

## SAFETY DATA SHEET

Preparation Date: 12/28/2018

Revision Number: E1

### 1. PRODUCT AND COMPANY IDENTIFICATION

#### 1.1 Product identifiers

Product name : Ondansetron Hydrochloride, USP

Product Number : O1370

Brand : Spectrum Chemical

CAS-No. : 103639-04-9

#### 1.2 Details of the supplier of the safety data sheet

Company : Spectrum Chemical  
14422 South San Pedro St.  
Gardena, CA 90248

Telephone : +1 310-516-8000

Fax : +1 310-516-9843

#### 1.3 Emergency telephone number

Emergency Phone # : +1-800-424-9300 (CHEMTREC)

### 2. HAZARDS IDENTIFICATION

#### 2.1 Classification of the substance or mixture

##### GHS Classification in accordance with 29 CFR 1910 (OSHA HCS)

Acute toxicity, Oral (Category 3), H301

Serious eye damage (Category 1), H318

Acute aquatic toxicity (Category 1), H400

Chronic aquatic toxicity (Category 2), H411

For the full text of the H-Statements mentioned in this Section, see Section 16.

#### 2.2 GHS Label elements, including precautionary statements

Pictogram



Signal word

Danger

Hazard statement(s)

H301 Toxic if swallowed.

H318 Causes serious eye damage.

H400 Very toxic to aquatic life.

H411 Toxic to aquatic life with long lasting effects.

Precautionary statement(s)

P264 Wash skin thoroughly after handling.

P270	Do not eat, drink or smoke when using this product.
P273	Avoid release to the environment.
P280	Wear protective gloves/ eye protection/ face protection.
P301 + P310	IF SWALLOWED: Immediately call a POISON CENTER/doctor.
P305 + P351 + P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P310	Immediately call a POISON CENTER/doctor.
P321	Specific treatment (see supplemental first aid instructions on this label).
P330	Rinse mouth.
P391	Collect spillage.
P405	Store locked up.
P501	Dispose of contents/ container to an approved waste disposal plant.

### 2.3 Hazards not otherwise classified (HNOC) or not covered by GHS - none

## 3. COMPOSITION/INFORMATION ON INGREDIENTS

### 3.1 Substances

Synonyms	: GR 38032F 1,2,3,9-Tetrahydro-9-methyl-3-[(2-methyl-1H-imidazol-1-yl)methyl]-4H-carbazol-4-one
Formula	: C <sub>18</sub> H <sub>19</sub> N <sub>3</sub> O · HCl · 2H <sub>2</sub> O
Molecular weight	: 365.85 g/mol
CAS-No.	: 103639-04-9

#### Hazardous components

Component	Classification	Concentration
<b>Ondansetron hydrochloride dihydrate</b>		
	Acute Tox. 3; Eye Dam. 1; Aquatic Acute 1; Aquatic Chronic 2; H301, H318, H400, H411	<= 100 %

For the full text of the H-Statements mentioned in this Section, see Section 16.

## 4. FIRST AID MEASURES

### 4.1 Description of first aid measures

#### General advice

Consult a physician. Show this safety data sheet to the doctor in attendance. Move out of dangerous area.

#### If inhaled

If breathed in, move person into fresh air. If not breathing, give artificial respiration. Consult a physician.

#### In case of skin contact

Wash off with soap and plenty of water. Take victim immediately to hospital. Consult a physician.

#### In case of eye contact

Flush eyes with water as a precaution.

#### If swallowed

Never give anything by mouth to an unconscious person. Rinse mouth with water. Consult a physician.

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

The most important known symptoms and effects are described in the labelling (see section 2.2) and/or in section 11

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

No data available

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## 5. FIREFIGHTING MEASURES

### 5.1 Extinguishing media

#### Suitable extinguishing media

Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.

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

Carbon oxides, Nitrogen oxides (NO<sub>x</sub>), Hydrogen chloride gas

### 5.3 Advice for firefighters

Wear self-contained breathing apparatus for firefighting if necessary.

### 5.4 Further information

No data available

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## 6. ACCIDENTAL RELEASE MEASURES

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

Wear respiratory protection. Avoid dust formation. Avoid breathing vapors, mist or gas. Ensure adequate ventilation.

Evacuate personnel to safe areas. Avoid breathing dust.

For personal protection see section 8.

### 6.2 Environmental precautions

Prevent further leakage or spillage if safe to do so. Do not let product enter drains.

### 6.3 Methods and materials for containment and cleaning up

Pick up and arrange disposal without creating dust. Sweep up and shovel. Keep in suitable, closed containers for disposal.

### 6.4 Reference to other sections

For disposal see section 13.

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## 7. HANDLING AND STORAGE

### 7.1 Precautions for safe handling

Avoid contact with skin and eyes. Avoid formation of dust and aerosols.

Provide appropriate exhaust ventilation at places where dust is formed. Normal measures for preventive fire protection.

