


SAFETY DATA SHEET

Date: 10/15/2019

Generic Name: Hydralazine Hydrochloride Tablets, USP 10 mg, 25 mg, 50 mg and 100 mg

Brand Equivalent: Hydralazine Hydrochloride Tablets

| SECTION 1: IDENTIFICATION | |
|--|---|
| Product Name | Hydralazine Hydrochloride Tablets, USP 10 mg, 25 mg, 50 mg and 100 mg |
| Active substance | Hydralazine Hydrochloride |
| Synonyms | N/A |
| Formula | C ₈ H ₈ N ₄ .HCl |
| Intended Use | vasodilator |
| Chemical Name | 1-hydrazinophthalazine monohydrochloride (or) Phthalazine, 1-hydrazino-, monohydrochloride. |
| How supplied | Orange, round tablets |
| Manufacturer Name & Address | ScieGen Pharmaceuticals, Inc. 89 Arkay drive, Hauppauge, NY 11788. |
| Telephone No. | 631-434-2723 |

| 2. HAZARDS IDENTIFICATION | |
|---|--|
| GHS-US Classification | H301 Acute toxicity, Oral (Category 3) H315 Skin irritation (Category 2) H319 Eye irritation (Category 2A) H335 Specific target organ toxicity - single exposure (Category 3), Respiratory system |
| GHS-US Labeling | Acute toxicity, oral Category 4 Skin corrosion/irritation Category 1 Serious eye damage/eye irritation Category 1 |
| OSHA hazard(s) | Not classified. |
| Symbol |  |
| Signal word | Danger |
| Hazard statements | Flammable. Irritant. This product, as supplied, is not an explosive. However, undiluted isosorbide dinitrate is explosive by percussion or excessive heat. Any separation of it from the diluent in this mixture, even in small amounts, is extremely hazardous. OSHA regulatory status: This product is considered hazardous under 29 CFR 1910.1200 (Hazard Communication). Hazard statement(s) H301 Toxic if swallowed. H315 Causes skin irritation. H319 Causes serious eye irritation. H335 May cause respiratory irritation. |
| Precautionary statements Prevention Response | Wash thoroughly after handling. Do not eat, drink or smoke when using this product. Wear protective gloves/protective clothing/eye protection/face protection. If swallowed: Call a poison center/doctor/medical professional/ if you feel unwell. If swallowed: Rinse mouth. Do NOT induce vomiting. If on skin (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower. If inhaled: Remove person to fresh air and keep comfortable for breathing. If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a poison center/doctor/medical professional. |
| Disposal | Dispose of contents/container to an approved disposal site. |

| 3. Composition/Information on ingredients | | |
|--|---------------|-----------------------------|
| Components | CAS-No | Concentration (%w/w) |
| Hydralazine Hydrochloride, USP | 304-20-1 | 17.86 |
| Microcrystalline Cellulose, NF (Avicel PH-102) | 9004-34-6 | * |
| Anhydrous Lactose, NF (SuperTab 21AN) | 63-42-3 | * |
| Sodium Starch Glycolate, NF Type A (Explotab) | 9063-38-1 | * |
| FD&C Yellow 6 Alum lake 17- 19% | NA | * |
| Stearic acid, NF (Parateck [®] LUB STA 50) | 57-11-4 | * |

| 4. FIRST AID MEASURES | |
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| Eye contact | Eye irritation. Flush immediately with large amounts of water for at least 15 minutes. Eyelids should be held away from the eyeball to ensure thorough rinsing. Get immediate medical attention. |
| Skin contact | Immediately flush the skin with plenty of water while removing contaminated clothing and shoes. Get immediate medical attention. Wash contaminated clothing before reuse. |
| Inhalation | Remove exposed person from source of exposure to fresh air. If not breathing, clear airway and start cardiopulmonary resuscitation (CPR). Avoid mouth-to-mouth resuscitation. |
| Ingestion | Get immediate medical attention. Do not induce vomiting unless directed by medical personnel. Never give anything by mouth to an unconscious person. Rinse mouth with water. |
| General information | Remove from exposure. Remove contaminated clothing. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention. If person is not breathing give artificial respiration. If breathing is difficult give oxygen. Obtain medical attention. |

