



# MATERIAL SAFETY DATA SHEET

Revision date: 18-Feb-2010

Version: 1.0

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## 1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND THE COMPANY/UNDERTAKING

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### Material Name: Dantrolene Sodium Capsules

**Trade Name:** DANTRIUM  
**Chemical Family:** Not determined  
**Intended Use:** Pharmaceutical product skeletal muscle relaxant

## 2. HAZARDS IDENTIFICATION

**Appearance:** Orange, tan hard gelatin capsules

**Statement of Hazard:** Non-hazardous in accordance with international standards for workplace safety.

**Additional Hazard Information:**  
**Short Term:** May cause irritation (based on components)  
**Long Term:** Repeat-dose studies in animals have shown a potential to cause adverse effects on liver  
**Known Clinical Effects:** Ingestion of this material may cause effects similar to those seen in clinical use including muscle weakness dizziness drowsiness gastrointestinal disturbances respiratory depression liver effects and crystals in urine (crystalluria)

**EU Indication of danger:** Not classified

**Australian Hazard Classification (NOHSC):** Non-Hazardous Substance. Non-Dangerous Goods.

**Note:** This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the active substance or its intermediates regardless of the potential risk. The precautionary statements and warnings included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

## 3. COMPOSITION/INFORMATION ON INGREDIENTS

### Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	Classification	%
Starch	9005-25-8	232-679-6	Not Listed	*
Magnesium stearate	557-04-0	209-150-3	Not Listed	*

Ingredient	CAS Number	EU EINECS/ELINCS List	Classification	%
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Dantrolene sodium	14663-23-1	238-706-8	Not Listed	25 or 50 mg***
Talc (non-asbestiform)	14807-96-6	238-877-9	Not Listed	*
Hard gelatin capsules	MIXTURE	Not listed	Not Listed	*
Lactose	63-42-3	200-559-2	Not Listed	*

**Additional Information:** \* Proprietary  
\*\*\* per tablet/capsule/lozenge/suppository  
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

### 4. FIRST AID MEASURES

**Eye Contact:** Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.

**Skin Contact:** Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.

**Ingestion:** Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

**Inhalation:** Remove to fresh air and keep patient at rest. Seek medical attention immediately.

**Symptoms and Effects of Exposure:** For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.

### 5. FIRE FIGHTING MEASURES

**Extinguishing Media:** Use carbon dioxide, dry chemical, or water spray.

**Hazardous Combustion Products:** Formation of toxic gases is possible during heating or fire.

**Fire Fighting Procedures:** During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

**Fire / Explosion Hazards:** Fine particles (such as dust and mists) may fuel fires/explosions.

### 6. ACCIDENTAL RELEASE MEASURES

**Health and Safety Precautions:** Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

**Measures for Cleaning / Collecting:** Contain the source of spill if it is safe to do so. Collect spilled material by a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of dry solids. Clean spill area thoroughly.

**Measures for Environmental Protections:** Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

**Additional Consideration for Large Spills:** Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

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### 7. HANDLING AND STORAGE

**General Handling:** Minimize dust generation and accumulation. Avoid breathing dust. Avoid contact with eyes, skin and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash hands and any exposed skin after removal of PPE. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

**Storage Conditions:** Store as directed by product packaging.

### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Refer to available public information for specific member state Occupational Exposure Limits.

#### Talc (non-asbestiform)

ACGIH Threshold Limit Value (TWA)	2 mg/m <sup>3</sup> TWA
ACGIH OELs - Notice of Intended Changes	Listed
Australia TWA	2.5 mg/m <sup>3</sup> containing no asbestos fibers
Austria OEL - MAKs	Listed
Belgium OEL - TWA	Listed
Bulgaria OEL - TWA	Listed
Czech Republic OEL - TWA	Listed
Denmark OEL - TWA	Listed
Estonia OEL - TWA	Listed
Finland OEL - TWA	Listed
Greece OEL - TWA	Listed
Hungary OEL - TWA	Listed
Ireland OEL - TWAs	Listed
Netherlands OEL - TWA	Listed
OSHA - Final PELs - Table Z-3 Mineral D:	TWA-20 mppcf
Poland OEL - TWA	Listed
Portugal OEL - TWA	Listed
Romania OEL - TWA	Listed
Slovenia OEL - TWA	Listed
Spain OEL - TWA	Listed
Sweden OEL - TWAs	Listed

#### Starch

ACGIH Threshold Limit Value (TWA)	10 mg/m <sup>3</sup> TWA
Australia TWA	10 mg/m <sup>3</sup>
Belgium OEL - TWA	Listed
Bulgaria OEL - TWA	Listed
Czech Republic OEL - TWA	Listed
Greece OEL - TWA	Listed
Ireland OEL - TWAs	Listed
OSHA - Final PELs - TWAs:	15 mg/m <sup>3</sup> total 5 mg/m <sup>3</sup>
Portugal OEL - TWA	Listed
Spain OEL - TWA	Listed

#### Magnesium stearate

ACGIH Threshold Limit Value (TWA)	10 mg/m <sup>3</sup> TWA
Australia TWA	10 mg/m <sup>3</sup>

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### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Belgium OEL - TWA	Listed
Ireland OEL - TWAs	Listed
Lithuania OEL - TWA	Listed
Portugal OEL - TWA	Listed
Spain OEL - TWA	Listed
Sweden OEL - TWAs	Listed

**Engineering Controls:** Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section.

**Environmental Exposure Controls:** Refer to specific Member State legislation for requirements under Community environmental legislation.

