

Issuing Date: 12-Dec-2016

Revision Date: 22-Apr-2022

**1. Identification****Product identifier**

SDS Number: 1277739  
Product Name: Osmitrol

**Other means of identification**

Product Code(s): AHB3026 and AHB3025

Synonyms: 10% Osmitrol® Intravenous Infusion (Mannitol Intravenous Infusion BP)  
20% Osmitrol® Intravenous Infusion (Mannitol Intravenous Infusion BP)

**Recommended use of the chemical and restrictions on use**

Product Use: Pharmaceutical.  
Product Type: Injectable solution  
Uses advised against: No information available

**Details of the supplier of the safety data sheet**

BAXTER HEALTHCARE  
33 Vestey Drive  
Mt Wellington Auckland, 1060 New Zealand  
Telephone: (09) 574 2400

**Emergency telephone number**

New Zealand: 0800 229 837 and Poison Information Centre 0800 764 766  
Verisk 3E Global Incident Response Hotline +1 760 476 3962; Access Code 335625

**2. Hazard(s) identification****GHS Classification**

Not a hazardous substance or mixture according to the Globally Harmonized System (GHS)

**Label elements****Hazard statements****Other hazards which do not result in classification**

No information available

**3. Composition/information on ingredients**

Chemical Name	CAS No.	Weight-%
Mannitol 69-65-8	69-65-8	10-20
Water 7732-18-5	7732-18-5	>80

## 4. First-aid measures

### Description of first aid measures

<b>General Advice</b>	Treat symptomatically and supportively.
<b>Inhalation:</b>	If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention if symptoms occur.
<b>Eye contact:</b>	In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. Get medical attention if irritation develops.
<b>Skin contact:</b>	Wash contaminated skin with soap and water. Get medical attention if irritation develops.
<b>Ingestion:</b>	Do NOT induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person. If large quantities of this material are swallowed, call a physician immediately.

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

No information available

### Indication of any immediate medical attention and special treatment needed

Treat symptomatically. See patient package insert in shipping carton for complete information.

## 5. Fire-fighting measures

### Suitable Extinguishing Media

Use extinguishing media suitable for surrounding materials.

### Specific hazards arising from the chemical

No information available

### Special protective actions for fire-fighters

Fire fighters should wear positive pressure self-contained breathing apparatus (SCBA) and full turnout gear.

## 6. Accidental release measures

### Personal precautions, protective equipment and emergency procedures

Use suitable protective equipment (Section 8). Follow all fire fighting procedures (Section 5).

### Environmental precautions

See Section 12 for environmental precautions.

### Methods and material for containment and cleaning up

#### **Methods for Containment:**

If emergency personnel are unavailable, contain spilled material.

#### **Methods for cleaning up:**

For small spills add absorbent (soil may be used in the absence of other suitable materials) scoop up material and place in a sealed, liquid-proof container for disposal. For large spills dike spilled material or otherwise contain material to ensure runoff does not reach a waterway. Place spilled material in an appropriate container for disposal.

### Precautions to prevent secondary hazards

**Prevention of secondary hazards** Clean contaminated objects and areas thoroughly observing environmental regulations.

## 7. Handling and storage

**Precautions for safe handling**

**Technical measures/precautions:** Wash thoroughly after handling.

**Conditions for safe storage, including any incompatibilities**

**Technical measures and storage conditions:** Keep containers tightly closed in a cool, well-ventilated place. Store below 30°C (86°F). Avoid excessive heat.

**Incompatible materials:** No information available

## 8. Exposure controls/personal protection

**Control parameters**

**Exposure Limits** This product, as supplied, does not contain any hazardous materials with occupational exposure limits established by the region specific regulatory bodies.

Chemical Name	New Zealand TWA	ACGIH TLV	Uk oes/mel:	Australia_nohsc :
Mannitol - 69-65-8	-	-	-	-
Water - 7732-18-5	-	-	-	-

**Biological occupational exposure limits** This product, as supplied, does not contain any hazardous materials with biological limits established by the region specific regulatory bodies.

