

Section 1: Identification

Common Name/Trade Name	HYDROXYZINE PAMOATE USP	
Supplier Information	Letco Medical, LLC 1316 Commerce Drive NW Decatur, AL 35601 1 (800) 239-5288 +1 (734) 843-4693	IN CASE OF EMERGENCY: Chemtrec 1 (800) 424-9300 (24 hours)
Product Synonym(s)	ethanol, 2-(2-(4-((4-chlorophenyl)phenylmethyl)-1-piperazinyl)ethoxy)-, compd. with 4-4'methylenebis (3-hydroxy-2-naphthalenecarboxylic acid) (1:1)	
Relevant Use(s) of Product	Manufacture or Compounding of Substances	

Section 2: Hazards Identification

Classification of Substance or Mixture	Acute toxicity, Oral (Category 4)	
Signal Word	Warning	
Hazard Statement(s)	H302	Harmful if swallowed
Pictogram(s)		
Precautionary Statement(s)	P264 P270 P301+P312 P330 P501	Wash hands thoroughly after handling. Do not eat, drink or smoke when using this product. IF SWALLOWED Call a POISON CENTER or doctor/physician if you feel unwell. Rinse mouth. Dispose of contents/container to an approved waste disposal plant.
Hazards Not Otherwise Classified	No data available	
Ingredient(s) with Unknown Toxicity	No data available	

Section 3: Composition/Information on Ingredients

Chemical Name	4-[[3-carboxy-2-hydroxynaphthalen-1-yl)methyl]-3-hydroxynaphthalene-2-carboxylic acid; 2-[2-[4-[(4-chlorophenyl)-phenylmethyl]piperazin-1-yl]ethoxy]ethanol
Common Name	Hydroxyzine Pamoate
CAS Number	10246-75-0
Impurities and/or Stabilizing Additives	No data available

Section 4: First Aid Measures

General Advice	Consult a physician. Show this safety data sheet to the doctor in attendance. Move out of dangerous area.
If Inhaled	Avoid breathing aerosols and dusts that may be generated from handling the product. Move the person from the exposed area to fresh air immediately. Get medical advice if adverse symptoms will appear or if the exposure was significantly long or intense.
In Case of Skin Contact	Remove contaminated clothes and shoes immediately. Wash affected area with soap or mild detergent and large amount of water until no evidence of substance remains (15-20 minutes). Get medical advice and show the label to the doctor.
In Case of Eye Contact	Wash thoroughly with water or saline. Keep the eyelids open during flushing. Consult your doctor and show the label in case of adverse effects.
If Swallowed	If swallowed, rinse mouth thoroughly with water if the person is conscious. Get immediately medical advice and show the label to the doctor.
Most Important Symptoms and Effects	Acute effects: Ingestion: harmful if swallowed. Exposure through inhalation: may cause irritation. Skin Contact: may cause irritation. Eye contact: may cause irritation. Delayed effects: There are no symptoms and delayed effects attributable to this substance. Indication of any immediate medical attention and special treatment needed: Medical monitoring: Not required on the basis of the classification of the substance. Antidotes, if known: There are no known antidotes. Contraindications: There are no contraindications. Immediate treatment at workplace: Not Required.

Section 5: Fire Fighting Measures

Suitable Extinguishing Media	Suitable: Water spray, CO ₂ , dry powder. Unsuitable: None
Special Hazards Arising From the Substance/Mixture	May produce toxic fumes of CO _x , NO _x , HCL
Special PPE and/or Precautions for Firefighters	Do not attempt to extinguish the fire without the use of self-contained breathing apparatus (SCBA) and appropriate protective clothing. Wear boots, gloves, eye and face protection, respirators, comply with relevant standards UNI for Italy and EN for Europe. Use the recommended devices in the best conditions of care based on the information reported in the previous subsection.

Section 6: Accidental Release Measures

Personal Precautions, Protective Equipment and Emergency Procedures	For non-emergency personnel: Eye: Wear appropriate protective equipment (see section 8). Skin: Wear full body protection clothing. Inhalation: In case of fire and explosion avoid breathing fumes and vapors. Use a self-contained breathing apparatus (SCBA) and appropriate protective clothing. the fumes can be eliminated by spraying with water. See also section 8. In case of accidental spilling (non in normal condition of use) the use of Personal Protection Equipment is always recommended. This PPE must be in accordance with EN criteria.
Methods and Materials Used for Containment	In case of accidental release in the environment avoid that the substance can reach drains, surface water and ground water. Limit leakages with earth or sand. Collect the product and send it to the incinerator. If necessary absorb it with inert material. After collection, rinse area and materials involved with water.
Cleanup Procedures	In case of accidental release in the environment avoid that the substance can reach drains, surface water and ground water. Limit leakages with earth or sand. Collect the product and send it to the incinerator. If necessary absorb it with inert material. After collection, rinse area and materials involved with water.

Section 7: Handling and Storage

Precautions for Safe Handling	Handle away from sparks and flames -sources of ignition. Handle in a well ventilated place. Avoid contact with incompatible materials. Wear suitable personal protective equipment (see section 8). Keep the mixture away from drains, surface or ground waters. Do not eat, drink, and smoke in the working areas. Wash hands after handling mixture. Remove contaminated clothing and protective equipment before entering eating areas.
Conditions for Safe Storage	Do not expose to temperatures exceeding 40°C, it could cause swelling of the container due to the development of gas. No containment procedure estimated. Store at room temperature (15-30°C). Below 40°C. Do not expose to direct sunlight. Do not store in humid environment. No containment procedure estimated.

