SAFETY DATA SHEET

Bezlotoxumab Formulation

Version 1.10  Revision Date: 25.09.2020  SDS Number: 818321-00011  Date of last issue: 16.09.2020

Date of first issue: 22.07.2016

1. PRODUCT AND COMPANY IDENTIFICATION

Product name: Bezlotoxumab Formulation

Manufacturer or supplier’s details
Company: MSD
Address: Briahnager - Off Pune Nagar Road
Wagholi - Pune - India 412 207
Telephone: +1-908-740-4000
Emergency telephone number: +1-908-423-6000
E-mail address: EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use
Recommended use: Pharmaceutical

2. HAZARDS IDENTIFICATION

Manufacture, Storage and Import of Hazardous Chemicals Rules 1989

Classification
Not classified as hazardous according to criteria laid down in Part I of Schedule-1.

GHS Classification
Not a hazardous substance or mixture.

GHS label elements
Not a hazardous substance or mixture.

Other hazards which do not result in classification
None known.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture: Mixture

Components

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bezlotoxumab</td>
<td>1246264-45-8</td>
<td>&gt;= 1 - &lt; 5</td>
</tr>
</tbody>
</table>

4. FIRST AID MEASURES

If inhaled: If inhaled, remove to fresh air. Get medical attention if symptoms occur.
In case of skin contact: Wash with water and soap as a precaution. Get medical attention if symptoms occur.
In case of eye contact: Flush eyes with water as a precaution.
Get medical attention if irritation develops and persists.
If swallowed:
  If swallowed, DO NOT induce vomiting.
  Get medical attention if symptoms occur.
  Rinse mouth thoroughly with water.
Most important symptoms and effects, both acute and delayed:
  None known.
Protection of first-aiders:
  No special precautions are necessary for first aid responders.
Notes to physician:
  Treat symptomatically and supportively.

5. FIREFIGHTING MEASURES

Suitable extinguishing media:
  Water spray
  Alcohol-resistant foam
  Carbon dioxide (CO2)
  Dry chemical

Unsuitable extinguishing media:
  None known.

Specific hazards during firefighting:
  Exposure to combustion products may be a hazard to health.

Hazardous combustion products:
  Carbon oxides

Specific extinguishing methods:
  Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
  Use water spray to cool unopened containers.
  Remove undamaged containers from fire area if it is safe to do so.
  Evacuate area.

Special protective equipment for firefighters:
  Wear self-contained breathing apparatus for firefighting if necessary.
  Use personal protective equipment.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures:
  Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

Environmental precautions:
  Avoid release to the environment.
  Prevent further leakage or spillage if safe to do so.
  Prevent spreading over a wide area (e.g. by containment or oil barriers).
  Retain and dispose of contaminated wash water.
  Local authorities should be advised if significant spillages cannot be contained.

Methods and materials for containment and cleaning up:
  Soak up with inert absorbent material.
  For large spills, provide dyking or other appropriate containment to keep material from spreading. If dyked material can be pumped, store recovered material in appropriate container.
  Clean up remaining materials from spill with suitable absorbent.
  Local or national regulations may apply to releases and disposal of this material, as well as those materials and items
employed in the cleanup of releases. You will need to determine which regulations are applicable.
Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

7. HANDLING AND STORAGE

Technical measures: See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.
Local/Total ventilation: Use only with adequate ventilation.
Advice on safe handling: Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment.
Take care to prevent spills, waste and minimize release to the environment.
Conditions for safe storage: Keep in properly labelled containers.
Store in accordance with the particular national regulations.
Materials to avoid: Do not store with the following product types:
Strong oxidizing agents

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bezlotoxumab</td>
<td>1246264-45-8</td>
<td>TWA</td>
<td>2 mg/m³ (OEB 1)</td>
<td>Internal</td>
</tr>
</tbody>
</table>

Engineering measures: Use appropriate engineering controls and manufacturing technologies to control airborne concentrations (e.g., drip-less quick connections).
All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.
Laboratory operations do not require special containment.