Chemical Name	New Zealand	ACGIH
Mannitol - 69-65-8	-	-
Water - 7732-18-5	-	-

**Appropriate engineering controls**

**Engineering Measures** No special containment is required.

**Individual protection measures, such as personal protective equipment**

**Eye/face protection** No special protective equipment required

**Hand protection** Use chemical resistant, impervious gloves.

**Skin and body protection** Work uniform or laboratory coat.

**Respiratory protection** No personal respiratory protective equipment normally required.

**Environmental exposure controls** No information available.

## 9. Physical and chemical properties

**Information on basic physical and chemical properties**

**Physical state:** Liquid  
**Appearance:** Aqueous solution.  
**Color:** No information available  
**Odor:** No information available  
**Odor Threshold:** No information available  
**pH:** 4.5-7.0

<b>Melting point / melting range:</b>	No information available
<b>Boiling point / boiling range:</b>	No information available
<b>Flash point:</b>	No information available
<b>Evaporation rate:</b>	No information available
<b>Flammability (solid, gas):</b>	No information available
<b>Flammable limits in air-upper (%):</b>	No information available
<b>Flammable limits in air-lower (%):</b>	No information available
<b>Vapor pressure:</b>	No information available
<b>Vapor density</b>	No information available
<b>Density:</b>	No information available
<b>Solubility:</b>	Soluble in water.
<b>Partition coefficient (n-octanol/water):</b>	No information available
<b>Autoignition temperature:</b>	No information available
<b>Decomposition temperature</b>	No information available
<b>Viscosity:</b>	No information available
<b>Explosive Properties:</b>	No information available
<b>Oxidizing Properties:</b>	No information available

**Other information****10. Stability and reactivity****Reactivity**

No information available.

**Chemical stability**

Stable under recommended storage conditions

**Specific methods:**

<b>Sensitivity to mechanical impact</b>	None.
<b>Sensitivity to static discharge</b>	None.

**Possibility of hazardous reactions**

None under normal use conditions

**Conditions to Avoid**

Do not freeze. Avoid excessive heat.

**Incompatible materials**

No data available

**Hazardous decomposition products**

No data available

**11. Toxicological information****Acute toxicity****Information on likely routes of exposure****Product Information**

<b>Inhalation:</b>	Inhalation not likely under normal use conditions.
<b>Eye contact:</b>	Not expected to cause eye irritation.

**Skin contact:** Not expected to cause skin irritation.

**Ingestion:** Hypersensitivity (may include drug fever, rash, itching, anaphylaxis). Nervous system effects (may include drowsiness, confusion, hallucinations, convulsions, visual disturbances, headache, coma). Fluid imbalances (may include water loss, electrolyte imbalances, dehydration).

**Symptoms:** No information available

### Acute Toxicity

#### Numerical measures of toxicity

The following values are calculated based on chapter 3.1 of the GHS document

ATEmix (oral) 67,500.00 mg/kg

#### Component Information

Chemical Name	Oral LD50	Dermal LD50	Inhalation LC50
Mannitol 69-65-8	= 13500 mg/kg ( Rat )	-	-
Water 7732-18-5	> 90 mL/kg ( Rat )	-	-

See section 16 for terms and abbreviations

#### Delayed and immediate effects as well as chronic effects from short and long-term exposure

**Corrosivity:** Not classified.

**Irritation:** Not classified.

**Sensitization:** Not classified.

**Mutagenic effects:** Not classified.

**Carcinogenic effects:** Not classified.

Chemical Name	New Zealand	IARC
Mannitol - 69-65-8	-	-
Water - 7732-18-5	-	-

**Reproductive toxicity:** No data is available on the product itself.

**STOT - single exposure:** Not classified.  
**Respiratory irritation** Not classified.  
**Narcotic effects** Not classified.

**STOT - repeated exposure:** Not classified.

**Aspiration hazard:** Not classified.

## 12. Ecological information

### Ecotoxicity

No information available

### Aquatic ecotoxicity

**Unknown aquatic toxicity** 0 % of the mixture consists of component(s) of unknown hazards to the aquatic

environment.

Chemical Name	Algae/aquatic plants	Fish	Crustacea
Mannitol 69-65-8	-	-	-
Water 7732-18-5	-	-	-

#### **Terrestrial ecotoxicity**

Chemical Name	Earthworm	Avian	Honeybees
Mannitol 69-65-8	-	-	-
Water 7732-18-5	-	-	-

#### **Persistence and Degradability**

No information available.

#### **Bioaccumulative potential**

No information available.

Chemical Name	Partition coefficient
Mannitol 69-65-8	-
Water 7732-18-5	-

#### **Mobility in soil**

No information available

#### **Other adverse effects**

This product does not contain any known or suspected endocrine disruptors.

