

## SECTION 1: Identification of the substance/mixture and of the company/undertaking

### 1.1. Product identifier

Product name : Revonto® (dantrolene sodium for injection)

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

Use of the substance/mixture : Lyophilized Pharmaceutical Product for Injection

### 1.3. Details of the supplier of the safety data sheet

US WorldMeds, LLC  
 4010 Dupont Circle, Suite L-07  
 Louisville, KY 40207  
 T 1-502-815-8000

Revonto Inquiries: 1-877-411-8796

Revonto After Hours Service and Support/Emergency Order/Adverse Events: 1-866-916-0581

### 1.4. Emergency telephone number

Emergency number : CHEMTREC 1-800-424-9300

## SECTION 2: Hazards identification

### 2.1. Classification of the substance or mixture

#### Classification (GHS-US)

Acute Tox. 4 (Inhalation) H332  
 Skin Irrit. 2 H315  
 Eye Irrit. 2A H319  
 STOT SE 3 H335

Full text of H-phrases: see section 16

### 2.2. Label elements

#### GHS-US labeling

Hazard pictograms (GHS-US) :



GHS07

Signal word (GHS-US) :

Warning

Hazard statements (GHS-US) :

H315 - Causes skin irritation  
 H319 - Causes serious eye irritation  
 H332 - Harmful if inhaled  
 H335 - May cause respiratory irritation

Precautionary statements (GHS-US) :

P261 - Avoid breathing dust/fume/gas/mist/vapors/spray  
 P264 - Wash thoroughly after handling  
 P271 - Use only outdoors or in a well-ventilated area  
 P280 - Wear protective gloves/protective clothing/eye protection/face protection  
 P302 + P352 - If on skin: Wash with plenty of water/...  
 P304 + P340 - If inhaled: Remove person to fresh air and keep comfortable for breathing  
 P305+P351+P338 - If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing  
 P312 - Call a poison center/doctor if you feel unwell  
 P321 - Specific treatment (see label)  
 P332+P313 - If skin irritation occurs: Get medical advice/attention  
 P337+P313 - If eye irritation persists: Get medical advice/attention  
 P362 - Take off contaminated clothing and wash before reuse  
 P403+P233 - Store in a well-ventilated place. Keep container tightly closed  
 P405 - Store locked up  
 P501 - Dispose of contents/container in accordance with local/regional/national/international regulations.

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### 2.3. Other hazards

No additional information available

### 2.4. Unknown acute toxicity (GHS US)

Not applicable

## SECTION 3: Composition/information on ingredients

### 3.1. Substance

Not applicable

### 3.2. Mixture

Name	Product identifier	%	Classification (GHS-US)
D-Mannitol	(CAS No) 69-65-8	Trade Secret	Not classified
tert-Butyl alcohol	(CAS No) 75-65-0	Trade Secret	Not classified
Water	(CAS No) 7732-18-5	Trade Secret	Not classified
Sodium hydroxide	(CAS No) 1310-73-2	Trade Secret	Met. Corr. 1, H290 Skin Corr. 1A, H314 Eye Dam. 1, H318
Dantrolene sodium	(CAS No) 24868-20-0	Trade Secret	Not classified

Full text of H-phrases: see section 16

## SECTION 4: First aid measures

### 4.1. Description of first aid measures

- First-aid measures after inhalation : Remove to fresh air. Seek medical attention if breathing becomes difficult.
- First-aid measures after skin contact : Remove contaminated clothing immediately. Wash affected area with soap or mild detergent and large amounts of water until no evidence of chemical remain. If irritation develops, seek medical attention.
- First-aid measures after eye contact : Flush with plenty of water for at least 15 minutes. Seek medical advice if irritation develops or persists.
- First-aid measures after ingestion : Wash out mouth with water provided person is conscious. Seek medical attention.

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

- Symptoms/injuries after inhalation : May be irritating to respiratory tract.
- Symptoms/injuries after skin contact : Causes skin irritation. Prolonged exposure may cause dermatitis.
- Symptoms/injuries after eye contact : Causes serious eye irritation. Prolonged exposure may cause visual disturbances.
- Symptoms/injuries after ingestion : Not considered a route of exposure under anticipated use conditions. May cause severe irritation and burns to the digestive tract if ingested.

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

No additional information available

## SECTION 5: Firefighting measures

### 5.1. Extinguishing media

- Suitable extinguishing media : Use extinguishing media appropriate for surrounding fire.
- Unsuitable extinguishing media : None.

### 5.2. Special hazards arising from the substance or mixture

- Fire hazard : Not flammable.
- Explosion hazard : None known.

