13 DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods	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

DOT	Not regulated
IATA	Not regulated
IMDG	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

TSCA inventory:	All ingredients are listed on the TSCA inventory or exempt.
DSL inventory	All components are listed on the DSL.
SARA 304 Extremely Hazardous Substances Reportable Quantity	This material does not contain any components with a section 304 EHS RQ.
SARA 311/312 Hazards	No known SARA hazards
SARA Title III	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.
California Proposition 65	Not listed for this form
Massachusetts, New Jersey and Pennsylvania RTK	None
Canada WHMIS	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.