Chemical Name	EU - Endocrine Disruptors Candidate List	EU - Endocrine Disruptors - Evaluated Substances	Endocrine disrupting potential
Mannitol 69-65-8	-	-	-
Water 7732-18-5	-	-	-

### **13. Disposal considerations**

#### **Waste treatment methods**

**Waste from residues/unused products**

In accordance with local and national regulations

**Contaminated Packaging**

In accordance with local and national regulations

### **14. Transport information**

**IATA**

Not regulated

**IMDG**

Not regulated

## 15. Regulatory information

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

#### New Zealand

##### **National regulations**

See Section 8 for any applicable tolerable exposure limits and environmental exposure limits

##### **Certified handlers, tracking and controlled substance licence requirements**

Certified handlers are required for some substances. This includes for substances requiring a controlled substance licence, including Class 1 explosives, vertebrate toxic agents (9.3A, B, C), and certain fumigants. Class 6.1A and 6.1B substances such as pesticides also require Certified handlers. Please check the Health and Safety at Work Act 2015 for further information.

Tracking is required for some highly hazardous substances. These substances need to be under the control of an appropriately trained person or appropriately secured. Please check the Health and Safety at Work Act 2015 for further information.

Controlled substance licences are required to possess certain class 1 (explosive) and class 6 (vertebrate toxic agents or fumigants) substances. See Part 7 of the Health and Safety at Work Regulation 2017 for more information.

#### International Inventories

<b>NZIOC</b>	Complies
<b>TSCA</b>	Does not comply
<b>DSL/NDSL</b>	Does not comply
<b>EINECS/ELINCS</b>	Does not comply
<b>ENCS</b>	Does not comply
<b>IECSC</b>	Does not comply
<b>KECL</b>	Does not comply
<b>PICCS</b>	Does not comply
<b>AICS</b>	Does not comply

**NZIOC** - New Zealand Inventory of Chemicals and Chemical Substances

**TSCA** - United States Toxic Substances Control Act Section 8(b) Inventory

**DSL/NDSL** - Canadian Domestic Substances List/Non-Domestic Substances List

**EINECS/ELINCS** - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances

**ENCS** - Japan Existing and New Chemical Substances

**IECSC** - China Inventory of Existing Chemical Substances

**KECL** - Korean Existing and Evaluated Chemical Substances

**PICCS** - Philippines Inventory of Chemicals and Chemical Substances

**AICS** - Australian Inventory of Chemical Substances

#### International Regulations

**The Montreal Protocol on Substances that Deplete the Ozone Layer** Not applicable

**The Stockholm Convention on Persistent Organic Pollutants** Not applicable

**The Rotterdam Convention** Not applicable

## 16. Other information

**Prepared by:** Baxter Research & Development  
**Issuing Date:** 12-Dec-2016  
**Revision Date:** 22-Apr-2022

**Revision Note:**

---

None

**Key or legend to abbreviations and acronyms**Legend Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

TWA	TWA (time-weighted average)
STEL	STEL (Short Term Exposure Limit)
Ceiling	Maximum limit value
*	Skin designation
C	Carcinogen

**Key literature references and sources for data used to compile the SDS**

Agency for Toxic Substances and Disease Registry (ATSDR)  
U.S. Environmental Protection Agency ChemView Database  
European Food Safety Authority (EFSA)  
EPA (Environmental Protection Agency)  
Acute Exposure Guideline Level(s) (AEGl(s))  
U.S. Environmental Protection Agency Federal Insecticide, Fungicide, and Rodenticide Act  
U.S. Environmental Protection Agency High Production Volume Chemicals  
Food Research Journal  
Hazardous Substance Database  
International Uniform Chemical Information Database (IUCLID)  
Japan GHS Classification  
Australia National Industrial Chemicals Notification and Assessment Scheme (NICNAS)  
NIOSH (National Institute for Occupational Safety and Health)  
National Library of Medicine's ChemID Plus (NLM CIP)  
National Library of Medicine's PubMed database (NLM PUBMED)  
National Toxicology Program (NTP)  
New Zealand's Chemical Classification and Information Database (CCID)  
Organization for Economic Co-operation and Development Environment, Health, and Safety Publications  
Organization for Economic Co-operation and Development High Production Volume Chemicals Program  
Organization for Economic Co-operation and Development Screening Information Data Set  
RTECS (Registry of Toxic Effects of Chemical Substances)  
World Health Organization

**Disclaimer**

To the best of our knowledge, the information contained herein is accurate. However, neither the above named supplier nor any of its subsidiaries assumes any liability whatsoever for the accuracy or completeness of the information contained herein. Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.

**End of Safety Data Sheet**