Ondansetron Tablets 4 mg, 8 mg

Safety Data Sheet

according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

Date of issue: 06/04/2015 Version: 1.0

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

1.1. Product identifier

Product form : Mixture

Product name : Ondansetron Tablets 4 mg, 8 mg

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

Use of the substance/mixture : Pharmaceutical

1.3. Details of the supplier of the safety data sheet

Dr. Reddy's Laboratories Louisiana LLC
8800 Line Avenue
Shreveport, Louisiana 71106
T 318 861 8200 - F 318 861 8297
www.drreddys.com

1.4. Emergency telephone number

Emergency number : CHEMTREC (24 hrs., 7 days per week): (800) 424-9300

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

GHS-US classification

Acute Tox. 4 (Oral) H302
Carc. 2 H351

Full text of H-statements: see section 16

(Carc. 2 through inhalation of dust due to Titanium Dioxide content)

2.2. Label elements

GHS-US labelling

Hazard pictograms (GHS-US) :

GHS07 GHS08

Signal word (GHS-US) : Warning

Hazard statements (GHS-US) : H302 - Harmful if swallowed
H351 - Suspected of causing cancer

Precautionary statements (GHS-US) : P201 - Obtain special instructions before use
P202 - Do not handle until all safety precautions have been read and understood
P264 - Wash hands thoroughly after handling
P270 - Do not eat, drink or smoke when using this product
P280 - Wear protective gloves
P301+P312 - If swallowed: Call a doctor if you feel unwell
P308+P313 - If exposed or concerned: Get medical advice/attention
P330 - Rinse mouth
P405 - Store locked up
P501 - Dispose of contents/container to an authorised waste collection point

2.3. Other hazards

No additional information available

2.4. Unknown acute toxicity (GHS-US)

6.9 percent of the mixture consists of ingredient(s) of unknown acute toxicity (Dermal)
6.9 percent of the mixture consists of ingredient(s) of unknown acute toxicity (Inhalation (Dust/Mist))

SECTION 3: Composition/information on ingredients

3.1. Substance

Not applicable

3.2. Mixture

Exact concentrations withheld as trade secret.

Name	Product identifier	%	GHS-US classification
Ondansetron hydrochloride dihydrate (Main constituent)	(CAS No) 99614-01-4	2 – 8	Acute Tox. 3 (Oral), H301
sodium starch glycolate	(CAS No) 9063-38-1	2 – 8	Eye Irrit. 2A, H319 STOT SE 3, H335
Titanium dioxide	(CAS No) 13463-67-7	0 – 3	Carc. 2, H351

Full text of H-statements: see section 16

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures general : Never give anything by mouth to an unconscious person.

First-aid measures after inhalation : Remove victim to fresh air and keep at rest in a position comfortable for breathing.

First-aid measures after skin contact : Gently wash with plenty of soap and water.

First-aid measures after eye contact : In case of contact, immediately flush eyes with plenty of water.

First-aid measures after ingestion : Rinse mouth. Call a POISON CENTER or doctor/physician if you feel unwell.

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

Symptoms/injuries after inhalation : May cause cancer by inhalation.

Symptoms/injuries after ingestion : Harmful if swallowed. May be harmful if swallowed in large quantities.

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

All treatments should be based on observed signs and symptoms of distress in the patient.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media : Foam. Dry powder. Carbon dioxide. Water spray. Sand.

Unsuitable extinguishing media : Do not use a heavy water stream.

5.2. Special hazards arising from the substance or mixture

Fire hazard : Burning produces irritating, toxic and noxious fumes.

Explosion hazard : Product is not explosive.

Reactivity : No dangerous reactions known.

5.3. Advice for firefighters

Firefighting instructions : Exercise caution when fighting any chemical fire. Prevent fire-fighting water from entering environment.

Protection during firefighting : Do not enter fire area without proper protective equipment, including respiratory protection. Wear fire/flame resistant/retardant clothing. Wear a self contained breathing apparatus.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General measures : Avoid creating or spreading dust. Avoid contact with skin and eyes.

6.1.1. For non-emergency personnel

Protective equipment : Chemical goggles or safety glasses. Dust impervious gloves.

Emergency procedures : Evacuate unnecessary personnel.

6.1.2. For emergency responders

Protective equipment : Chemical goggles or safety glasses. Dust impervious gloves.

Emergency procedures : Ventilate area.

6.2. Environmental precautions

Avoid release to the environment.

6.3. Methods and material for containment and cleaning up

Methods for cleaning up : On land, sweep or shovel into suitable containers. Minimize generation of dust.

6.4. Reference to other sections

Section 13: disposal information. Section 7: safe handling. Section 8: personal protective equipment.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : Obtain special instructions before use. Do not handle until all safety precautions have been read and understood.

Hygiene measures : Always wash your hands immediately after handling this product, and once again before leaving the workplace.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Store in original container.

Incompatible products : Strong oxidizing agents. Strong acids. Strong bases.

Prohibitions on mixed storage : Incompatible materials.