For precautions see section 2.2.

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

Keep container tightly closed in a dry and well-ventilated place.

Recommended storage temperature -20 °C

### 7.3 Specific end use(s)

Apart from the uses mentioned in section 1.2 no other specific uses are stipulated

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## 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

### 8.1 Control parameters

#### Components with workplace control parameters

Contains no substances with occupational exposure limit values.

### 8.2 Exposure controls

#### Appropriate engineering controls

Avoid contact with skin, eyes and clothing. Wash hands before breaks and immediately after handling the product.

#### Personal protective equipment

##### Eye/face protection

Face shield and safety glasses Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU).

##### Skin protection

Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands.

### **Body Protection**

Complete suit protecting against chemicals. The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.

### **Respiratory protection**

Where risk assessment shows air-purifying respirators are appropriate use (EN 143) respirator cartridges as a backup to engineering controls. Otherwise, full-face supplied air respirator. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

### **Control of environmental exposure**

Prevent further leakage or spillage if safe to do so. Do not let product enter drains.

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## **9. PHYSICAL AND CHEMICAL PROPERTIES**

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

- |   |                      |
|---|----------------------|
| a) Appearance                                   | Form: solid          |
| b) Odor   | No data available    |
| c) Odor Threshold                               | No data available    |
| d) pH   | No data available    |
| e) Melting point/freezing point                 | No data available    |
| f) Initial boiling point and boiling range      | No data available    |
| g) Flash point                                  | ( )No data available |
| h) Evaporation rate                             | No data available    |
| i) Flammability (solid, gas)                    | No data available    |
| j) Upper/lower flammability or explosive limits | No data available    |
| k) Vapor pressure                               | No data available    |
| l) Vapor density                                | No data available    |
| m) Relative density                             | No data available    |
| n) Water solubility                             | No data available    |
| o) Partition coefficient: n-octanol/water       | No data available    |
| p) Auto-ignition temperature                    | No data available    |
| q) Decomposition temperature                    | No data available    |
| r) Viscosity                                    | No data available    |
| s) Explosive properties                         | No data available    |
| t) Oxidizing properties                         | No data available    |

### **9.2 Other safety information**

No data available

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## **10. STABILITY AND REACTIVITY**

**10.1 Reactivity**

No data available

**10.2 Chemical stability**

Stable under recommended storage conditions.

### 10.3 Possibility of hazardous reactions

No data available

### 10.4 Conditions to avoid

No data available

### 10.5 Incompatible materials

Strong oxidizing agents

### 10.6 Hazardous decomposition products

Hazardous decomposition products formed under fire conditions. - Carbon oxides, Nitrogen oxides (NOx), Hydrogen chloride gas

Other decomposition products - No data available

In the event of fire: see section 5

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## 11. TOXICOLOGICAL INFORMATION

### 11.1 Information on toxicological effects

#### Acute toxicity

LD50 Oral - Rat - 94.8 mg/kg(Ondansetron hydrochloride dihydrate)

Remarks: Sense Organs and Special Senses (Nose, Eye, Ear, and Taste):Eye:Other. Behavioral:Tremor.

Behavioral: Convulsions or effect on seizure threshold.

Inhalation: No data available(Ondansetron hydrochloride dihydrate)

Dermal: No data available(Ondansetron hydrochloride dihydrate)

No data available(Ondansetron hydrochloride dihydrate)

#### Skin corrosion/irritation

largely based on animal evidence(Ondansetron hydrochloride dihydrate)

#### Serious eye damage/eye irritation

largely based on animal evidence(Ondansetron hydrochloride dihydrate)

#### Respiratory or skin sensitization

largely based on animal evidence(Ondansetron hydrochloride dihydrate)

#### Germ cell mutagenicity

No data available(Ondansetron hydrochloride dihydrate)

#### Carcinogenicity

IARC: No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

ACGIH: No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by ACGIH.

NTP: No component of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

OSHA: No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by OSHA.

#### Reproductive toxicity

No data available(Ondansetron hydrochloride dihydrate)

No data available(Ondansetron hydrochloride dihydrate)

#### Specific target organ toxicity - single exposure

No data available(Ondansetron hydrochloride dihydrate)

#### Specific target organ toxicity - repeated exposure

No data available

#### Aspiration hazard

No data available(Ondansetron hydrochloride dihydrate)

## Additional Information

Repeated dose toxicity - Rat - Oral - No observed adverse effect level - 1 mg/kg(Ondansetron hydrochloride dihydrate)  
RTECS: FE6375500

To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated. Certain individuals may exhibit hypersensitivity reactions such as: purpuric skin rash, hives, Itching, Difficulty in breathing, Exposure can cause damage by Constipation, Headache, flushing, May cause nervous system disturbances.(Ondansetron hydrochloride dihydrate)

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## 12. ECOLOGICAL INFORMATION