| 5. FIRE-FIGHTING MEASURES | |
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| Suitable extinguishing media | Use dry chemical, alcohol-resistant foam, or carbon dioxide. |
| Fire Fighting Procedures: | Do not flush down sewers or other drainage systems. Exposed firefighters must wear NIOSH-approved positive pressure self-contained breathing apparatus with full-face mask and full protective clothing. |
| Conditions of flammability | Not flammable or combustible. |
| Combustion Products: | Irritating or toxic substances may be emitted upon thermal decomposition. Thermal decomposition products may include Carbon Oxides (CO, CO ₂) and Nitrogen Oxides (NO _x), Hydrogen Chloride Gas. |
| Flash Point | Not found. |
| Auto-Ignition Temperature | Not found. |
| Minimum explosive concentration for dust | Not found |

| 6. ACCIDENTAL RELEASE MEASURES | |
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| Personal precautions | Avoid dust formation. Avoid breathing vapors, mist or gas. |
| Environmental precautions | Do not let product enter drains. REFER TO SECTION 15 FOR SPILL/RELEASE REPORTING INFORMATION. |
| Spill/Clean-up | Isolate area to restrict unnecessary personnel. Put on suitable protective clothing and equipment. Collect spilled material with paper toweling or other absorbent material. For larger spills of material, use a scoop or shovel to collect spilled material into a labeled container for recovery or disposal. Clean area thoroughly using several washes with detergent and water. Treat product, and contaminated materials (including wash/rinse liquid) as hazardous waste and place in a suitable container for disposal. |

| 7. HANDLING AND STORAGE | |
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| Precautions for safe handling | Use with adequate ventilation. Avoid crushing tablets. If tablets are crushed, avoid contact with eye, skin and clothing. Minimize aerosol generation and avoid inhalation of material. Avoid prolonged or repeated exposure. Wash thoroughly after handling. Use gloves and protective clothing as recommended in Section 8. |
| Container Requirements | Store in sturdy containers appropriate to maintain the integrity of this material for its intended use. |
| Storage Conditions | Store at 25°C (77°F), excursions permitted to 15-30°C (59-86°F). [See USP Controlled Room Temperature.] Keep bottles tightly closed. |
| Specific use(s) | Pharmaceutical product |

| 8. Exposure controls/Personal protection | |
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| Engineering Controls | Local exhaust ventilation may be necessary to control air contaminants to their exposure limits. General room ventilation is adequate unless the process generates aerosol. If aerosol generation is probable, use appropriate ventilation such as a fume hood. |
| Respiratory Protection | Respiratory protection is not required under normal conditions. If exposure limits are exceeded, use type N95 (US) or type P1 (EN 143) dust masks. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU). |
| Eye protection | Wear chemical safety goggles and face shield. Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU). Have eye-wash stations available where eye contact can occur. |
| Hand protection | Chemically compatible gloves. For handling solutions, ensure that the glove material is Protective against the solvent being used. Use handling practices that minimize direct hand contact. Employees who are sensitive to natural rubber (latex) should use nitrile or other synthetic nonlatex gloves. Use of powdered latex gloves should be avoided due to the risk of latex allergy. This material is corrosive. To reduce the risk of contamination of skin and surfaces, wear two pairs of gloves. Remove the outer gloves after handling and cleanup of the material, and remove the inner gloves only after removing other personal protective equipment. |
| Skin and body Protection | Avoid skin contact. Wear gloves impervious to conditions of 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. |
| Environmental exposure controls | Prevent release to drains and waterways. |
| General hygiene considerations | Handle in accordance with good industrial hygiene and safety practice. |
| Thermal hazards | Not available |
| Other | For handling of laboratory scale quantities, a cloth lab coat is recommended. Where Significant quantities are handled, work clothing may be necessary to prevent take-home contamination. |

