SAFETY DATA SHEETS

This SDS packet was issued with item: 078946113

N/A



SAFETY DATA SHEET

In accordance with Regulation (EC) 1907/2006 as amended

SECTION 1. IDENTIFICATION OF THE SUBSTANCE AND OF THE COMPANY

1.1. Substance identifier

Substance name:	HYDROXYZINE PAMOATE
Other names (if available):	ethanol, 2-(2-(4-((4-chlorophenyl)phenylmethyl)-1-piperazinyl)ethoxy)-,
Sinonyms:	compd. with 4-4' methylenebis (3-hydroxy-2-naphtalenecarboxylic acid)
	(1:1)
CAS number	10246-75-0
IUPAC name (if CAS is not available)	4-[(3-carboxy-2-hydroxynaphthalen-1-yl)methyl]-3-hydroxynaphthalene-2-
	carboxylic acid; 2-[2-[4-[(4-chlorophenyl)-phenylmethyl]piperazin-1-
	yl]ethoxy]ethanol
REACH Pre/Registration number	Not applicable, the substance is exempted from registration

1.2. Relevant identified uses of the substance and uses advised against

Relevant use(s)	Active pharmaceutical ingredient for the preparation of drugs. Professional use only
Uses advised against	Different from above mentioned uses

1.3. Details of the supplier of the safety data sheet

Manufacturer/Distributor/Importer: COSMA SPA VIA COLLEONI 15/17 24040 CISERANO BG (ITALIA) TEL 0039-035- 883055 FAX 0039 -035-4820501. E-mail address of competent person responsible for the SDS: info@cosma.it

1.4. Emergency telephone number

Poison control centre – Niguarda Hospital, Milan: 0039 02 66101029 (24 hours) National centre for toxicological information, Poison control centre, Pavia: 0039 03 8224444 (24 hours)

SECTION 2 HAZARDS IDENTIFICATION

2.1 Classification of the substance

- Classification of the substance in accordance with Regulation (CE) n. 1272/2008:

Hazard class	Class code and hazard	Hazard statement	Hazard warning
	category		
Acute tossicity	Category 4	H302	Harmful if swallowed.
Main adverse effects			
Physico-chemical effects	No known physical / cł	nemical effects due to this su	bstance
Health effects	Adverse effects may in	Adverse effects may include drowsiness, dizziness, dry mouth, nose or throat and skin	
	rash.		
	Ingestion: harmful if swallowed.		
	Exposure through inhal	lation: may cause irritation.	
HVDROXVZINE PAMOAT	<u>י</u> ד		Issued on • November 2010



Skin Contact: may cause irritation. Eye contact: may cause irritation. Sensitization: No data found in the literature search carried out

No negative environmental impacts expected

Environmental effects See also sections from 9 to 12

2.2 Label elements

- Labelling in accordance with regulation n. 1272/2008/EC

Pictogram	GHS07
Warning	Warning
Hazard indication (H)) ^[1]	H302
	Harmful if swallowed
Safety statements (P) ^[1]	
- Prevention	P264
	P270
- Reaction	P301 + P312
	P330
- Storage	
- Disposal	P501

^[1] For the explanation of H and P statements: see Section 16

2.3 Other hazards (which do not results in the classification)

The substance satisfies the criteria - PBT - vPvB	e PBT YES NO X X
- Health hazards	Ingestion: harmful if swallowed. Exposure through inhalation: may cause irritation. Skin Contact: may cause irritation. Eye contact: may cause irritation
Environmental hazardsPhysico-chemical hazards	There are no known environmental hazards As with all dry powders it is advisable to perform the grounding of the equipment in contact with them in order to dissipate the static electricity potential. No smoking. The substance may emit toxic fumes in case of fire.
- Specific effects	Negative effects may include: drowsiness, dizziness, dry mouth, nose or throat and cutaneous rash. The product may cause allergic reaction if inhaled, swallowed or in contact with the skin.

SECTION 3 COMPOSITION/INFORMATION ON INGREDIENTS

Description

Name of the component	Hydroxyzine pamoate
Concentration	Pure substance



Structural formula	
Chemical formula	$C_{21}H_{27}ClN_2O_2$. $C_{23}H_{16}O_6$
Molecular weight	733.39
Substance with Community OEL	
CAS name	
CAS number	10246-75-0
IUPAC 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
EC number	233-582-1
Index number	
Impurity/ies (if classified)	Not know.
Additive/ies (if classified)	No additives.

