




MATERIAL SAFETY DATA SHEET

VERAPAMIL HYDROCHLORIDE INJECTION USP 2.5MG/ML

1. IDENTIFICATION

| | | | | | |
|--------------------------------|---|---|-------------------------|---|---|
| Material Identification | : | Verapamil Hydrochloride Injection USP 2.5mg/ml | | | |
| Active ingredient | : | .alpha.-[3-[[2-(3,4-dimethoxyphenyl)ethyl]methylamino]propyl]-3,4-dimethoxy-.alpha.-(1-methylethyl)-benzeneacetonitrile, monohydrochloride. | | | |
| Molecular Formula | : | C ₂₇ H ₃₈ N ₂ O ₄ . HCL | Molecular Weight | : | 491.07 g/mol |
| CAS Number | : | 152-11-4 | | | |
| Product Use | : | Indicated for the treatment of high blood pressure. | | | |
| Manufactured by | : | Micro Labs Limited Plot no. 113-116, KIADB, Bommasandra Industrial Area, Bommasandra-Jigani Link Road, Anekal taluk, Bangalore-560099, Karnataka, India | Manufactured for | : | Micro Labs USA Inc 106 Allen Road, Suite 102, Basking Ridge, New Jersey-07920, USA Tel:+1-908-484-7410 |
| Emergency Contact | : | +91-80-27839033 | | | |

2. HAZARDS IDENTIFICATION

| | | | | | |
|--|---|--|---|--|--|
| Label Elements | | | | | |
| Signal | : | Danger |  | | |
| Physical hazards | : | Not classified | | | |
| Classification of the substance | : | Acute toxicity, Oral (Category 3) | | | |
| Hazard statements | : | H301: Toxic if swallowed H311: Toxic if contact with skin H335: May cause respiratory irritation | | | |
| Precautionary statements | : | P261: Avoid breathing dust/ fume/ gas/ mist/ vapours/ spray. P280: Wear protective gloves/ protective clothing/eye protection/face protection. P301 + P310: IF SWALLOWED: Immediately call a POISON CENTER or doctor/ physician. P302+P352: IF ON SKIN: Wash with soap and water. P304-P340: IF INHALED: Remove victim to fresh air keep at rest in a position comfortable for breathing. P501: Dispose of contents/ container to an approved waste disposal plant. | | | |
| Hazard(s) not otherwise classified (HNOC) | : | None known. | | | |



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3. COMPOSITION/INFORMATION ON INGREDIENTS

| Material | % |
|-------------------------|--------|
| Verapamil Hydrochloride | 0.25% |
| Sodium Chloride | 0.85% |
| Hydrochloric acid | 0.02% |
| Sodium Hydroxide | 0.008% |

Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

4. FIRST AID MEASURES

| | | |
|---------------------|---|---|
| Eyes Contact | : | Immediately flush eyes with plenty of water while holding eyelids open for at least 15 minutes. Get medical attention immediately. |
| Skin Contact | : | Flush skin with plenty of water for at least 15 minutes. Remove the contaminated clothing. Get medical attention immediately. |
| Ingestion | : | Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Get medical attention immediately. |
| Inhalation | : | Move to fresh air. Do not use mouth-to-mouth methods if victim ingested or inhaled the substance; give artificial respiration with the aid of a pocket mask equipped with a one-way valve or other proper respiratory medical device. Immediate medical attention is required. If not breathing, give artificial respiration. |
| General information | : | Remove from exposure. Remove contaminated clothing. For treatment advice, get the guidance from an occupational health physician or other licensed health-care provider familiar with workplace chemical exposures. In the United States, the national poison control center phone number is 1-800-222-1222. If person is not breathing, give artificial respiration. If breathing is difficult, give oxygen if available. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention. |

5. FIRE FIGHTING MEASURES

| | | |
|--|---|---|
| Extinguishing media | : | In case of fire, use water, dry chemical, chemical foam, or alcohol-resistant foam. |
| General Information | | |
| As in any fire, wear a self-contained breathing apparatus in pressure-demand, MSHA/NIOSH approved or equivalent), and full protective gear. During a fire, irritating and highly toxic fumes such as oxides of nitrogen and chlorine gas may be generated by Hazardous Combustion. | | |



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6. ACCIDENTAL RELEASE MEASURES

