

# SAFETY DATA SHEET

# hikma.

**Dantrolene Sodium for Injection USP, 20 mg per vial**

## Section 1. Identification

<b>GHS product identifier</b>	: Dantrolene Sodium for Injection USP, 20 mg per vial
<b>Product code</b>	: Not available.
<b>Other means of identification</b>	: Not available.
<b>Product type</b>	: Lyophilized powder.
<b>Container information</b>	: 100 mL vial.

### Relevant identified uses of the substance or mixture and uses advised against

<b>Identified uses</b>	: Dantrolene Sodium for Injection is indicated for the management of the fulminant hypermetabolism of skeletal muscle characteristic of malignant hyperthermia crises in patients of all ages. Dantrolene Sodium for Injection is also indicated preoperatively, and sometimes postoperatively, to prevent or attenuate the development of clinical and laboratory signs of malignant hyperthermia in individuals judged to be malignant hyperthermia susceptible.
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<b>Manufacturer</b>	: Hikma Farmacêutica (Portugal) S.A Estrada do Rio da Mó, 8, 8A e 8B – Fervença, Portugal Tel: + 351 21 960 84 10 Fax: +351 21 961 51 02 Email: agageiro@hikma.com
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<b>Supplier's details</b>	: Hikma Pharmaceuticals USA Inc. 246 Industrial Way West Eatontown, New Jersey (NJ) 07724
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<b>Emergency telephone number (with hours of operation)</b>	: CHEMTREC, U.S.: 1-800-424-9300    International: +1-703-527-3887 24/7
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## Section 2. Hazards identification

<b>OSHA/HCS status</b>	: This material is considered hazardous by the OSHA Hazard Communication Standard (29 CFR 1910.1200).
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<b>Classification of the substance or mixture</b>	: ACUTE TOXICITY (oral) - Category 4
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### GHS label elements

<b>Hazard pictograms</b>	: 
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<b>Signal word</b>	: Warning
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<b>Hazard statements</b>	: H302 - Harmful if swallowed.
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**This is a pharmaceutical product designed to be prescribed by a licensed health care professional. Should any person while using this product observe any adverse health effects, they should seek medical treatment.**

### Precautionary statements

## Section 2. Hazards identification

- Prevention** : P270 - Do not eat, drink or smoke when using this product.  
P264 - Wash hands thoroughly after handling.
- Response** : P301 + P312 + P330 - IF SWALLOWED: Call a POISON CENTER or physician if you feel unwell. Rinse mouth.
- Storage** : Not applicable.
- Disposal** : P501 - Dispose of contents and container in accordance with all local, regional, national and international regulations.

**Hazards not otherwise classified** : None known.

## Section 3. Composition/information on ingredients

- Substance/mixture** : Mixture
- Other means of identification** : Not available.

Ingredient name	%	CAS number
Dantrolene Sodium Hemiheptahydrate	80 - 100	24868-20-0

Active pharmaceutical ingredient	%	CAS number
Dantrolene Sodium Hemiheptahydrate	80 - 100	24868-20-0

The exact percentage (concentration) in the composition has been withheld as a trade secret in accordance with paragraph (i) of §1910.1200.

There are no additional ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified as hazardous to health or the environment and hence require reporting in this section.

Occupational exposure limits, if available, are listed in Section 8.

See Package Insert for further information.

## Section 4. First aid measures

### Description of necessary first aid measures

- Eye contact** : Immediately flush eyes with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses. Continue to rinse for at least 20 minutes. Get medical attention if irritation occurs.
- Inhalation** : Remove victim to fresh air and keep at rest in a position comfortable for breathing. If not breathing, if breathing is irregular or if respiratory arrest occurs, provide artificial respiration or oxygen by trained personnel. It may be dangerous to the person providing aid to give mouth-to-mouth resuscitation. Get medical attention if adverse health effects persist or are severe. If unconscious, place in recovery position and get medical attention immediately. Maintain an open airway. Loosen tight clothing such as a collar, tie, belt or waistband. In case of inhalation of decomposition products in a fire, symptoms may be delayed. The exposed person may need to be kept under medical surveillance for 48 hours.
- Skin contact** : Flush contaminated skin with plenty of water. Get medical attention if symptoms occur. Wash clothing before reuse. Clean shoes thoroughly before reuse.
- Ingestion** : Wash out mouth with water. Remove dentures if any. Remove victim to fresh air and keep at rest in a position comfortable for breathing. If material has been swallowed and the exposed person is conscious, give small quantities of water to drink. Stop if the exposed person feels sick as vomiting may be dangerous. Do not induce vomiting unless directed to do so by medical personnel. If vomiting occurs, the head should be kept low so that vomit does not enter the lungs. Get medical attention. If necessary, call a poison center or physician. Never give anything by mouth to an unconscious

## Section 4. First aid measures

person. If unconscious, place in recovery position and get medical attention immediately. Maintain an open airway. Loosen tight clothing such as a collar, tie, belt or waistband.