Storage area : Store in dry, cool, well-ventilated area.

7.3. Specific end use(s)

Pharmaceuticals.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Ondansetron Tablets 4 mg, 8 mg	
ACGIH	Not applicable
OSHA	Not applicable

Ondansetron hydrochloride dihydrate (99614-01-4)	
Dr. Reddy's OEL	20 µg/m3 (8-hr TWA)
ACGIH	Not applicable
OSHA	Not applicable

sodium starch glycolate (9063-38-1)		
ACGIH	Not applicable	
OSHA	OSHA PEL (TWA) (mg/m³)	15 mg/m³ total dust
OSHA	OSHA PEL (STEL) (mg/m³)	5 mg/m³ respirable fraction

Titanium dioxide (13463-67-7)		
ACGIH	ACGIH TWA (mg/m³)	10 mg/m³
OSHA	OSHA PEL (TWA) (mg/m³)	15 mg/m³

8.2. Exposure controls

Appropriate engineering controls : Avoid dispersal of dust in the air (ie, clearing dust surfaces with compressed air). Either local exhaust or general room ventilation is usually required.

Personal protective equipment : Avoid all unnecessary exposure.

Hand protection : Dust impervious gloves.

Eye protection : Chemical goggles or safety glasses.

Respiratory protection : Where exposure through inhalation may occur from use, respiratory protection equipment is recommended. Use air-purifying respirator equipped with particulate filtering cartridges.

Consumer exposure controls : Keep out of reach of children.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state : Solid

Appearance : Tablets.

Colour : white Yellow

Odour : odourless

Odour threshold : No data available

pH : No data available

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
Explosive limits	:	No data available
Explosive properties	:	No data available
Oxidising properties	:	No data available
Vapour pressure	:	No data available
Relative density	:	No data available
Relative vapour density at 20 °C	:	No data available
Solubility	:	No data available
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

SECTION 10: Stability and reactivity

10.1. Reactivity

No dangerous reactions known.

10.2. Chemical stability

The product is stable at normal handling and storage conditions.

10.3. Possibility of hazardous reactions

Hazardous polymerization will not occur.

10.4. Conditions to avoid

Extremely high or low temperatures.

10.5. Incompatible materials

Strong acids. Strong bases. Strong oxidizers.

10.6. Hazardous decomposition products

Calcium (Ca). Fluorine (F). Nitrogen oxides. Burning produces irritating, toxic and noxious fumes.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Likely routes of exposure	:	Ingestion; Inhalation; Skin and eye contact
Acute toxicity	:	Oral: Harmful if swallowed.

Ondansetron Tablets 4 mg, 8 mg	
ATE US (oral)	1376.812 mg/kg bodyweight

Ondansetron hydrochloride dihydrate (99614-01-4)	
LD50 oral rat	95 mg/kg
ATE US (oral)	95.000 mg/kg bodyweight

Titanium dioxide (13463-67-7)	
LD50 oral rat	> 5000 mg/kg
LC50 inhalation rat (mg/l)	> 6.82 mg/l/4h

Skin corrosion/irritation	:	Not classified
Serious eye damage/irritation	:	Not classified
Respiratory or skin sensitisation	:	Not classified
Germ cell mutagenicity	:	Not classified Ondansetron hydrochloride dihydrate - Ondansetron was not mutagenic in standard tests for mutagenicity

Carcinogenicity : Suspected of causing cancer.

Ondansetron hydrochloride dihydrate - Carcinogenic effects were not seen in 2-year studies in rats and mice with oral ondansetron doses up to 10 and 30 mg/kg/day, respectively

Titanium dioxide (13463-67-7)	
NOAEL (chronic, oral, animal/male, 2 years)	5 mg/kg bodyweight rat
IARC group	2B - Possibly carcinogenic to humans, as dust

Reproductive toxicity : Not classified

Ondansetron hydrochloride dihydrate - Reproduction studies have been performed in pregnant rats and rabbits at daily oral doses up to 15 and 30 mg/kg/day, respectively, and have revealed no evidence of impaired fertility or harm to the fetus due to ondansetron. Oral administration of ondansetron up to 15 mg/kg/day did not affect fertility or general reproductive performance of male and female rats.

Specific target organ toxicity (single exposure) : Not classified

Specific target organ toxicity (repeated exposure) : Not classified

Aspiration hazard : Not classified

Symptoms/injuries after inhalation : May cause cancer by inhalation.

Symptoms/injuries after ingestion : Harmful if swallowed. May be harmful if swallowed in large quantities.

SECTION 12: Ecological information

12.1. Toxicity

No additional information available

12.2. Persistence and degradability

No additional information available

12.3. Bioaccumulative potential

No additional information available

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

Sewage disposal recommendations : Do not dispose of waste into sewer.

Waste disposal recommendations : Dispose in a safe manner in accordance with local/national regulations.

SECTION 14: Transport information

Department of Transportation (DOT)

In accordance with DOT

Not considered a dangerous good for transport regulations

Additional information

Other information : No supplementary information available.

