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Material Safety Data Sheet For Active pharmaceutical Ingredient			 THERAPIVA
Name of the Product:	ONDANSETRON HYDROCHLORIDE DIHYDRATE		
Version No	01	Unit	TU-II
Effective Date	26/11/18	Page no:	1 of 10

SECTION 1 – CHEMICAL PRODUCT AND COMPANY IDENTIFICATION:

Product Identifier	ONDANSETRON HYDROCHLORIDE DIHYDRATE: "4H-carbazol-4-one, 1, 2, 3, 9-tetrahydro- 9methyl-3-[(2-methyl-1H-), imidazol-1-yl]		WHMIS Classification]
Product Use	Antinauseant, antiemetic.		
Molecular Weight	349.86	Molecular Formula	C18H20N3OCl.H2O
Manufacturer's Name	Therapiva Private Limited,		Supplier's Name Therapiva Private Limited,
Street Address	TU-II Plot No. 9/A, Phase-III, Jeedimetla (V), Quthbullapur (M), Medchal-Malkajgiri District-500055, Telangana state, India		
Emergency Telephone 040-23092999	Province: Hyderabad Telangana, India		
	City: Hyderabad		
	Postal Code 500055		


SECTION 2 – HAZARDS IDENTIFICATION

HAZARD RATINGS	Flammability: 1 Toxicity: 3 Body Contact: 3 Reactivity: 1 Chronic: 2
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GHS Classification/ As per EU guidelines no 1357/2014:	<p>H301 Toxic if swallowed.</p> <p>H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.</p> <p>H317 May cause an allergic skin reaction. H318 Causes serious eye damage.</p> <p>H410 Very toxic to aquatic life with long lasting effects.</p> <p>Precautionary statement(s)</p> <p>Prevention Code Phrase</p> <p>P261 Avoid breathing dust/ fume/ gas/ mist/ vapors/ spray. P264 Wash ... thoroughly after handling.</p> <p>P273 Avoid release to the environment.</p> <p>P280 Wear protective gloves/protective clothing/eye protection/face protection. P285 In case of inadequate ventilation wear respiratory protection.</p> <p>Response Code Phrase</p> <p>P301+P310 IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician.</p> <p>P302+P352 IF ON SKIN: Wash with plenty of soap and water.</p> <p>P304+P341 IF INHALED: If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing.</p> <p>P333+P313 If skin irritation or rash occurs: Get medical advice/attention. P391 Collect spillage.</p> <p>Safety advice</p> <p>S01 Keep locked up.</p> <p>S02 Keep out of reach of children. S22 Do not breathe dust.</p> <p>S39 Wear eye/face protection.</p> <p>S51 Use only in well ventilated areas.</p> <p>S09 Keep container in a well-ventilated place.</p> <p>Other Hazards</p> <p>R20? Inhalation may produce health damage*.</p> <p>R33? Cumulative effects may result following exposure*. R42/43? Possible respiratory and skin sensitizer*</p>
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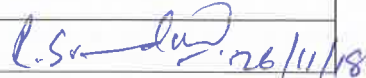
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SECTION 3 – COMPOSITION/INFORMATION ON INGREDIENTS


Hazardous Ingredients specific)	%	CAS Number	LD50 of Ingredient (Oral-Mouse)	LC50 of Ingredient (specify species)
Ondansetron HCl Dihydrate	100	103639-04-9	Oral (rat) LD50: 94.9 mg/kg	

SECTION 4 – FIRST AID MEASURES:

Swallowed	For advice, contact a Poisons Information Centre or a doctor. Urgent hospital treatment is likely to be needed. In the meantime, qualified first-aid personnel should treat the patient following observation and employing supportive measures as indicated by the patient's condition.
Eye	If this product comes in contact with the eyes: Immediately hold eyelids apart and flush the eye continuously with running water. Ensure complete irrigation of the eye by keeping eyelids apart and away from eye and moving the eyelids by occasionally lifting the upper and lower lids. Continue flushing until advised to stop by the Poisons Information Centre or a doctor, or for at
Skin	Immediately remove all contaminated clothing, including foot wear. Flush skin and hair
Inhalation	If fumes or combustion products are inhaled remove from contaminated area. Lay patient down. Keep warm and rested. Apply artificial respiration if not breathing, preferably with a demand valve resuscitator, bag-valve mask

