

**Section 1. Product and Company Identification**

Product Name Ondansetron Hydrochloride Dihydrate
Product ID O5212
Chemical Name (Synonyms) Zofran; Zophren
Supplier LKT Laboratories, Inc
545 Phalen Blvd.
St. Paul, MN 55130 USA
Ph: 651-644-8424 Fax: 651-644-8357
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Emergency Phone # 1-800-424-9300

Section 2. Hazards Identification

GHS Classification Acute toxicity, Oral (Category 3) H301
Serious eye damage (Category 1) H318
Acute aquatic toxicity (Category 1) H400
Chronic aquatic toxicity (Category 2) H411

GHS Label elements including precautionary statements**Pictogram****Signal word** Danger**Hazard and precautionary statements****Hazard statements**

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 statements

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.
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.

HMIS Classification

Health hazard: 2
Chronic health hazard: *
Flammability: 0
Physical hazard: 0

NFPA Rating

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

Potential Health Effects

Inhalation - May be harmful if inhaled. May cause respiratory tract irritation.
Skin - May be harmful if absorbed through skin. May cause skin irritation.
Eyes - May cause eye irritation.

Ingestion - Toxic if swallowed. May be harmful if swallowed.

Section 3. Composition/Information on Ingredients

Substances	Ingredient: Title Compound	Percent: 100	
Formula	$C_{18}H_{19}N_3O \cdot HCl \cdot 2H_2O$	Formula Wt.	365.86
CAS No.	103639-04-9	EC No.	

Section 4. First Aid Measures

General advice	Consult a physician. Show this safety data sheet to the doctor in attendance. Move out of dangerous area.
Eye Contact	Flush eyes with water as a precaution.
Skin Contact	Wash off with soap and plenty of water. Take victim immediately to hospital. Consult a physician.
Inhalation	If breathed in, move person into fresh air. If not breathing, give artificial respiration. Consult a physician.
Ingestion	Never give anything by mouth to an unconscious person. Rinse mouth with water. Consult a physician.

Section 5. Firefighting Measures

Flash Point	Not available.
Extinguishing Media	Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.
Firefighting Procedures	Wear self-contained breathing apparatus for firefighting if necessary.
Unusual Fire Hazards	Not available.

Section 6. Accidental Release Measures

Personal Precautions	Wear respiratory protection. Avoid dust formation. Avoid breathing dust, vapors, mist, or gas. Ensure adequate ventilation. Evacuate personnel to safe areas.
Environmental Precautions	Prevent further leakage or spillage if safe to do so. Do not let product enter drains.
Methods and materials for containment and cleanup	Pick up and arrange disposal without creating dust. Sweep up and shovel. Keep in suitable, closed containers for disposal.

Section 7. Handling and Storage

Handling	Avoid contact with skin and eyes. Avoid formation of dust and aerosols. Provide appropriate exhaust ventilation at places where dust is formed.
Storage Conditions	Keep container tightly closed in a dry and well-ventilated place. Recommended storage temperature: -20°C
Hazardous Decomposition Products	Not available.
Other Remarks	

Section 8. Exposure Controls/Personal Protection

Personal protective equipment

EXPOSURE CONTROLS

Contains no substances with occupational exposure limit values. Avoid contact with skin, eyes and clothing. Wash hands before breaks and immediately after handling the product.

PERSONAL PROTECTION

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 a full-face particle respirator type N100 (US) or type P3 (EN 143) respirator cartridges as a backup to engineering controls. If the respirator is the sole means of protection, use a full-face supplied air respirator. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

Section 9. Physical and Chemical Properties

Physical State	Solid.	Color	White crystal powder.
Boiling Point	Not available.	Volatility	Not available.
Melting Point	178.5-179.5°C	Density	Not available.
Solubility	Soluble in water.	pH	Not available.
Flash Point	Not available.	Ignition temperature	Not available.
Lower explosion limit	Not available.	Autoignition temperature	Not available.
Upper explosion limit	Not available.	Vapor pressure	Not available.
Water solubility	Soluble in water.	Odor	Not available.
Partition coefficient: n-octanol/water	Not available.	Odor Threshold	Not available.
Relative vapor density	Not available.	Evaporation rate	Not available.