### 5.3. Advice for firefighters

- Protection during firefighting : Firefighters should wear full protective gear.

## SECTION 6: Accidental release measures

### 6.1. Personal precautions, protective equipment and emergency procedures

#### 6.1.1. For non-emergency personnel

No additional information available

#### 6.1.2. For emergency responders

No additional information available

### 6.2. Environmental precautions

Avoid release to the environment.

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### 6.3. Methods and material for containment and cleaning up

- For containment : Stop the flow of material, if this is without risk.
- Methods for cleaning up : Absorb material and place in a suitable container for reclamation or disposal. Do not discharge into drains or sewers. Discard any product, residue, disposable container or liner in full compliance with federal, state, and local regulations.

### 6.4. Reference to other sections

No additional information available

## SECTION 7: Handling and storage

### 7.1. Precautions for safe handling

- Precautions for safe handling : Avoid inhalation and contact with skin and eyes.

### 7.2. Conditions for safe storage, including any incompatibilities

- Storage conditions : Keep in a tightly closed container, stored in a cool, dry, well ventilated area. Store unreconstituted product at 20-25° C (68-77° F)

### 7.3. Specific end use(s)

Injectable pharmaceutical drug product when reconstituted with 60 mL sterile water per vial. For intravenous use only.

## SECTION 8: Exposure controls/personal protection

### 8.1. Control parameters

Water (7732-18-5)		
ACGIH	Not applicable	
OSHA	Not applicable	
Sodium hydroxide (1310-73-2)		
ACGIH	ACGIH Ceiling (mg/m <sup>3</sup> )	2 mg/m <sup>3</sup>
OSHA	OSHA PEL (TWA) (mg/m <sup>3</sup> )	2 mg/m <sup>3</sup>
Dantrolene sodium (24868-20-0)		
ACGIH	Not applicable	
OSHA	Not applicable	
D-Mannitol (69-65-8)		
ACGIH	Not applicable	
OSHA	Not applicable	
tert-Butyl alcohol (75-65-0)		
ACGIH	ACGIH TWA (ppm)	100 ppm
OSHA	OSHA PEL (TWA) (mg/m <sup>3</sup> )	300 mg/m <sup>3</sup>
OSHA	OSHA PEL (TWA) (ppm)	100 ppm

### 8.2. Exposure controls

- Appropriate engineering controls : General mechanical ventilation is adequate for normal use. Local exhaust is recommended for confined areas.
- Hand protection : Use gloves to protect hands.
- Eye protection : None required under normal product handling conditions.
- Skin and body protection : Wear suitable working clothes.
- Respiratory protection : None required under normal product handling conditions.

## SECTION 9: Physical and chemical properties

### 9.1. Information on basic physical and chemical properties

- Physical state : Liquid
- Color : Colorless
- Odor : Odorless
- Odor threshold : No data available
- pH : No data available

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Melting point	: No data available
Freezing point	: No data available
Boiling point	: No data available
Flash point	: No data available
Relative evaporation rate (butyl acetate=1)	: No data available
Flammability (solid, gas)	: No data available
Explosion limits	: No data available
Explosive properties	: No data available
Oxidizing properties	: No data available
Vapor pressure	: No data available
Specific gravity	: >1
Relative vapor density at 20 °C	: No data available
Solubility	: Soluble
Log Pow	: No data available
Log Kow	: No data available
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
Viscosity	: No data available
Viscosity, kinematic	: No data available
Viscosity, dynamic	: No data available

### 9.2. Other information

No additional information available

## SECTION 10: Stability and reactivity

### 10.1. Reactivity

No additional information available

### 10.2. Chemical stability

The product is stable at normal handling and storage conditions.

### 10.3. Possibility of hazardous reactions

Will not occur.

### 10.4. Conditions to avoid

None.

### 10.5. Incompatible materials

Oxidizing agents

### 10.6. Hazardous decomposition products

Oxides of carbon.

## SECTION 11: Toxicological information

### 11.1. Information on toxicological effects

Acute toxicity : Inhalation: Harmful if inhaled.