ADR

No additional information available

Transport by sea

No additional information available

Air transport

No additional information available

SECTION 15: Regulatory information

15.1. US Federal regulations

Ondansetron hydrochloride dihydrate (99614-01-4)
Not listed on the United States TSCA (Toxic Substances Control Act) inventory

sodium starch glycolate (9063-38-1)
Listed on the United States TSCA (Toxic Substances Control Act) inventory

Titanium dioxide (13463-67-7)
Listed on the United States TSCA (Toxic Substances Control Act) inventory

15.2. International regulations

CANADA

Ondansetron hydrochloride dihydrate (99614-01-4)
Not listed on the Canadian DSL (Domestic Substances List) inventory.

sodium starch glycolate (9063-38-1)
Listed on the Canadian DSL (Domestic Substances List) inventory.

Titanium dioxide (13463-67-7)
Listed on the Canadian DSL (Domestic Substances List) inventory.

EU-Regulations

Ondansetron hydrochloride dihydrate (99614-01-4)
Not listed on the EEC inventory EINECS (European Inventory of Existing Commercial Chemical Substances)

sodium starch glycolate (9063-38-1)
Not listed on the EEC inventory EINECS (European Inventory of Existing Commercial Chemical Substances)

Titanium dioxide (13463-67-7)
Listed on the EEC inventory EINECS (European Inventory of Existing Commercial Chemical Substances)

Classification according to Regulation (EC) No. 1272/2008 [CLP]
Acute Tox. 4 (Oral) H302
Carc. 2 H351
Full text of H-statements: see section 16

National regulations

Ondansetron hydrochloride dihydrate (99614-01-4)
Not listed on the Canadian Non-Domestic Substances List (NDSL).

Titanium dioxide (13463-67-7)
Listed on the AICS (Australian Inventory of Chemical Substances) Listed on IECSC (Inventory of Existing Chemical Substances Produced or Imported in China) Listed on the Japanese ENCS (Existing & New Chemical Substances) inventory Listed on KECI (Korean Existing Chemicals Inventory) Listed on Taiwan National Chemical Inventory Listed on PICCS (Philippines Inventory of Chemicals and Chemical Substances) Listed on NZIoC (New Zealand Inventory of Chemicals)

15.3. US State regulations

Titanium dioxide (13463-67-7)				
U.S. - California - Proposition 65 - Carcinogens List	U.S. - California - Proposition 65 - Developmental Toxicity	U.S. - California - Proposition 65 - Reproductive Toxicity - Female	U.S. - California - Proposition 65 - Reproductive Toxicity - Male	No significant risk level (NSRL)
Yes	No	No	No	

Titanium dioxide (13463-67-7)
U.S. - Minnesota - Hazardous Substance List U.S. - New Jersey - Right to Know Hazardous Substance List

SECTION 16: Other information

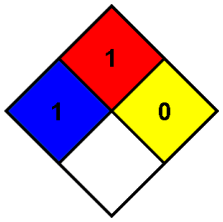
Indication of changes : Original Document.

Data sources	:	ACGIH 2000. European Chemicals Agency (ECHA) Registered Substances list. Accessed at http://echa.europa.eu/. Krister Forsberg and S.Z. Mansdorf, "Quick Selection Guide to Chemical Protective Clothing", Fifth Edition. National Fire Protection Association; Fire Protection Guide to Hazardous Materials; 10th edition. OSHA 29CFR 1910.1200 Hazard Communication Standard. TSCA Chemical Substance Inventory. Accessed at http://www.epa.gov/oppt/existingchemicals/pubs/tscainventory/howto.html.
Abbreviations and acronyms	:	ACGIH (American Conference of Governement Industrial Hygienists). ATE: Acute Toxicity Estimate. CAS (Chemical Abstracts Service) number. CLP: Classification, Labelling, Packaging. EC50: Environmental Concentration associated with a response by 50% of the test population. GHS: Globally Harmonized System (of Classification and Labeling of Chemicals). LD50: Lethal Dose for 50% of the test population. OSHA: Occupational Safety & Health Administration. TSCA: Toxic Substances Control Act. TWA: Time Weight Average.

Full text of H-statements:

Acute Tox. 3 (Oral)	Acute toxicity (oral), Category 3
Acute Tox. 4 (Oral)	Acute toxicity (oral), Category 4
Carc. 2	Carcinogenicity, Category 2
Eye Irrit. 2A	Serious eye damage/eye irritation, Category 2A
STOT SE 3	Specific target organ toxicity — Single exposure, Category 3, Respiratory tract irritation
H301	Toxic if swallowed
H302	Harmful if swallowed
H319	Causes serious eye irritation
H335	May cause respiratory irritation
H351	Suspected of causing cancer

NFPA health hazard	:	1 - Exposure could cause irritation but only minor residual injury even if no treatment is given.
NFPA fire hazard	:	1 - Must be preheated before ignition can occur.
NFPA reactivity	:	0 - Normally stable, even under fire exposure conditions, and not reactive with water.



Redstone SDS US GHS for Dr Reddy's

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