Section 10. Stability and Reactivity

Stability Stable under recommended storage conditions.

Materials To Avoid Strong oxidizing agents.

Hazardous Decomposition Products Not available.

Possibility of hazardous reactions Not available.

Conditions to avoid Not available.

Section 11. Toxicological Information

Oral LD50 Rat - 94.8 mg/kg Remarks: Sense organs and special senses (Nose, Eye, Ear and Taste): Eye: Other. Behavioral:Tremor. Behavioral: Convulsions or effect on seizure threshold.

Skin corrosion/irritation Largely based on animal evidence.

Inhalation LC50 Not available.

Serious eye damage/irritation Largely based on animal evidence.

Dermal LD50 Not available.

Respiratory or skin sensitization Largely based on animal evidence.

Other information on acute toxicity Not available.

Germ cell mutagenicity Not available.

Reproductive Toxicity Rabbit - Oral Effects on Newborn: Growth statistics (e.g., reduced weight gain). Maternal Effects: Other effects. Effects on Newborn: Growth statistics (e.g., reduced weight gain).

Aspiration Hazard Not available.

Specific organ toxicity single exposure (GHS) Not available.

Synergistic effects Not available.

Specific organ toxicity repeated exposure (GHS) Not available.

Additional Information RTECS: FE6375500
To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated.

Teratogenicity Not available.

Signs and symptoms of exposure Certain individuals may exhibit hypersensitivity reactions such as: Purpuric skin rash, hives, itching, difficulty in breathing. Constipation, headache, flushing. May cause nervous system disturbances.

Potential Health Effects Inhalation - May be harmful if inhaled. May cause respiratory tract irritation.
Skin - May be harmful if absorbed through skin. May cause skin irritation.
Eyes - May cause eye irritation.
Ingestion - Toxic if swallowed. May be harmful if swallowed.

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.

Section 12. Ecological Information

Toxicity Toxic to fish - Static test EC50 - Oncorhynchus mykiss (rainbow trout) - 6.5mg/l - 96 h NOEC - Oncorhynchus mykiss (rainbow trout) - 2.6 mg/l - 96h
Toxicity to daphnia & other aquatic invertebrates: static test EC50 - Daphnia

Mobility in soil Not available.

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

(water flea) - 28 mg/l - 48 h.

conducted.

Persistence and degradability

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

Other adverse effects Not available.

Bioaccumulative potential

Not available.

Section 13. Disposal Considerations

Waste Disposal

Dispose of material according to all federal, state and local regulations.
Offer material to a licensed, professional waste disposal company to dispose of as unused product. Dissolve or mix the material with a combustible solvent and burn in a chemical incinerator equipped with an afterburner and scrubber.

Section 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

IATA

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

IMDG

UN number: 2811 Class: 6.1 Packing Group: III EMS No: F-A, S-A
Proper shipping name: TOXIC SOLID, ORGANIC, Toxic solids, organic, n.o.s. (Ondansetron hydrochloride dihydrate)

Further Information

Section 15. Regulatory Information

Reach No.

SARA 302 Components

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

SARA 313 Components

SARA 313: 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 Components

Acute health hazard.

Massachusetts Right To Know Components

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

Pennsylvania Right To Know Components

Ondansetron hydrochloride dihydrate CAS #: 103639-04-9 Revision Date:

New Jersey Right To Know Components

Ondansetron hydrochloride dihydrate CAS #: 103639-04-9 Revision Date:

California Prop 65 Components

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

Section 16. Other Information

Other information

The information in this document is believed to be correct but is not necessarily complete. LKT does not guarantee the accuracy of the information. The burden of verifying the information in this document rests solely upon the user.

Updated 6/11/2020

For emergencies in the USA, call
CHEMTREC 800-424-9300