<b>Revonto</b>	
ATE US (gases)	4500.000 ppmV/4h
ATE US (vapors)	11.000 mg/l/4h
ATE US (dust, mist)	1.500 mg/l/4h
<b>Water (7732-18-5)</b>	
LD50 oral rat	> 90 ml/kg
<b>Sodium hydroxide (1310-73-2)</b>	
LD50 dermal rabbit	1350 mg/kg
ATE US (dermal)	1350.000 mg/kg
<b>D-Mannitol (69-65-8)</b>	
ATE US (oral)	13500.000 mg/kg

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<b>tert-Butyl alcohol (75-65-0)</b>	
LD50 oral rat	2200 mg/kg
LD50 dermal rabbit	> 2 g/kg
LC50 inhalation rat (ppm)	> 10000 ppm/4h
ATE US (oral)	2733.000 mg/kg body weight

Skin corrosion/irritation	: Causes skin irritation. pH: 5 - 6.5
Serious eye damage/irritation	: Causes serious eye irritation. pH: 5 - 6.5
Respiratory or skin sensitization	: Not classified
Germ cell mutagenicity	: Not classified
Carcinogenicity	: Not classified

<b>tert-Butyl alcohol (75-65-0)</b>	
National Toxicology Program (NTP) Status	1 - Evidence of Carcinogenicity

Reproductive toxicity	: Not classified
Specific target organ toxicity (single exposure)	: May cause respiratory irritation.
Specific target organ toxicity (repeated exposure)	: Not classified
Aspiration hazard	: Not classified

## SECTION 12: Ecological information

### 12.1. Toxicity

<b>Sodium hydroxide (1310-73-2)</b>	
LC50 fish 1	45.4 mg/l (Exposure time: 96 h - Species: Oncorhynchus mykiss [static])

<b>tert-Butyl alcohol (75-65-0)</b>	
LC50 fish 1	6130 - 6700 mg/l (Exposure time: 96 h - Species: Pimephales promelas [flow-through])
EC50 Daphnia 1	933 mg/l (Exposure time: 48 h - Species: Daphnia magna)
EC50 Daphnia 2	4607 - 6577 mg/l (Exposure time: 48 h - Species: Daphnia magna [Static])

### 12.2. Persistence and degradability

No additional information available

### 12.3. Bioaccumulative potential

<b>tert-Butyl alcohol (75-65-0)</b>	
BCF fish 1	1.09
Log Pow	0.35

### 12.4. Mobility in soil

No additional information available

### 12.5. Other adverse effects

Effect on the global warming : No known ecological damage caused by this product.

## SECTION 13: Disposal considerations

### 13.1. Waste treatment methods

Waste disposal recommendations : Dispose of contents/container in accordance with local/regional/national/international regulations.

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### SECTION 14: Transport information

#### Department of Transportation (DOT)

In accordance with DOT  
Not a dangerous good as defined in transport regulations

### SECTION 15: Regulatory information

#### 15.1. US Federal regulations

##### Water (7732-18-5)

Listed on the United States TSCA (Toxic Substances Control Act) inventory

##### Sodium hydroxide (1310-73-2)

Listed on the United States TSCA (Toxic Substances Control Act) inventory

##### D-Mannitol (69-65-8)

Listed on the United States TSCA (Toxic Substances Control Act) inventory

##### tert-Butyl alcohol (75-65-0)

Listed on the United States TSCA (Toxic Substances Control Act) inventory  
Listed on SARA Section 313 (Specific toxic chemical listings)

SARA Section 313 - Emission Reporting	1.0 %
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#### 15.2. US State regulations

##### Sodium hydroxide (1310-73-2)

U.S. - Massachusetts - Right To Know List  
U.S. - Minnesota - Hazardous Substance List  
U.S. - New Jersey - Right to Know Hazardous Substance List  
U.S. - Pennsylvania - RTK (Right to Know) List

##### tert-Butyl alcohol (75-65-0)

U.S. - Massachusetts - Right To Know List  
U.S. - Minnesota - Hazardous Substance List  
U.S. - New Jersey - Right to Know Hazardous Substance List  
U.S. - Pennsylvania - RTK (Right to Know) List

### SECTION 16: Other information

Full text of H-phrases:

Acute Tox. 4 (Inhalation)	Acute toxicity (inhalation) Category 4
Eye Dam. 1	Serious eye damage/eye irritation Category 1
Eye Irrit. 2A	Serious eye damage/eye irritation Category 2A
Met. Corr. 1	Corrosive to metals Category 1
Skin Corr. 1A	Skin corrosion/irritation Category 1A
Skin Irrit. 2	Skin corrosion/irritation Category 2
STOT SE 3	Specific target organ toxicity (single exposure) Category 3
H290	May be corrosive to metals
H314	Causes severe skin burns and eye damage
H315	Causes skin irritation
H318	Causes serious eye damage
H319	Causes serious eye irritation
H332	Harmful if inhaled
H335	May cause respiratory irritation

*This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product*