

**MATERIAL SAFETY DATA SHEET****CNT52120 – 125 u**Prepared: November 2009  
Supersedes: 09/01Revision: 09/02  
Version : 0**SECTION 1 – PRODUCT & COMPANY IDENTIFICATION****Ipsen Limited**  
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**SECTION 2 – PRODUCT COMPOSITION**

**Active Component:** Clostridium botulinum Type A toxin – 125 units per vial  
**Other Components:**  
Common Name: Lactose  
Common Name: Human Serum Albumin

**SECTION 3 – HEALTH HAZARDS IDENTIFICATION**

**Skin Contact:** Absorption through cuts abrasions and needle – stick injuries may cause temporary local paralysis, respiratory and pulmonary paralysis may occur.

**Eye Contact:** May cause local paralysis.

**Inhalation:** Inhalation if aerosol may cause respiratory / pulmonary failure

**Ingestion:** No toxic effects expected at therapeutic concentrations.

**SECTION 4 – FIRST AID MEASURES**

**Skin Contact:** Remove contaminated clothing. Wash affected area with copious amount of water, seek medical attention, depending on quantity individuals are exposed to.

**Eye Contact:** Wash eyes with large amounts of water or normal saline for fifteen minutes. Seek medical attention depending on quantity individuals are exposed to.

**Inhalation:** Remove to fresh air. Seek medical attention, depending on quantity individuals are exposed to.

**Ingestion:** Wash out mouth with water, do not swallow washings. Repeat several times. Seek medical attention depending on quantity individuals are exposed to.

## SECTION 5 – FIRE FIGHTING MEASURES

<b>Extinguishing Media:</b>	Use extinguishing media appropriate to surrounding fire conditions.
<b>Flash Point:</b>	Not determined.
<b>Special Hazards:</b>	As for surrounding materials. Heat will neutralise toxin.
<b>Special Fire Fighting Procedures:</b>	Self-contained breathing apparatus, protective clothing.

## SECTION 6 – ACCIDENTAL RELEASE MEASURES

<b>Personal Precautions:</b>	Isolate spill area. Wear suitable eye protection and chemically compatible gloves during spill clean-up and isolate spill area.
<b>Spill:</b>	Place paper towels or other absorbent material over the spill. Pour on a neutralising solution consisting of 10 % v/v of sodium hypochlorite solution and allow to stand for at least 20 minutes. Place spillage material in an appropriate container labelled for waste disposal. Wash spill site. The inactivated material must be disposed of in accordance with local procedures and regulations. The product may also be inactivated by autoclaving. Minimum conditions, 121°C for 15 minutes.
<b>Occupational Exposure Limit (OEL):</b>	Not established.

## SECTION 7 – HANDLING & STORAGE

<b>Handling:</b>	Avoid contact with eyes, skin and clothing. Do not ingest or inhale. Wash hands after use.
<b>Storage:</b>	Product should be stored in a refrigerator between 2 – 8 °C. Reconstituted product may be stored in these conditions for up to 8 hours. However, as the product does not contain an anti-microbial agent, it is recommended that it is used immediately. The product must not be frozen. Protect against physical damage.
<b>Shelf-life</b>	The product has a shelf-life of 24 months providing it is stored at optimum conditions.

## SECTION 8 – EXPOSURE CONTROLS

A COSHH (Control of Substances Hazardous to Health) assessment should be undertaken prior to use to assess the risk of exposure during use.

<b>Respiratory Protection:</b>	Respiratory protection should not be required under normal handling of this product
<b>Skin Protection:</b>	Gloves should be worn. Risk of needle stick injuries should be minimised. Avoid contact with broken skin.
<b>Eye Protection:</b>	Suitable eye protection should be worn if there is a risk of contact.

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**SECTION 9 – PHYSICAL & CHEMICAL PROPERTIES**

<b>Appearance:</b>	Clear glass vial containing a white to off-white lyophilised powder plug for reconstitution.		
<b>Odour:</b>	Odourless.	<b>pH:</b>	5.5 – 6.2
<b>Melting Point:</b>	Not determined	<b>Water Solubility</b>	Soluble

**SECTION 10 – STABILITY AND REACTIVITY**

<b>Incompatibility:</b>	Not determined
<b>Stability:</b>	Stable at specified storage temperature
<b>Conditions to avoid:</b>	This product is heat liable so elevated temperatures or temperature extremes should be avoided. Avoid oxidisers and pH extremes.
<b>Hazardous decomposition products:</b>	Carbon monoxide, carbon dioxide

**SECTION 11 – TOXICOLOGICAL INFORMATION**

Teratological and other reproductive studies have not been performed with this product. The safety of its use in pregnant or lactating women has not been demonstrated. There are no known cases of it effecting people driving or operating machinery.

Product contains material of human origin (albumin) prepared from source material found non-reactive for hepatitis B Surface Antigen and antibodies to HIV-1, HIV-2, and HVC.

This product could cause paralysis, respiratory and pulmonary failure if incorrect dosing is used.

**SECTION 12 – ECOLOGICAL INFORMATION**

Do not release into surface water.

**SECTION 13 – DISPOSAL CONSIDERATIONS**

Dispose of product in accordance with local and national regulations.

**SECTION 14 – TRANSPORT INFORMATION**

Unclassified: Medicinal product - Not regulated as a hazardous material.

**SECTION 15 – REGULATORY INFORMATION**

None applicable.

**SECTION 16 – OTHER**

All information presented above is believed to be correct, but does not purport to be all inclusive and should only be used as a guide. Ipsen Limited shall not be held liable for any damage resulting from the inappropriate handling of and exposure to this product.