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

#### Potential acute health effects

- Eye contact** : No known significant effects or critical hazards.
- Inhalation** : No known significant effects or critical hazards.
- Skin contact** : No known significant effects or critical hazards.
- Ingestion** : Harmful if swallowed.

#### Over-exposure signs/symptoms

- Eye contact** : No known significant effects or critical hazards.
- Inhalation** : No known significant effects or critical hazards.
- Skin contact** : No known significant effects or critical hazards.
- Ingestion** : No known significant effects or critical hazards.

### Indication of immediate medical attention and special treatment needed, if necessary

- Notes to physician** : In case of inhalation of decomposition products in a fire, symptoms may be delayed. The exposed person may need to be kept under medical surveillance for 48 hours.
- Specific treatments** : No specific treatment.
- Protection of first-aiders** : No action shall be taken involving any personal risk or without suitable training. It may be dangerous to the person providing aid to give mouth-to-mouth resuscitation.

See toxicological information (Section 11)

## Section 5. Fire-fighting measures

### Extinguishing media

- Suitable extinguishing media** : Use an extinguishing agent suitable for the surrounding fire.
- Unsuitable extinguishing media** : None known.

- Specific hazards arising from the chemical** : No specific fire or explosion hazard.

- Hazardous thermal decomposition products** : Decomposition products may include the following materials:  
carbon dioxide  
carbon monoxide  
nitrogen oxides

- Special protective actions for fire-fighters** : Promptly isolate the scene by removing all persons from the vicinity of the incident if there is a fire. No action shall be taken involving any personal risk or without suitable training.

- Special protective equipment for fire-fighters** : Fire-fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full face-piece operated in positive pressure mode.

## Section 6. Accidental release measures

### Personal precautions, protective equipment and emergency procedures

- For non-emergency personnel** : No action shall be taken involving any personal risk or without suitable training. Evacuate surrounding areas. Keep unnecessary and unprotected personnel from entering. Do not touch or walk through spilled material. Provide adequate ventilation. Wear appropriate respirator when ventilation is inadequate. Put on appropriate personal protective equipment.
- For emergency responders** : If specialized clothing is required to deal with the spillage, take note of any information in Section 8 on suitable and unsuitable materials. See also the information in "For non-emergency personnel".
- Environmental precautions** : Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers. Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air).

### Methods and materials for containment and cleaning up

- Spill** : Move containers from spill area. Approach release from upwind. Prevent entry into sewers, water courses, basements or confined areas. Avoid dust generation. Do not dry sweep. Vacuum dust with equipment fitted with a HEPA filter and place in a closed, labeled waste container. Dispose of via a licensed waste disposal contractor. Note: see Section 1 for emergency contact information and Section 13 for waste disposal.

## Section 7. Handling and storage

### Precautions for safe handling

- Protective measures** : Put on appropriate personal protective equipment (see Section 8). Do not ingest. Avoid contact with eyes, skin and clothing. Keep in the original container or an approved alternative made from a compatible material, kept tightly closed when not in use. Empty containers retain product residue and can be hazardous. Do not reuse container.
- Advice on general occupational hygiene** : Eating, drinking and smoking should be prohibited in areas where this material is handled, stored and processed. Workers should wash hands and face before eating, drinking and smoking. See also Section 8 for additional information on hygiene measures.
- Conditions for safe storage, including any incompatibilities** : Store in accordance with local regulations. Store in original container protected from direct sunlight in a dry, cool and well-ventilated area, away from incompatible materials (see Section 10) and food and drink. Keep container tightly closed and sealed until ready for use. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Do not store in unlabeled containers. Use appropriate containment to avoid environmental contamination. See Section 10 for incompatible materials before handling or use.

## Section 8. Exposure controls/personal protection

### Control parameters

#### Occupational exposure limits

Ingredient name	Exposure limits
Dantrolene Sodium Hemiheptahydrate	None.