Section 8: Exposure Controls/Personal Protection

Components with Workplace Control Parameters	Not present in the consulted databases. The measurements of the substance(s) in the workplace must be carried out in accordance with standardized methods described by EN guidances.
Appropriate Engineering Controls	The adoption of the most appropriate engineering controls is also based on the local Risk Assessment done by the employer in its workplace conditions (use of mixture), particularly when a standardized exposure scenario is not available (ingredients in the mixture are not yet REACH registered).
PPE - Eye/Face Protection	Safety goggles as for EN 166; facial shield
PPE - Skin Protection	Wear protective gloves for non classified substances. Gloves resistant to chemical agents as for the EN 374, parts 1, 2, e 3 and the European Directive 89/89/CEE for classified substances. The gloves material must be waterproof and stable against the mixture content. Select the glove material on the basis of the type of the material, typical or minimal breakdown times, permeability ranges, thickness.
PPE - Body Protection	Select the suitable protective equipment based on the activity of use and possible exposure. Wear gauntlets, boots, bodysuit and other devices in accordance with EN 14605 in case of sketches or EN 13982 in case of powders.
PPE - Respiratory Protection	When the risk evaluation foresees the need to use respirator devices with assisted ventilation, use a powder filter like P1, P2, and P3. Use only devices approved by the Competent Authorities such as NIOSH (USA) and CEN (EU).

Section 9: Physical and Chemical Properties

Appearance	Yellow powder.
Upper/Lower Flammability or Explosive Limits	Lower: 90 mg/L
Odor	Odorless
Vapor Pressure	Not present in the consulted databases
Odor Threshold	Not present in the consulted databases
Vapor Density	Not present in the consulted databases
pH	Not present in the consulted databases
Relative Density	Not present in the consulted databases
Melting Point/Freezing Point	>250°C
Solubility	Water solubility: Insoluble. Organic solvent solubility: Soluble in dimethylformamide.
Initial Boiling Point and Boiling Range	Not present in the consulted databases
Flash Point	Not present in the consulted databases
Evaporation Rate	Not present in the consulted databases
Flammability (Solid, Gas)	Not present in the consulted databases
Partition Coefficient	Not present in the consulted databases
Auto-Ignition Temperature	420°C
Decomposition Temperature	Not present in the consulted databases
Viscosity	Not present in the consulted databases

Section 10: Stability and Reactivity

Reactivity	Under normal operating conditions the substance is not considered reactive.
Chemical Stability	The substance is stable at the normal condition of temperature and pressure and if stored in closed containers in well ventilated and cool place.
Possibility of Hazardous Reactions	Possibility of an exothermic reaction: No. Possibility of a reaction releasing excessive pressure: No. Possible degradation with instable product formation: No
Conditions to Avoid	Do not expose to heat sources. Keep away from temperature above 40°C.
Incompatible Materials	Avoid contact with alkalis.
Hazardous Decomposition Products	If heated at high temperatures, decomposes releasing fumes and toxic gases of COx, NOx, HCL.

Section 11: Toxicological Information

Acute Toxicity - LD50 Oral	LD50 rat: 1740 mg/kg
Acute Toxicity - Inhalation	None present in the consulted databases
Acute Toxicity - Dermal	None present in the consulted databases
Acute Toxicity - Eye	No data available
Skin Corrosion/Irritation	None present in the consulted databases.
Serious Eye Damage/Irritation	Severe ocular lesion: None expected.
Respiratory or Skin Sensitization	None present in the consulted databases
Germ Cell Mutagenicity	None present in the consulted databases. Negative in the Ames test.
Carcinogenicity IARC	Not available studies. Not present in the NTP, IARC and OSHA lists.
Carcinogenicity ACGIH	Not available studies. Not present in the NTP, IARC and OSHA lists.
Carcinogenicity NTP	Not available studies. Not present in the NTP, IARC and OSHA lists.
Carcinogenicity OSHA	Not available studies. Not present in the NTP, IARC and OSHA lists.
Reproductive Toxicity	Studies in rats have shown that it causes fetal abnormalities at doses substantially above the human therapeutic range. RTECS number: QL2200000
Specific Target Organ Toxicity - Single Exposure	Not present in the consulted databases.
Specific Target Organ Toxicity - Repeated Exposure	Not present in the consulted databases.
Aspiration Hazard	Not present in the consulted databases.

Section 12: Ecological Information

Toxicity	No data available
Persistence and Degradability	Not present in the consulted databases.
Bio-accumulative Potential	Not present in the consulted databases. Log Pow (pred.) idrossizine: 2.82
Mobility in Soil	Not present in the consulted databases
Other Adverse Effects	Not present in the consulted databases

Section 13: Disposal Considerations

Waste Treatment Methods Product	Mixture wastes: Incineration. Contaminated packaging: Incineration. Recover if possible. Send to authorized disposal plants or for incineration under controlled conditions. Operate in compliance with local and national regulations.
Waste Treatment Methods Packaging	Mixture wastes: Incineration. Contaminated packaging: Incineration. Recover if possible. Send to authorized disposal plants or for incineration under controlled conditions. Operate in compliance with local and national regulations.
Special Precautions Landfill or Incinerations	No data available
Other Information	No data available

Section 14: Transport Information

UN Number	Not dangerous goods.
UN Proper Shipping Name	N/A
Transport Hazard Class(es)	N/A
Packaging Group	N/A
Environmental Hazards	N/A

Section 15: Regulatory Information

Safety, Health and Environmental regulation/legislation specific for the mixture of its ingredients: Council Directive 89/391/EEC of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work (Official Journal L 183, 29/06/1989 P. 0001-0008) and following amendment and national reinforcements. Council Directive 89/686 /EEC of 21 December 1989 on the approximation of the laws of the Member States relating to the personal protective equipment. Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work (fourteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) Official Journal L 131, 05/05/1998 P. 0011-0023.

Section 16: Other Information

Additional Information	N/A
Prepared By	Lisa Russell
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