SECTION 4 FIRST AID MEASURES

4.1 Description of the first aid measures		
- 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.	
- 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.	
- Ingestion	If swallowed, rinse mouth thoroughly with water if the person is conscious. Get immediately medical advice and show the label to the doctor.	
- Inhalation	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.	
4.2 Most important symp	toms and effects (acute and delayed)	
- Acute effects	Ingestion: harmful if swallowed. Exposure through inhalation: may cause irritation. Skin Contact: may cause irritation. Eve contact: may cause irritation	
- Delayed effects:	Not known	



4.3 Indication of any immediate medical attention and special treatment needed

- Medical monitoring:
- Not required on the basis of the classification of the substance There are no known antidotes.
- Antidotes, if known - Contraindications
- Immediate treatment at workplace

There are no known contraindications. Not known

SECTION 5 FIREFIGHTING MEASURES

5.1 Extinguishing media

- Suitable estinguishing media - Unsuitable estinguishing media

Water spray, CO₂, dry powder None

5.2 Special hazards arising from the substance

- Hazardous combustion products - Other special hazards	May produce toxic fumes of COx, NOx, HCl None
5.3 Advice fo firefighters	
- Technical actions for protection - Special protective equipmen firefighters	Do not attempt to extinguish the fire without the use of a self-contained breathing apparatus (SCBA) and appropriate protective clothing. <i>t</i> for 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 information reported in the previous subsection.

SECTION 6 ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

- For non-emergency personnel

- Wear appropriate protective equipment (see Section 8) - Eye
- Skin Wear full body protection clothing.

In case of fire and explosion avoid breathing fumes and vapors. Use a self-contained - Inhalation 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.

- For emergency responders: see section 8

- Eye Use special protective equipment
- Skin Use special protective equipment
- Inhalation Use special protective equipment

6.2 Environmental precautions

In case of accidental release in the environment avoid that the substance can reach drains, surface water and ground water.



6.3 Methods and material for containment and clearing up

- Containment procedures:
- Cleaning up procedures:

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.

6.4 Reference to other sections

See also section 8 and 13

SECTION 7 HANDLING AND STORAGE

7.1. Precautions for safe handling

- Recommandation for handling:	Handle away from sparkles and flames - sources of ignition Handle in a well ventilated place
	Avoid contact with incompatible materials
	Wear suitable Personal Protection Equipment (see section 8)
	Keep the substance away from drains, surface or ground waters
- Recommandation for personal hygiene:	Do note eat, drink and smoke in the working areas
<i>J</i> 1 <i>J G</i>	Wash hands after handling the substance
	Remove contaminated clothing and protective equipment before entering eating
	areas

7.2. Condition for safe storage including any incompatibilities

The risk management procedures described in this section are consistent with the physical and chemical properties reported in section 9.

The substance is not classified for any physical and chemical properties and no risk management is foreseen.

Risk Management measures related to :

- *Explosive atmosphere:* Organic powder, can cause explosive mixtures when finely dispersed air. Avoid the formation of clouds and deposits (layer accumulations) with any suitable device.

Procedure to control other effects

- Weather conditions:	Do not expose to direct sunlight.
- Ambient pressure:	Not applicable
- Humidity	Protect from moisture.
- Vibration:	Not applicable

The adoption of the Risk Management procedure related to the physical and chemical properties is also based on the local Risk Assessment done by the employer in its workplace conditions (use of the substance), particularly when a standardized exposure scenario is not available.

Material to keep the integrity of the substance

- Stabilisers/antioxidants: Use of stabilizers not expected.

Other advice	
- Ventilation requirements	Provide adequate ventilation
- Specific design of storage rooms	Not requested on the basis of the classification
- Quantity limits for storage	Not requested on the basis of the classification
- Packaging compatibilities	See also 10.5

7.3. Specific end use(s)

- Recommendation for specific final use(s)



	YES	NO
- Exposure scenario attached		Х
- Chemical Safety Assessment (CSA) attached		Х
- Industry or sector specific guidance available and attached		Х

SECTION 8 EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters

- National/European Occupational Exposure	Not present in the data bases consulted.
Limits	•
- Other National/European Occupational	Not present in the data bases consulted.
Exposure Limits	
- National/European Biological Limits (BEI):	Not present in the data bases consulted.
- Other National/European Biological Limits	Not present in the data bases consulted.
(BEI):	•
- Recommended monitoring procedures	The measurements of the substance/s) in the workplace must be carried out
	in accordance with standardized methods described by EN guidances.
- DNEL values (components)	Not present in the data bases consulted.
- PNEC values (components)	Not present in the data bases consulted.