- Appropriate engineering controls** : Good general ventilation should be sufficient to control worker exposure to airborne contaminants.
- Environmental exposure controls** : Emissions from ventilation or work process equipment should be checked to ensure they comply with the requirements of environmental protection legislation.

## Section 8. Exposure controls/personal protection

### Individual protection measures

- Hygiene measures** : Wash hands, forearms and face thoroughly after handling chemical products, before eating, smoking and using the lavatory and at the end of the working period. Appropriate techniques should be used to remove potentially contaminated clothing. Wash contaminated clothing before reusing. Ensure that eyewash stations and safety showers are close to the workstation location.
- Eye/face protection** : Safety eyewear complying with an approved standard should be used when a risk assessment indicates this is necessary to avoid exposure to liquid splashes, mists, gases or dusts. If contact is possible, the following protection should be worn, unless the assessment indicates a higher degree of protection: safety glasses with side-shields.
- Skin protection**
- Hand protection** : Chemical-resistant, impervious gloves complying with an approved standard should be worn at all times when handling chemical products if a risk assessment indicates this is necessary. Considering the parameters specified by the glove manufacturer, check during use that the gloves are still retaining their protective properties. It should be noted that the time to breakthrough for any glove material may be different for different glove manufacturers. In the case of mixtures, consisting of several substances, the protection time of the gloves cannot be accurately estimated.
- Body protection** : Personal protective equipment for the body should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.
- Other skin protection** : Appropriate footwear and any additional skin protection measures should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.
- Respiratory protection** : Based on the hazard and potential for exposure, select a respirator that meets the appropriate standard or certification. Respirators must be used according to a respiratory protection program to ensure proper fitting, training, and other important aspects of use.

## Section 9. Physical and chemical properties

### Appearance

- Physical state** : Solid. [Lyophilized powder.]
- Color** : Orange to yellowish.
- Odor** : Not available.
- Odor threshold** : Not available.
- pH** : 8.8 to 11 [Conc. (% w/w): 100%]
- Melting point** : Not available.
- Boiling point** : Not available.
- Flash point** : Not available.
- Evaporation rate** : Not available.
- Flammability (solid, gas)** : Not available.
- Lower and upper explosive (flammable) limits** : Not available.
- Vapor pressure** : Not available.
- Vapor density** : Not available.
- Relative density** : 1.02
- Solubility** : Not available.
- Partition coefficient: n-octanol/water** : Not available.

## Section 9. Physical and chemical properties

<b>Auto-ignition temperature</b>	: Not available.
<b>Decomposition temperature</b>	: Not available.
<b>Viscosity</b>	: Not available.
<b>Flow time (ISO 2431)</b>	: Not available.

## Section 10. Stability and reactivity

<b>Reactivity</b>	: No specific test data related to reactivity available for this product or its ingredients.
<b>Chemical stability</b>	: The product is stable.
<b>Possibility of hazardous reactions</b>	: Under normal conditions of storage and use, hazardous reactions will not occur.
<b>Conditions to avoid</b>	: No specific data.
<b>Incompatible materials</b>	: Reactive or incompatible with the following materials: oxidizing materials.
<b>Hazardous decomposition products</b>	: Under normal conditions of storage and use, hazardous decomposition products should not be produced.

## Section 11. Toxicological information

### Information on toxicological effects

#### Acute toxicity

There is no data available.

#### Irritation/Corrosion

There is no data available.

#### Sensitization

There is no data available.

#### Mutagenicity

There is no data available.

#### Carcinogenicity

There is no data available.

#### Reproductive toxicity

There is no data available.

#### Teratogenicity

There is no data available.

#### Specific target organ toxicity (single exposure)

There is no data available.

#### Specific target organ toxicity (repeated exposure)

There is no data available.

#### Aspiration hazard

There is no data available.

**Information on the likely routes of exposure** : Dermal contact. Eye contact. Inhalation. Ingestion.

#### Potential acute health effects

## Section 11. Toxicological information

Eye contact	: No known significant effects or critical hazards.
Inhalation	: No known significant effects or critical hazards.
Skin contact	: No known significant effects or critical hazards.
Ingestion	: Harmful if swallowed.

### Symptoms related to the physical, chemical and toxicological characteristics

Eye contact	: No known significant effects or critical hazards.
Inhalation	: No known significant effects or critical hazards.
Skin contact	: No known significant effects or critical hazards.
Ingestion	: No known significant effects or critical hazards.

### Delayed and immediate effects and also chronic effects from short and long term exposure

#### Short term exposure

Potential immediate effects	: No known significant effects or critical hazards.
Potential delayed effects	: No known significant effects or critical hazards.