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SECTION 5 – FIRE FIGHTING MEASURES:

Flammability	Combustible solid which burns but propagates flame with difficulty
Means of Extinction	Water spray or fog. Foam. Dry chemical powder. BCF (where
Flashpoint (°C) and Method	Not available
Auto ignition Temperature (°C)	Not available
Hazardous Combustion Products [NFPA]	Avoid contamination with oxidising agents i.e. nitrates, oxidising acids, chlorine bleaches, pool chlorine etc. as ignition may result

SECTION 6 – ACCIDENTAL RELEASE MEASURES:

Clean up waste regularly and abnormal spills immediately. Avoid breathing dust and contact with skin and eyes. Wear Protective clothing, gloves, safety glasses and dust respirator. Use dry clean up procedures and avoid generating dust. Vacuum up or sweep up.

SECTION 7 – HANDLING AND STORAGE:

Handling Procedures and Equipment: Avoid all personal contact, including inhalation. Wear protective clothing when risk of exposure occurs. Store in a cool well-ventilated area. Protect containers against physical damage.




Storage condition:

Store in original containers


Keep containers securely sealed

Store away from incompatible materials and foodstuff containers. Protect containers against physical damage and check regularly for leaks.

(Preserve in well closed containers at 25°C (Excursions allowed between 15 and 30°C)

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SECTION 8 – EXPOSURE CONTROL/PERSONAL PROTECTION:

It is the goal of the ACGIH (and other Agencies) to recommend TLVs (or their equivalent) for all substances for which there is evidence of health effects at airborne concentrations encountered in the work place.

cause inflammation

- cause increased susceptibility to other irritants and infectious agents
- lead to permanent injury or dysfunction
- permit greater absorption of hazardous substances and
- Acclimate the worker to the irritant warning properties of these substances thus increasing the risk of overexposure.

Airborne particulate or vapor must be kept to levels as low as is practicably achievable given access to

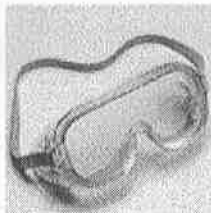
Modern engineering controls and monitoring hardware. CEL TWA: 0.03 mg/m³ (cf OEL TWA USP MSDS)

Personal Protective

Equipment

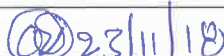


Use personal protective equipment as required.

Glove ☐ Footwear ☐ Clothing




Chemical goggles or Face shield.

Rubber gloves, PVC gloves, Protective shoe covers, Head covering.
High Efficiency Dust Respirators

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SECTION 9 – PHYSICAL AND CHEMICAL PROPERTIES:




Physical State: Solid.	Threshold (ppm)	
Specific Gravity: 1.2 approx	Vapour Density (air = 1): Not Applicable	Vapour Pressure (mmHg): Negligible
Evaporation Rate: Non Volatile	Boiling Point (°C): Not available	Melting range(°C): 217-218°C
pH(1% solution): Not applicable	Coefficient of Water/Oil Distribution	[Solubility in Water): Miscible

SECTION 10 – STABILITY AND REACTIVITY:


Chemical Stability If no, under which conditions	Product is considered stable. Hazardous polymerization will not occur
Incompatibility with Other Substances	Avoid contamination with oxidizing agents

SECTION 11 – TOXICOLOGICAL INFORMATION:

Effects of Acute Exposure SWALLOWED: Toxic effects may result from the accidental ingestion of the material; animal Experiments indicate that ingestion of less than 40 gram maybe fatal or may produce serious damage to the health of the individual.
EYE: If applied to the eyes, this material causes severe eye damage
SKIN: The material is not thought to produce adverse health effects or skin irritation following contact (as Classified by EC Directives using animal models). Nevertheless, good hygiene practice requires that exposure be kept to a minimum and that suitable gloves be used in an occupational setting. Open cuts, abraded or irritated skin should not be exposed to this material. Entry into the blood-stream, through, for example, cuts, abrasions or lesions, may produce systemic injury with harmful effects. Examine the skin prior to the use of the material

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INHALED: The material is not thought to produce respiratory irritation (as classified by EC Directives

using animal models). Nevertheless inhalation of dusts, or fumes, especially for prolonged periods, may produce respiratory discomfort and occasionally, distress. Inhalation of dusts, generated by the material during the course of normal handling, may be damaging to the health

Effects of Chronic Exposure: Substance accumulation, in the human body, may occur and may cause

some concern following repeated or long-term occupational exposure.