| 9. PHYSICAL AND CHEMICAL PROPERTIES | |
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| General Information | |
| <i>Appearance</i> | |
| Physical State | solid |
| Color | orange |
| Form | tablets |
| <i>Odour</i> | |
| Odour | Not available |
| Odor Threshold | Not available |
| pH | Not available |
| <i>Other information</i> | |
| Bulk density | Not available |
| Evaporation rate | Not available |
| Molecular formula | Not applicable |
| Hydrolysis/Photolysis | Not available |
| Hygroscopicity | Not available |
| Molecular Weight | Not applicable |
| Log Octanol/Water Partition Coeff [log Kow] | Not available |
| Surface Tension | Not available |
| pKa | Not available |
| Particle Size | Not available |
| Solubility, Water | very slightly soluble |
| Specific Gravity/ Relative Density | Not available |
| Viscosity, dynamic | Not available |
| Viscosity, kinematic | Not available |
| % Volatile | Not available |
| <i>Thermal/Stability properties</i> | |
| Autoignition temperature | Not available |
| Boiling Point | Not available |
| Thermal decomposition | Not available |
| Explosive Limits, LEL | Not available |
| Explosive limits, UEL | Not available |
| Explosiveness | Not available |
| Flammability | Not available |
| Flash point | Not available |
| Melting Point | Not available |
| Oxidizing Potential | Not available |
| <i>Vapor Properties</i> | |
| Vapor Density | Not available |
| Vapor Pressure | Not available |
| Saturated Vapor Concentration | Not available |

| 10. Stability and Reactivity | |
|---|---|
| stability | |
| Chemical Stability | Stable under normal conditions |
| Incompatibilities | Water, acids, alkalis, and strong oxidizers |
| Conditions of Reactivity | Heat, flames and sparks |
| Hazardous Decomposition products | Carbon oxides, nitrogen oxides, hydrogen chloride gas |
| Hazardous Polymerization | Not expected to polymerize. |

| 11. Toxicological Information | |
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| Routes of Entry | Ingestion, Inhalation, Eye contact, Skin contact |
| Eye Irritation | Mild irritating to eyes |
| Respiratory Irritation | Mild Respiratory Irritant |
| Acute Toxicity Study | Due to lack of data the classification is not possible |
| Repeated Dose Toxicity | Due to lack of data the classification is not possible |
| Genetic Toxicity | Due to lack of data the classification is not possible |
| Carcinogenicity | Due to lack of data the classification is not possible. This material is not considered to be a carcinogen by IARC, NTP, or OSHA |
| Reproductive Toxicity | Due to lack of data the classification is not possible |
| Developmental Toxicity | Due to lack of data the classification is not possible |
| Pharmacokinetics/Toxicokinetics | Due to lack of data the classification is not possible |
| Other Toxicity Information | Due to lack of data the classification is not possible |

| 12. Ecological Information | |
|--------------------------------------|--|
| Ecotoxicity | No ecotoxicity data noted for the ingredient(s). |
| Persistence and degradability | No data is available on the degradability of this product. |
| Bioaccumulative potential | Not available |
| Mobility in soil | Not available |
| Other adverse effects | Not available |

| 13. Disposal considerations | |
|---|--|
| Advice On Disposal And Packaging | Disposal should be in accordance with applicable regional, national and local laws and regulations. Local regulations may be more stringent than regional or national requirements. This information presented only applies to the material as supplied. |
| Other information | Disposal by incineration is recommended. |

| 14. Transport Information | |
|----------------------------------|---------------------|
| DOT (US) | Not dangerous goods |
| IMDG | Not dangerous goods |
| IATA | Not dangerous goods |

| 15. Regulatory Information |
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| This Section Contains Information relevant to compliance with other Federal and/or state laws. |

| 16. Other information | |
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| Recommended Restrictions for Use: | Not available |
| Prepared on | 10/15/2019 |
| Revision | 01 |
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