Remove any ignition source. Wear protective clothing, gloves and goggles. Pick up without raising dust. Keep contaminated material tightly closed containers. Wash with water. Don't throw this substance in sewer or ground water.

| | | |
|---|---|---|
| Personal precautions, protective equipment and emergency procedures | : | Use personal protective equipment. Ensure adequate ventilation. Avoid dust formation. Keep people away from and upwind of spill/leak. Evacuate personnel to safe areas. |
| Environmental precautions | : | Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release. Do not let product enter drains. |
| Methods and material for containment and cleaning up | : | Contain the source of spill if it is safe to do so. Collect spilled material by a method that controls dust generation and transfer to a chemical waste container for disposal in accordance with local regulations. A damp cloth or a filtered vacuum should be used to clean spills of dry solids. Clean spill area thoroughly. |

7. HANDLING AND STORAGE

| | | |
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| Precautions for safe handling | : | Wear personal protective equipment. Avoid contact with skin, eyes and clothing. Use only in area provided with appropriate exhaust ventilation. Do not eat, drink or smoke when using this product. Remove and wash contaminated clothing before re-use. |
| Conditions for safe storage, including any incompatibilities | | |
| Storage conditions | : | Store at 20 ⁰ C to 25 ⁰ C (68 ⁰ F to 77 ⁰ F) [See USP Controlled Room Temperature]. Protect From Light By Retaining In Package Until Ready To Use. |
| Specific end use(s) | : | Pharmaceutical drug product for patients |

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

| | | |
|-------------------------------|---|--|
| Engineering Controls | : | Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits. Use process enclosure, local exhaust ventilation, or other engineering controls to control airborne levels. Ensure that eyewash stations and safety showers are close to the workstation location. |
| Personal Protective Equipment | : | Contact your safety and health professional or safety equipment supplier for assistance in selecting the correct protective clothing/equipment based on an assessment of the workplace conditions, other chemicals used or present in the workplace and specific operational processes. |



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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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|------------------------|---|---|
| Respiratory Protection | : | If airborne exposures are within or exceed the Occupational Exposure Band (OEB) range, wear an appropriate respirator with a protection factor sufficient to control exposures to the bottom of the OEB range. Wear a NIOSH/MSHA or European Standard EN 149 approved full-face piece airline respirator in the positive pressure mode with emergency escape provisions. |
| Hands | : | 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. |
| Eye Protection | : | Use equipment. Employee must wear Face shield and safety glasses for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU) to prevent the substance getting into eyes. Specific equipment must be available at the workplace: where contact between workers and the substance is possible, employer must have safety shower and eye bath available within the immediate work area for emergency use. |
| Skin 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. Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations. |

9. PHYSICAL AND CHEMICAL PROPERTIES

| | | |
|-------------------|---|---|
| Physical State | : | Injection |
| Color | : | Clear, colorless solution |
| Appearance | : | Verapamil Hydrochloride Injection USP, 2.5mg/mL: Clear, colorless solution, free from visible particles. |
| Molecular Formula | : | $C_{27}H_{38}N_2O_4$. HCL |
| Molecular Weight | : | 491.07 g/mol |

10. STABILITY AND REACTIVITY

| | | |
|------------------------|---|---|
| Reactivity | : | Stable under recommended storage conditions. |
| Conditions to Avoid | : | Fine particles, such as dust and mists, may fuel fires/explosions; excess heat. |
| Incompatible Materials | : | Strong oxidizing agents/bases. |



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11. TOXICOLOGICAL INFORMATION