### 12.1 Toxicity

Toxicity to fish	static test EC50 - Oncorhynchus mykiss (rainbow trout) - 6.5 mg/l – 96h (Ondansetron hydrochloride dihydrate) NOEC - Oncorhynchus mykiss (rainbow trout) - 2.6 mg/l - 96 h(Ondansetron hydrochloride dihydrate)
Toxicity to daphnia and other aquatic invertebrates	static test EC50 - Daphnia (water flea) - 28 mg/l - 48 h(Ondansetron hydrochloride dihydrate) static test NOEC - Daphnia (water flea) - 16 mg/l - 48 h(Ondansetron hydrochloride dihydrate)
Toxicity to algae	IC50 - Algae - 0.87 mg/l - 72 h(Ondansetron hydrochloride dihydrate) NOEC - Algae - 0.31 mg/l - 72 h(Ondansetron hydrochloride dihydrate)
Toxicity to bacteria	IC50 - other microorganisms - > 1,000 mg/l - 3 h(Ondansetron hydrochloride dihydrate)

### 12.2 Persistence and degradability

Biodegradability aerobic - Exposure time 28 d(Ondansetron hydrochloride dihydrate)  
Result: 18.9 % - Not readily biodegradable.  
(OECD Test Guideline 301)

### 12.3 Bioaccumulative potential

No data available

### 12.4 Mobility in soil

No data available(Ondansetron hydrochloride dihydrate)

### 12.5 Results of PBT and vPvB assessment

PBT/vPvB assessment not available as chemical safety assessment not required/not conducted

### 12.6 Other adverse effects

No data available

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## 13. DISPOSAL CONSIDERATIONS

### 13.1 Waste treatment methods

#### Product

Offer surplus and non-recyclable solutions to a licensed disposal company. Contact a licensed professional waste disposal service to dispose of this material. Dissolve or mix the material with a combustible solvent and burn in a chemical scrubber.

#### Contaminated packaging

Dispose of as unused product.

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## 14. TRANSPORT INFORMATION

### DOT (US)

UN number: 2811

Class: 6.1

Packing group: III

Proper shipping name: Toxic solids, organic, n.o.s. (Ondansetron hydrochloride dihydrate)  
Poison Inhalation Hazard: No

**IMDG**

UN number: 2811      Class: 6.1      Packing group: III      EMS-No: F-A, S-A  
Proper shipping name: TOXIC SOLID, ORGANIC, N.O.S. (Ondansetron hydrochloride dihydrate)

**IATA**

UN number: 2811      Class: 6.1      Packing group: III  
Proper shipping name: Toxic solid, organic, n.o.s. (Ondansetron hydrochloride dihydrate)

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**15. REGULATORY INFORMATION**

**SARA 302 Components**

No chemicals in this material are subject to the reporting requirements of SARA Title III, Section 302.

**SARA 313 Components**

This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

**SARA 311/312 Hazards**

Acute Health Hazard

**Massachusetts Right To Know Components**

No components are subject to the Massachusetts Right to Know Act.

**Pennsylvania Right To Know Components**

	CAS-No.	Revision Date
Ondansetron hydrochloride dihydrate	103639-04-9	

**New Jersey Right To Know Components**

	CAS-No.	Revision Date
Ondansetron hydrochloride dihydrate	103639-04-9	

**California Prop. 65 Components**

This product does not contain any chemicals known to State of California to cause cancer, birth defects, or any other reproductive harm.

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**16. OTHER INFORMATION**

**Full text of H-Statements referred to under sections 2 and 3.**

H301      Toxic if swallowed.  
H318      Causes serious eye damage.  
H400      Very toxic to aquatic life.  
H411      Toxic to aquatic life with long lasting effects.

**HMIS Rating**

Health hazard:            2  
Chronic Health Hazard:    0  
Flammability:            0  
Physical Hazard            0

**NFPA Rating**

Health hazard:            2  
Fire Hazard:              0  
Reactivity Hazard:        0

**Further information**

Disclaimer:

All chemicals may pose unknown hazards and should be used with caution. This Safety Data Sheet (SDS) applies only



to the material as packaged. If this product is combined with other materials, deteriorates, or becomes contaminated, it may pose hazards not mentioned in this SDS. The physical properties reported in this SDS are obtained from the literature and do not constitute product specifications. Information contained herein does not constitute a warranty, whether expressed or implied, as to the safety, merchantability or fitness of the goods for a particular purpose. Spectrum Chemicals & Laboratory Products, Inc. assumes no responsibility for results obtained or for incidental or consequential damages, including lost profits, arising from the use of these data. No warranty against infringement of any patent, copyright or trademark is made or implied. It shall be the user's responsibility to develop proper methods of handling and personal protection based on the actual conditions of use. While this SDS is based on technical data judged to be reliable, Spectrum assumes no responsibility for the completeness or accuracy of the information contained herein.

End of Safety Data Sheet  
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