#### Long term exposure

Potential immediate effects	: No known significant effects or critical hazards.
Potential delayed effects	: No known significant effects or critical hazards.

#### Potential chronic health effects

General	: No known significant effects or critical hazards.
Carcinogenicity	: No known significant effects or critical hazards.
Mutagenicity	: No known significant effects or critical hazards.
Teratogenicity	: No known significant effects or critical hazards.
Developmental effects	: No known significant effects or critical hazards.
Fertility effects	: No known significant effects or critical hazards.

### Numerical measures of toxicity

#### Acute toxicity estimates

Route	ATE value
Oral	996.5 mg/kg

## Section 12. Ecological information

### Toxicity

There is no data available.

### Persistence and degradability

There is no data available.

### Bioaccumulative potential

There is no data available.

### Mobility in soil

## Section 12. Ecological information

**Soil/water partition coefficient ( $K_{oc}$ )** : Not available.

**Other adverse effects** : No known significant effects or critical hazards.

## Section 13. Disposal considerations

**Disposal methods** : The generation of waste should be avoided or minimized wherever possible. Disposal of this product, solutions and any by-products should comply with the requirements of environmental protection and waste disposal legislation and any regional local authority requirements. Dispose of surplus and non-recyclable products via a licensed waste disposal contractor. Waste should not be disposed of untreated to the sewer unless fully compliant with the requirements of all authorities with jurisdiction. Waste packaging should be recycled. Incineration or landfill should only be considered when recycling is not feasible. This material and its container must be disposed of in a safe way. Care should be taken when handling empty containers that have not been cleaned or rinsed out. Empty containers or liners may retain some product residues. Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers.

## Section 14. Transport information

	DOT Classification	IMDG	IATA
UN number	Not regulated.	Not regulated.	Not regulated.
UN proper shipping name	-	-	-
Transport hazard class(es)	-	-	-
Packing group	-	-	-
Environmental hazards	No.	No.	No.

**AERG** : Not applicable

**Special precautions for user** : **Transport within user's premises:** always transport in closed containers that are upright and secure. Ensure that persons transporting the product know what to do in the event of an accident or spillage.

## Section 15. Regulatory information

Drug products are considered exempt from hazard communication labeling under the criteria of the Federal OSHA Hazard Communication Standard 29 CFR 1910.1200.

**FDA** : Dantrolene Sodium for Injection is an approved prescription medication.

**U.S. Federal regulations** : **United States inventory (TSCA 8b):** Not determined.

**Clean Air Act Section 112 (b) Hazardous Air Pollutants (HAPs)** : Not listed

**Clean Air Act Section 602 Class I Substances** : Not listed



## Section 15. Regulatory information

**Clean Air Act Section 602 Class II Substances** : Not listed

**DEA List I Chemicals (Precursor Chemicals)** : Not listed

**DEA List II Chemicals (Essential Chemicals)** : Not listed

### SARA 302/304

No products were found.

**SARA 304 RQ** : Not applicable.

### SARA 311/312

**Classification** : ACUTE TOXICITY (oral) - Category 4

### Composition/information on ingredients

Name	Classification
Dantrolene Sodium Hemiheptahydrate	ACUTE TOXICITY (oral) - Category 4

### SARA 313

There is no data available.

### State regulations

**Massachusetts** : None of the components are listed.

**New York** : None of the components are listed.

**New Jersey** : None of the components are listed.

**Pennsylvania** : None of the components are listed.

### California Prop. 65

California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins.

## Section 16. Other information

### Procedure used to derive the classification

Classification	Justification
ACUTE TOXICITY (oral) - Category 4	Calculation method

### History

**Date of issue mm/dd/yyyy** : 02/28/2019

**Date of previous issue** : Not applicable

**Version** : 1

**Prepared by** : KMK Regulatory Services Inc.

**Key to abbreviations** : ATE = Acute Toxicity Estimate  
BCF = Bioconcentration Factor  
GHS = Globally Harmonized System of Classification and Labelling of Chemicals  
IATA = International Air Transport Association  
IBC = Intermediate Bulk Container  
IMDG = International Maritime Dangerous Goods  
LogPow = logarithm of the octanol/water partition coefficient  
MARPOL = International Convention for the Prevention of Pollution From Ships, 1973 as modified by the Protocol of 1978. ("Marpol" = marine pollution)  
UN = United Nations

## **Section 16. Other information**

### **Notice to reader**

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.