

SAFETY DATA SHEET

According to Globally Harmonized System of Classification and Labelling of Chemicals (GHS),
Third Revised Edition UNITED NATIONS
New York and Geneva, 2019

VERAPAMIL HYDROCHLORIDE INJECTION USP, 5 mg/2 mL (2.5 mg/mL) VERAPAMIL HYDROCHLORIDE INJECTION USP, 10 mg/4 mL (2.5 mg/mL)

1. IDENTIFICATION

GHS Product identifier: Verapamil Hydrochloride Injection USP.

Product code: #

Chemical Description: 2-(3,4-dimethoxyphenyl)-5-[[2-(3,4-dimethoxyphenyl)ethyl](methyl)amino}-2-(propan-2-yl)pentanenitrile

Other means of identification: -

Recommended use: Verapamil is an L-type calcium channel blocker with antiarrhythmic, antianginal, and antihypertensive activity. Used in treatment of irregular heart beat or flutter

Restrictions on use: The product should be used only for the above-mentioned use and may not be used for any other purpose than stated above.

Manufactured by:

Mankind Pharma Ltd.,
Unit III, Opp. Dental College, Rampur Ghat,
Teh. -Paonta Sahib (HP-173025), India.
CIN No.: U74899DL1991PLC044843

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2. HAZARDS IDENTIFICATION

Classification

Globally Harmonized System, UN (GHS)

Classification	Category	Exposure Route
Reproductive toxicity	2	-

Labelling

Globally Harmonized System, UN GHS



Classification	
Signal Word	Warning
Hazard Statements:	H361 – Suspected of damaging fertility or the unborn child
Precautionary Statements:	P264: Wash hands thoroughly after handling. P272: Contaminated work clothing should not be allowed out of the Workplace. P273: Avoid release to the environment. P280: Wear protective gloves/protective clothing/eye protection/face Protection. P284: Wear respiratory protection. P305 + P351 + P338 If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing 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. P405: Store locked up.
Other hazards	Under fire conditions can emit toxic substances.

3. COMPOSITION / INFORMATION ON INGREDIENTS

Chemical nature: Mixture containing Verapamil HCl

Hazardous ingredients	CAS	Content
Verapamil Hydrochloride	152-11-4	2.5 mg/mL (0.25%)
Sodium chloride	7647-14-5	<1 %
Hydrochloric acid	7647-01-0	q.s.
Sodium hydroxide	1310-73-2	q.s.
Non-Hazardous ingredients		
Water for injection	7732-18-5	q.s.

4. FIRST-AID MEASURES

Inhalation

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

Skin contact

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

Eye contact

Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary

Ingestion

If this product is swallowed, CALL PHYSICIAN OR POISON CONTROL CENTRE. Rinse mouth with water
Never give anything by mouth to an unconscious person.

5. FIRE-FIGHTING MEASURES

Fire extinguishing agents

Use dry chemical powder or carbon dioxide or foam.

Fire/explosion hazard

None anticipated for this aqueous product.

Specific hazards arising from the chemical

Not known.

Personal protection

Self-contained breathing apparatus. Fire-fighters must wear self-contained breathing apparatus for firefighting if necessary

Special exposure hazards

Do not release chemically contaminated water into drains, soil, or surface water. Absorb liquid with suitable material. Clean affected area with soap and water. Dispose contaminated water and soil according to local regulations.

6. ACCIDENTAL RELEASE MEASURES

Personal protection

Wear respiratory protection. Avoid breathing vapors, mist or gas. Ensure adequate ventilation. Evacuate personnel to safe areas.

Environmental precautions

Prevent product from entering sewer or confined spaces, waterways, soil or public waters. Do not flush to sewer.

7. HANDLING AND STORAGE

Handling

Occupational hygiene

Avoid ingestion, inhalation, skin and eye contact. Handle in accordance with good industrial hygiene practice and any legal requirements.

Conditions for safe storage

No special storage required for hazard control. For product protection, follow storage recommendations noted on the product case label, the primary container label, or the insert.

Storage facilities

Store away from light, in a cool, dry area with adequate ventilation. Keep tightly closed.

Segregation

Store locked up.

Storage conditions

Light sensitive. Keep containers closed. Store at 25 °C

8. EXPOSURE CONTROLS AND PERSONAL PROTECTION

Exposure limit values

Components with occupational exposure limits

CAS No	Name	TWA
152-11-4	Verapamil HCl	Not known
7647-14-5	Sodium chloride	5 mg/m ³
7647-01-0	Hydrochloric acid	2 ppm

Occupational exposure controls

Appropriate engineering controls

Maintain air concentrations below occupational exposure standards. Prevent Spillage.

General Personal Protection

Goggles, gloves, protective clothing.

Respiratory protection

Where the neat active ingredient is weighed and diluted, wear a NIOSH-approved half face respirator equipped with an organic vapor/acid gas cartridge (specific for organic vapors, HCl, acid gas and SO₂) with a dust/mist filter. (NTP, 1992).