8.2. Exposure controls

	YES	NO
- Exposure scenario attached		Х
- Chemical Safety Assessment (CSA) attached		Х

8.2.1. 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 the substance), particularly when a standardized exposure scenario is not available.

8.2.2. Individual protection measures, such as Personal Protective Equipment (PPE)

The adoption of the most appropriate Personal Protective Equipment is also based on the local Risk Assessment done by the employer in its workplace conditions (use of the substance), particularly when a standardized exposure scenario is not available.

If the results of such risk evaluation done in accordance with Directive 98/24/EEC showed that the collective and general risk management measures are not sufficient to reduce the risks and, if the exposure to the substance cannot be reduce by other containment means, appropriate PPE must be adopted in compliance with technical EN guidance indication.

a) Eye and Face protectionb) Skin protection	Safety goggles as for EN 166; facial shield
- hands protection	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 substance content.
	Select the glove material on the basis of the type of the material, typical or minimal
	breakdown times, permeability ranges, thickness.
	Penetration time of glove material: the exact break through time has to be found out
	by the manufacturer of the protective gloves and must be observed.
- other, 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
c) 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)
	For your information powders are divide in three categories :



2a (inert powder with TLV= 10 mg/m3),
2b (hazards powders with TLV = 0,1-10 mg/m3 (excluding asbestos),
2c (toxic powders with TLV < 0,1 mg/m3 (asbestos, carcinogens, bacteria, viruses, enzymes, spores, etc).
Cat. 2a: P1 filter, Cat. 2b: P2 filter, Cat.2c: P3 filter
Not foreseen in the standard use.
Assess possible Personal Protection Equipment on the basis of specific uses of the substance.

d) Thermal hazards

8.2.3 Environmental exposure controls

	YES	NO
- Exposure scenario attached		Х
- Chemical Safety Assessment (CSA) attached		Х

SECTION 9 PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

Appearance:	Yellow powder.
Odor:	Odorless.
Melting point/freezing point:	>250°C
Lower flammability or explosive limits	90 mg / L
Water solubility:	Insoluble.
Organic solvent solubility:	Soluble in dimethylformamide.
Partition coefficient Octonol/water (Log	Log Pow (hydroxyzine): 2.82 (pred. consensus Pharma Algorithm,
Kow):	EPIsuite)
Auto-ignition temperature:	420 ° C
Odour threshold/pH/Initial boiling point and	boiling range/Flash point/Evaporation rate/Flammability (solids,
gas)/Vapour pressure/Vapour density/Relative d	lensity/Decomposition temperature/Viscosity/Explosive properties/
Oxidising properties: not present in the data bases of	consulted
9.2. Other information	

Resistivity:	5,60 · 10	¹⁵ ohm∙cm
MIE (Minimum Ignition Energy) :	45 mJ	(L=0 mH)
	24 mJ	(L=1 mH)

SECTION 10 STABILITY AND REACTIVITY

10.1. Reactivity

Under normal operating conditions the substance is not considered reactive.

10.2. 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.

- Stabilisers:

NO	YES	Used stabiliser
X		
Х		

NO

Х

Х

Х

YES

10.3. Possibility of hazardous reactions

- Change in physical appearance

- Possibility of an exothermic reaction:

- Possibility of a reaction re leasing excessive pressure

- Possible degradation with instable product formation



10.4. Condition to avoid

Do not expose to heat sources.

10.5. Incompatible materials

Avoid contact with alkalis.

10.6. hazardous decomposition products

If heated at high temperatures, decomposes re leasing fumes and toxic gases of COx, NOx, HCl.

