
MATERIAL SAFETY DATA SHEET

1. Product Identification:

Kaimax classic Injection 100U (Clostridium Botulinum Toxin Type A)

Manufacturer: JETEMA, Co., Ltd. 321, Joecom-ro, Jijeong-myeon, Wonju-si, Gangwon-do, Republic of Korea

2. Composition/ Hazardous Ingredients:

Chemical Name	Botulinum Toxin Type A
CAS #	93384-43-1
Content	<0.002% wt

3. Hazards Identification:

The product is safe when handled as described per the product package insert information. Regulatory agencies, NTP and IARC do not list this product or its ingredients as carcinogens.

Hazard Classification (GHS)	Target Organ Systemic Toxicant – Category 2
Signal Word and Hazard Statements (GHS)	Warning – Ingestion may cause nervous system effects including difficulty in swallowing and breathing.



4. Exposure Limits in Air:

None established.

5. Emergency First Aid Procedures:

For eye contact, immediately flush the eyes with water for 5-10 minutes. Consult a physician immediately. For skin contact, wash the skin with soap and water. Launder clothing before reuse. For ingestion, consult a physician immediately and induce vomiting or aspirate stomach contents as soon as possible in a hospital emergency room.

6. Fire Fighting Measures:

The material is non-flammable. There are no known unusual fire or explosion hazards.

7. Accidental Release Measures:

During normal patient use, any spilled material should be wiped up and the waste disposed of as medical waste. For large quantity releases, such as at manufacturing or distribution centers, contain the spill and neutralize all contaminated services and equipment using either exposure to sodium hypochlorite or autoclaving. Sodium hypochlorite in concentrations of 0.5% or greater (equivalent to a 1:10 dilution of household bleach) may be used to bathe all surfaces exposed to botulinum toxin for a period of five minutes. Following this, the product is rendered safe and the materials may be disposed through standard methods. For spills onto surface areas, the contaminated surface should be thoroughly sprayed or rinsed for five minutes with a 0.5% sodium hypochlorite solution, then wiped dry. Autoclaving may be applied to botulinum toxin contaminated material which is in solution or to which the autoclave steam has access. Autoclaving at 121°C for 30 minutes or greater will render the product safe.

8. Handling and Storage:

See the product information described on the package insert for proper information on handling and storage. Do not store with food.

9. Exposure Control and Personal Protection:

There are no engineering controls or respiratory protection required for regular handling of individual vials. Wash hands thoroughly after handling. No eating, drinking or smoking in or around the use area.

10. Physical and Chemical Properties:

The product is soluble in water. The specific gravity of the product is approximately 1.1. There is no data for this product concerning vapor pressure. The product appears as a residue inside the vial. There is no odor with the product. See below for details.

Information on basic physical and chemical properties

<u>Physical state</u>	<u>Solid</u>	<u>Appearance</u>	<u>Dehydrated product Contained in a Vial</u>
<u>Color</u>	<u>White</u>	<u>Odor</u>	<u>No information available</u>
<u>Odor threshold</u>	<u>No information available</u>		
<u>Property</u>		<u>Values</u>	
<u>pH</u>		No information available	
<u>Melting point/freezing point</u>		No information available	
<u>Boiling point / boiling range</u>		No information available	
<u>Flash point</u>		No information available	
<u>Evaporation rate</u>		No information available	
<u>Flammability (solid, gas)</u>		No information available	
<u>Flammability Limit in Air</u>			
- <u>Upper flammability limit:</u>		No information available	
- <u>Lower flammability limit:</u>		No information available	
<u>Vapor pressure</u>		No information available	
<u>Vapor density</u>		No information available	
<u>Specific Gravity</u>		No information available	
<u>Water solubility</u>		No information available	
<u>Solubility in other solvents</u>		No information available	
<u>Partition coefficient</u>		No information available	
<u>Autoignition temperature</u>		No information available	
<u>Decomposition temperature</u>		No information available	
<u>Explosive properties</u>		No information available	
<u>Oxidizing properties</u>		No information available	
<u>Other Information</u>			
<u>Molecular weight</u>		No information available	
<u>VOC Content (%)</u>		No information available	
<u>Density</u>		No information available	
<u>Bulk density</u>		No information available	

11. Stability and Reactivity:

Stability and biological activity of the product is influenced by factors such as heat, salts, acids, bases, organic

solvents, physical and/or chemical environments, photooxidation, and irradiation. The product does not polymerize and there are no materials to avoid, which could result in a reaction.

12. Toxicological Information:

Based on toxicological studies, it has been estimated that the human LD₅₀ by injection is approximately 2800 Units for a 70kg adult. It should be administered to pregnant women only if clearly needed and only if the potential benefit justifies the potential risk to the fetus.

13. Ecological Information:

There is no information available for the product.

14. Disposal Considerations:

All vials, including expired vials, and equipment or materials used with the drug should be disposed of carefully as is done with all medical waste. For disposal of multiple vials, contact JETEMA for further information.

15. Transport Information:

UN TDG : Not dangerous goods

IATA : Not dangerous goods

IMDG : Not dangerous goods

Special precautions

- Fire EmS Guide : F-A (Recommendation)

- Spillage EmS Guide : Not dangerous goods

16. Other Information:

The preceding information is based on available data and is believed to be correct. However, no warranty is expressed or to be implied regarding the accuracy of this information, the results to be obtained from the use thereof or the hazards connected with the use of the material. Since the information contained herein may be applied under conditions beyond our control and with which we may be unfamiliar, JETEMA does not assume any responsibility for the results of its use.