| | |
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| Acute Toxicity | <p>Sodium chloride Rat Oral LD50 3000 mg/kg Mouse Oral LD50 4000 mg/kg</p> <p>Verapamil Hydrochloride Rat Oral LD 50 108 mg/kg Mouse Oral LD 50 163mg/kg Rat Intravenous LD 50 16mg/kg Mouse Intravenous LD 50 5795mg/kg Rat Subcutaneous LD 50 107mg/kg</p> <p>Hydrochloric Acid Rat Oral LD 50 238-277 mg/kg Ingestion Acute Toxicity May be harmful if swallowed</p> |
| Skin corrosion/Irritation | : None anticipated from normal handling of this product. |
| Serious Eye damage/irritation | : None anticipated from normal handling of this product. However, inadvertent contact of this product with eyes may produce irritation with redness and tearing. |
| Germ cell mutagenicity | <p>Verapamil Hydrochloride Bacterial Mutagenicity (Ames) Salmonella , E. coli – Negative</p> <p>Hydrochloric Acid Bacterial Mutagenicity (Ames) Salmonella - Negative In Vivo Micronucleus Rat - Negative</p> |
| Carcinogenicity | <p>Verapamil Hydrochloride Studies in rats using verapamil dosages of 6 times the recommended maximum human dosage for 18 months did not reveal evidence of carcinogenicity. There was no evidence of a carcinogenic potential of verapamil administered in the diet of rats for 2 years at dosages of 10, 35, and 120 mg/kg per day or approximately 1x, 3.5x, and 12x, respectively, the maximum recommended human daily dose (480 mg per day or 9.6 mg/kg/day).</p> <p>Hydrochloric Acid IARC: Group 3 (Not Classifiable)</p> |
| 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. |
| 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. |



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|------------------------|---|--|
| Reproductive toxicity: | : | <p>None anticipated from normal handling of this product. Studies in female rats at daily dietary doses up to 5.5 times (55 mg/kg/day) the maximum recommended human dose did not show impaired fertility. Effects on male fertility have not been determined.</p> <p>Reproduction studies have been performed in rabbits and rats at oral verapamil doses up to 1.5 (15 mg/kg/day) and 6 (60 mg/kg/day) times the human oral daily dose, respectively, and have revealed no evidence of teratogenicity. In the rat, this dose was embryocidal and retarded fetal growth and development, probably because of adverse maternal effects reflected in reduced weight gains of the dams. This oral dose has also been shown to cause hypotension in rats.</p> |
|------------------------|---|--|

12. ECOLOGICAL INFORMATION

| | | |
|-------------------------------|---|---|
| General Notes | : | Releases to the environment should be avoided. See Aquatic toxicity data of the active ingredient, below: |
| Toxicity: | : | <p>Aquatic Toxicity: (Species, Method, End Point, Duration, Result) Verapamil Hydrochloride: Oncorhynchus mykiss (Rainbow Trout) LC50 96 Hours 2.72 mg/L Daphnia magna (Water Flea) LC50 48 Hours 7.04 mg/L</p> <p>Chronic Aquatic Toxicity: (Species, Method, Duration, Endpoint, Result, Adverse Endpoint) Verapamil Hydrochloride: 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</p> |
| Persistence and degradability | : | Soluble in water Persistence is unlikely based on information available. |
| Bioaccumulative potential | : | <p>Partition Coefficient: (Method, pH, Endpoint, Value) Verapamil Hydrochloride Measured Log P 3.79</p> |
| Mobility in soil | : | Will likely be mobile in the environment due to its water solubility. |
| Results of PBT and vPvB | : | data not available |



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13. DISPOSAL CONSIDERATIONS

| | | |
|--------------------------------|---|---|
| Waste Treatment Methods | : | Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater. |
|--------------------------------|---|---|

14. TRANSPORTATION INFORMATION

| | | |
|------------------------------|---|-------------------|
| Environmental hazards | : | No data available |
| Special precautions for user | : | No data available |
| Transport hazard class(es) | : | No data available |
| Packing group | : | No data available |
| IATA UN number | : | No data available |
| Environmental hazards | : | No data available |
| Special precautions for user | : | No data available |

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

15. REGULATORY / STATUTORY INFORMATION

| | | |
|--|---|---------------|
| Seveso regulation (Directive 96/82/EC) | : | Not Available |
| Candidate list (art. 59-REACH): | : | Not Available |
| Ozone depletion substance (2000/2037/EC) | : | Not Available |
| Import/export dangerous chemical (2008/689/EC) | : | Not Available |



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16. OTHER INFORMATION

Date of preparation: 03-April-2019

The information contained in this Material Safety Data Sheet is believed to be accurate and represents the best information available at the time of preparation. However, no warranty, express or implied, with respect to such information, is made. The data in this Material Safety Data Sheet relate only to the specific material designated herein and does not relate to use in combination with any other material. The data in this Material Safety Data Sheet are subject to revision as additional knowledge and experience are gained.

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End of Safety Data Sheet