There is some evidence that inhaling this product is more likely to cause a sensitization reaction in some persons compared to the general population. There is limited evidence that,

LD50 of Ingredient:

TOXICITY IRRITATION

Oral (rat) LD50: 94.9

mg/kg Oral

(woman) TDLo: 0.16

mg/kg Oral (Dog)

LD50: >45 mg/kg

Oral (Human)

TDLo: 0.16 mg/kg

Oral (Rat)

LD50: 94.897 mg/kg

Intravenous (Rat)

LD50: 20.201 mg/kg Oral

(Dog) LD50: >45 mg/kg




Intravenous (Dog)

LD50: >15 mg/kg

Intraperitoneal (Mouse)


LDLo: 5 mg/kg Oral

(Mouse) LDLo: 15 mg/kg

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SECTION 12 – ECOLOGICAL INFORMATION:

Marine Pollutant :

Not Determined

Do NOT allow product to come in contact with surface waters or to intertidal areas below the mean high water mark. Do not contaminate water when cleaning equipment or disposing of equipment wash-waters. Wastes resulting from use of the product must be disposed of on site or at approved waste sites. DO NOT discharge into sewer or waterways. Daphnia pulex EC50 (24 h): 32 mg/l; (48 h) 28 mg/l (Ondansetron) Activated Sludge Respiration Inhibition EC50: >802 mg/L (Ondansetron).

SECTION 13 – DISPOSAL CONSIDERATIONS:

Reduction

Reuse


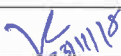
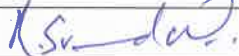
Recycling

Disposal (if all else fails)

DO NOT allow wash water from cleaning or process equipment to enter drains. It may be necessary to collect all wash water for treatment before disposal.


In all cases disposal to sewer may be subject to local laws and regulations and these should be considered first. Where in doubt contact the responsible authority.

Recycle wherever possible. Consult manufacturer for recycling options or consult local or regional waste management authority for disposal if no suitable treatment or disposal facility can be identified

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SECTION 14 – TRANSPORT INFORMATION:

Labels Required: TOXIC

HAZCHEM: 2X

Shipping Name: MEDICINE, SOLID, TOXIC, N.O.S



Land Transport (ADR/RID/GGVSE)

Class or division: 6.1

Subsidiary risk: None

UN No.: 2811 UN packing
group: II

Shipping name: MEDICINE, SOLID, TOXIC, N.O.S. (contains Ondansetron hydrochloride dihydrate)

Air Transport (ICAO-
IATA/DGR)

Class: 6.1 ICAO/IATA
Sub risk: None




UN/ID Number: 2811
Packing Group: II
Special provisions: A3

Shipping name: TOXIC, SOLID, ORGANIC N.O.S (Ondansetron hydrochloride dihydrate).

Maritime Transport IMDG:


IMDG Class: 6.1 IMDG
Sub risk: None

UN Number: 2811
Packing Group: II

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EMS Number: F-A, S-A Special provisions: 221

Shipping name: TOXIC, SOLID, ORGANIC N.O.S (Ondansetron hydrochloride dihydrate).

SECTION 15 – REGULATORY INFORMATION:



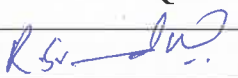
Ondansetron hydrochloride (CAS: 103639-04-9) is found on the following regulatory lists; This safety data sheet is in compliance with the following EU legislation and its adaptations- as far as applicable:

67/548/EEC, 1999/45/EC, 98/24/EC, 92/85/EEC, 94/33/EC, 91/689/EEC, 1999/13/EC, Regulation (EU) No

453/2010, Regulation (EC) No 1907/2006, Regulation (EC) No 1272/2008, and their amendments as well as British legislation.

SECTION 16 – OTHER INFORMATION:

The information provided in this Material Safety Data Sheet (MSDS) has been compiled from our experience and the data presented in various technical publications. It is the users responsibility to determine the suitability of this information for the adaptation of safety precautions as may be necessary. We reserve the right to revise the MSDS from time to time as new information becomes available. It is recommended that the user contact the company to make sure the MSDS in use is the latest one issued

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