Hand protection

Protective gloves.

Eye 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 and body 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.

The selected protective gloves have to satisfy the specifications of EU Directive 89/686/EEC and the standard EN 374 derived from it.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance: Clear liquid

Form: Solution Injection

Colour: Colourless

Odour: Odourless

pH: 4 - 6.5

Melting point: Not applicable

Boiling point: Not applicable

Flash point: Not applicable

Flammability: Not applicable

Vapour pressure: Not tested

Auto-ignition temperature: Not tested

Decomposition temperature: Not tested

Density: : 1 gm/cm³

Solubility in water: Soluble

Solubility in solvents: Not tested

n-Octanol/Water Partition Coefficient: Not applicable

Viscosity: Not applicable

10. STABILITY AND REACTIVITY

Conditions to avoid

Verapamil HCl should be stored at room temperature & protected from light.

Materials to avoid

Incompatible with bases

Hazardous decomposition products

When heated to decomposition it may emit toxic fumes of nitrogen oxides and HCl.

11. TOXICOLOGICAL INFORMATION

Acute toxicity

Verapamil HCl active ingredient has been tested for acute toxicity.

LC₅₀: 16 and 5.8 mg/kg (rat and mouse respectively) Route: IV

LD₅₀: 150 mg/kg Route: oral Species: rat

LD₅₀: 163 mg/kg Route: oral Species: mouse

Hydrochloric acid LD₅₀ 238-277 mg/kg

Based on toxicity data of Verapamil and its excipients, mixture is not classifiable.

Primary Irritation

Skin irritation

Sodium chloride – rabbit – mild

Verapamil HCl – rabbit – mild

HCl – category 1A

Eye Irritation

Sodium chloride - rabbit – moderate

HCl – Category 1

Respiratory or Skin sensitization

Verapamil is not classifiable for respiratory or skin sensitization

CMR consideration:

Germ cell mutagenicity:

Not mutagenic. Mixture not classifiable.

Carcinogenicity

Verapamil HCl

2 Year(s) Rat Oral 120 mg/kg/day NOAEL

Not carcinogenic

Not classifiable as human carcinogen.

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.

Reproductive toxicity

Reproductive & Fertility Rat Oral 55 mg/kg/day NOAEL Fertility

Embryo / Fetal Development Rat Oral 60 mg/kg/day NOAEL Not Teratogenic

Embryo / Fetal Development Rat Oral 60 mg/kg/day LOAEL Fetotoxicity

Mixture is classified as Category 2 based on classification of active ingredient (cat. 2)

Specific target organ toxicity single exposure:

Mixture is not classifiable for STOT-SE

Specific target organ toxicity repeated exposure:

Due to lack of data the GHS classification is not possible.

Aspiration hazard:

GHS Classification is not possible.

12. ECOLOGICAL INFORMATION

Ecotoxicity

Verapamil Hydrochloride

Acute toxicity

Oncorhynchus mykiss (Rainbow Trout) LC₅₀ 96 Hours 2.72 mg/L

Daphnia magna (Water Flea) LC₅₀ 48 Hours 7.04 mg/L

Chronic toxicity

Pimephales promelas (Fathead Minnow) OECD 28 Day(s) NOEC 0.3 mg/L growth

Pimephales promelas (Fathead Minnow) OECD 28 Day(s) NOEC 0.6 mg/L Survival

Mixture is not classifiable owing to extremely low concentration of <1%

Persistence and degradability

Data not available.

Behaviour in treatment plants

Data not available. GHS Classification is not possible.

Additional information

Do not discharge product uncontrolled into the environment.

13. DISPOSAL CONSIDERATIONS

Product disposal

All waste materials must be properly characterized. Further, disposal should be performed in accordance with the federal, state or local regulatory requirements.

Contaminated packaging

Contaminated, empty containers must be disposed of as chemical waste.

14. TRANSPORT INFORMATION

DOT

Not regulated as dangerous goods.

IATA

Not regulated as dangerous goods.

IMDG

Not regulated as dangerous goods.

15. REGULATORY INFORMATION

CLASSIFICATION AND LABELLING

Compliance with following regulations:

- Globally Harmonized System of Classification and Labelling of Chemicals (GHS), UNECE 2019 as amended
- UN Recommendations on the Transport of Dangerous Goods, UNECE 2009

Note: *Medicinal products are exempt from the requirements of the EU Dangerous Preparations Directive.

*In the EU, classification under GHS/CLP does not apply to certain substances and mixtures, such as medicinal products as defined in Directive 2001/83/EC, which are in the finished state, intended for the final user.

16. OTHER INFORMATION

Recommended restrictions on use

This product should be stored, handled and used in accordance with good industrial hygiene practices and in conformity with any legal regulation. The information contained herein is based on the present state of our knowledge and is intended to describe our products from the point of view of safety requirements. It should not therefore be construed as guaranteeing specific properties.

MSDS Changes

Prepared on 10/06/2022