Personal protective equipment

Respiratory protection: If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.
Filter type: Particulates type
Hand protection Material: Chemical-resistant gloves
Eye protection: Wear safety glasses with side shields or goggles.
If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles.
Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.
Skin and body protection: Work uniform or laboratory coat.
Hygiene measures: If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. Wash contaminated clothing before re-use. The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance: Aqueous solution
Colour: Colorless to pale yellow
Odour: No data available
Odour Threshold: No data available
pH: 5.7 - 6.3
Melting point/freezing point: No data available
Initial boiling point and boiling range: No data available
Flash point: No data available
Evaporation rate: No data available
Flammability (solid, gas): Not applicable
Flammability (liquids): No data available
Upper explosion limit / Upper flammability limit: No data available
Lower explosion limit / Lower flammability limit: No data available
Vapour pressure: No data available
Relative vapour density: No data available
Relative density: No data available
Density: 1.0146 g/cm³
Solubility(ies)
  Water solubility: No data available
Partition coefficient: n-octanol/water: Not applicable
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Auto-ignition temperature : No data available
Decomposition temperature : No data available

Viscosity
Viscosity, dynamic : 1.2 mPa.s (25 °C)
Viscosity, kinematic : 1.833 mm²/s (4 °C)
1.183 mm²/s (25 °C)

Explosive properties : Not explosive

Oxidizing properties : The substance or mixture is not classified as oxidizing.
Molecular weight : No data available
Particle size : Not applicable

10. STABILITY AND REACTIVITY

Reactivity : Not classified as a reactivity hazard.
Chemical stability : Stable under normal conditions.
Possibility of hazardous reactions : Can react with strong oxidizing agents.
Conditions to avoid : None known.
Incompatible materials : Oxidizing agents
Hazardous decomposition products : No hazardous decomposition products are known.

11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure
Inhalation
Skin contact
Ingestion
Eye contact

Acute toxicity
Not classified based on available information.

Components:
Bezlotoxumab:
Acute toxicity (other routes of administration) : LD50 (Mouse): > 125 mg/kg
Application Route: Intravenous Remarks: No adverse effect has been observed in acute toxicity tests.

Skin corrosion/irritation
Not classified based on available information.

Serious eye damage/eye irritation
Not classified based on available information.
Respiratory or skin sensitisation

Skin sensitisation
Not classified based on available information.

Respiratory sensitisation
Not classified based on available information.

Germ cell mutagenicity
Not classified based on available information.

Carcinogenicity
Not classified based on available information.

Reproductive toxicity
Not classified based on available information.

STOT - single exposure
Not classified based on available information.

STOT - repeated exposure
Not classified based on available information.

Repeated dose toxicity

Components:
Bezloixoab:
Species: Mouse
NOAEL: 50 mg/kg
Application Route: Intravenous
Exposure time: 15 d
Remarks: No significant adverse effects were reported

Species: Mouse
NOAEL: 125 mg/kg
Application Route: Intravenous
Exposure time: 21 d
Remarks: No significant adverse effects were reported

Aspiration toxicity
Not classified based on available information.

Experience with human exposure

Components:
Bezloixoab:
Inhalation: Symptoms: Nausea, Headache, Diarrhoea, Fever

12. ECOLOGICAL INFORMATION

Ecotoxicity
No data available

Persistence and degradability
No data available
Bioaccumulative potential
No data available

Mobility in soil
No data available

Other adverse effects
No data available

13. DISPOSAL CONSIDERATIONS

Disposal methods
Waste from residues: Dispose of in accordance with local regulations.
Contaminated packaging: Empty containers should be taken to an approved waste handling site for recycling or disposal.
If not otherwise specified: Dispose of as unused product.

14. TRANSPORT INFORMATION

International Regulations

UNRTDG
Not regulated as a dangerous good

IATA-DGR
Not regulated as a dangerous good

IMDG-Code
Not regulated as a dangerous good

Transport in bulk according to IMO instruments
Not applicable for product as supplied.

15. REGULATORY INFORMATION

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

The components of this product are reported in the following inventories:
AICS: not determined
DSL: not determined
IECSC: not determined

16. OTHER INFORMATION

Further information

Date format: dd.mm.yyyy
The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user’s end product, if applicable.

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