**Personal Protective Equipment:** Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).

**Hands:** Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.

**Eyes:** Wear safety glasses or goggles if eye contact is possible.

**Skin:** Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.

**Respiratory protection:** If the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL.

### 9. PHYSICAL AND CHEMICAL PROPERTIES

**Physical State:** Hard-gelatin Capsule  
**Molecular Formula:** Mixture

**Color:** Orange, tan  
**Molecular Weight:** Mixture

### 10. STABILITY AND REACTIVITY

**Stability:** Stable under normal conditions of use.

**Conditions to Avoid:** Fine particles (such as dust and mists) may fuel fires/explosions.

**Incompatible Materials:** As a precautionary measure, keep away from strong oxidizers

### 11. TOXICOLOGICAL INFORMATION

**General Information:** The information included in this section describes the potential hazards of the individual ingredients.

#### Acute Toxicity: (Species, Route, End Point, Dose)

##### Talc (non-asbestiform)

Rat Oral LD50 > 1600 mg/kg

##### Magnesium stearate

Rat Oral LD50 > 2000 mg/kg

Rat Inhalation LC50 > 2000 mg/m<sup>3</sup>

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### 11. TOXICOLOGICAL INFORMATION

#### Dantrolene sodium

Rat Oral LD50 7432 mg/kg  
Rat Intravenous LD50 > 50 mg/kg

#### Lactose

Rat Oral LD50 > 10 g/kg

#### Reproduction & Development Toxicity: (Duration, Species, Route, Dose, End Point, Effect(s))

##### Dantrolene sodium

Reproductive & Fertility	Rat	No route specified	45 mg/kg/day	NOAEL	No effects at maximum dose
Embryo / Fetal Development	Rabbit	Oral	7 times human dose	LOAEL	Embryotoxicity
Embryo / Fetal Development	Rat	Oral	7 times human dose	LOAEL	Fetal mortality

#### Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

##### Dantrolene sodium

*In Vitro* Bacterial Mutagenicity (Ames) *Salmonella* Positive

#### Carcinogenicity: (Duration, Species, Route, Dose, End Point, Effect(s))

##### Dantrolene sodium

24 Month(s)	Mouse	No route specified	NOAEL	Not carcinogenic
18 Month(s)	Rat	Oral, in feed	15 mg/kg/day	LOAEL Benign tumors, Malignant tumors, Mammary gland

**Carcinogen Status:** None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

#### Talc (non-asbestiform)

IARC: Group 3

### 12. ECOLOGICAL INFORMATION

**Environmental Overview:** Environmental properties have not been investigated. Releases to the environment should be avoided.

### 13. DISPOSAL CONSIDERATIONS

#### Disposal Procedures:

Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

### 14. TRANSPORT INFORMATION

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

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## 15. REGULATORY INFORMATION

EU Indication of danger: Not classified

### OSHA Label:

Non-hazardous in accordance with international standards for workplace safety.

### Canada - WHMIS: Classifications

#### WHMIS hazard class:

None required

This product has been classified in accordance with the hazard criteria of the CPR and the MSDS contains all of the information required by the CPR.

#### Dantrolene sodium

EU EINECS/ELINCS List 238-706-8

#### Talc (non-asbestiform)

Inventory - United States TSCA - Sect. 8(b) Listed  
Australia (AICS): Listed  
EU EINECS/ELINCS List 238-877-9

#### Starch

Inventory - United States TSCA - Sect. 8(b) Listed  
Australia (AICS): Listed  
REACH - Annex IV - Exemptions from the obligations of Register: Present  
EU EINECS/ELINCS List 232-679-6

#### Magnesium stearate

Inventory - United States TSCA - Sect. 8(b) Listed  
Australia (AICS): Listed  
EU EINECS/ELINCS List 209-150-3

#### Lactose

Inventory - United States TSCA - Sect. 8(b) Listed  
Australia (AICS): Listed  
EU EINECS/ELINCS List 200-559-2

## 16. OTHER INFORMATION

Data Sources: Publicly available toxicity information. Safety data sheets for individual ingredients.

Prepared by: Toxicology and Hazard Communication  
Pfizer Global Environment, Health, and Safety Operations

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Pfizer Inc believes that the information contained in this Material Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time.

**End of Safety Data Sheet**