SECTION 11 INFORMATION ON TOXICOLOGICAL EFFECTS

- Exposure routes:

- Inhalation:
- Ingestion:
- Skin contact:
- Eye contact:

NO

- Effects (acute, delayed, chronic) following the exposure (short and/or prolonged):

- Inhalation: It may cause irritation.
- Ingestion: Harmful if swallowed
- Skin contact: It may cause irritation
- *Eye contact:* It may cause irritation

- Toxico-kinetics information (ADME = Adsorption, Distribution, Metabolism, Excretion):

The product is rapidly absorbed from the gastrointestinal tract; its onset of action is within 15 or 60 minutes, and its duration of action is 4 to 6 hours.

- Acute toxicity effects:

- Oral::	LD50 rat: 1740 mg/kg $^{(1)}$	
- Dermal:	Not present in the data bases consulted.	
- Inhalation:	Not present in the data bases consulted.	
- Other effects:	Not present in the data bases consulted.	
- Corrosion/Irritation effects:	Not present in the data bases consulted.	
- Severe ocular lesion :	Not present in the data bases consulted.	
- Sensitisation:	-	
- Dermal:	Not present in the data bases consulted.	
- Respisratory:	Not present in the data bases consulted.	

- **Repeated dose toxicity (experimental.):** clinical effects from repeated administration studies are not reported. NOAEL not available.

- CMR effects:

Mutagenicity
Germinal cell mutagenicity
Carcinogenicity:
Reproductive toxicity:
AMES test: negative (hydroxyzine, pred. ACD/ToxSuite, Leadscope)
Not present in the data bases consulted.
Not available studies. Not present in the NTP, IARC and OSHA lists.
Studies in rats have shown that it causes fetal abnormalities at doses substantially above the human therapeutic range.

Specific Target Organ Toxicity (STOT)-single exposure: Not present in the data bases consulted.
Specific Target Organ Toxicity (STOT)- repeated exposure : Not present in the data bases consulted.



- Aspiration hazards:

- Not present in the data bases consulted.
- Epidemiological information:
- Not present in the data bases consulted.

- Other information

Not present in the data bases consulted.

- Reasons for the lack of classification:

Where the substance resulted non classified, this may be due to the availability of data which does not impose a classification for that specific end-point, or due to lack of data, or due to availability of inconclusive data or data which are not sufficient to get a classification as for the criteria adopted in Directives mentioned in this data sheet.

SECTION 12 ECOLOGICAL INFORMATION

12.1. Toxicity

- Acute toxicity on Daphnia magna (48 hours) idrossizine:

LC50: 4,34 mg / 1 (pred. ECOSAR)

12.2. Persistence and degradability

Not present in the data bases consulted.

12.3. Bioaccumulative potential

Log Pow (hydroxyzine): 2.82 (pred. consensus Pharma Algorithm, EPIsuite)

12.4. Mobility in soil

Not present in the data bases consulted.

12.5. Results of PBT e vPvB assessment

Based on the available information the substance does not satisfy the criteria to be considered a PBT or vPvB.

12.6. Other adverse effects

Not present in the data bases consulted

SECTION 13 DISPOSAL CONSIDERATION

13.1. Waste treatment methods

- Substance wastes:

- Contaminated packaging:

Incineration	Recycling	Landfilling
Х		
Х		

Recover if possible. Send to authorized disposal plants or for incineration under controlled conditions. Operate in compliance with local and national regulations.

SECTION 14 TRANSPORT INFORMATION

Special provision for transport: not applicable.



SECTION 15 REGULATORY INFORMATION

In this section, all other information on regulation are reported if not provided in other sections/subsection of the Safety Data Sheet.

15.1 Safety, Health and Environmental regulation/legislation specific for the substance or 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

15.2. Chemical Safety Assessment

- Exposure scenario attached
- Chemical Safety Assessment (CSA) attached

/ES	NO
	Х
	Х

SECTION 16 OTHER INFORMATION

Revisions:

- Edition n. 01 November 2010
- Revision n. 01 October 2011
- Revision n. 02 June 2015
- Revision n. 03 June 2020

Acronyms

- ACGIH: American Conference of Governmental Industrial Hygienists
- ADR: Agreement concerning the carriage of dangerous goods by Road
- BCF: Bioaccumulative factor
- BEI : Biological Esposure Indices (Indici di esposizione biologica)
- CAS: Chemical Abstract Service (division of the American Chemical Society
- CHETAH : Computer programme for chemical termodynamics and energy release evaluation
- CLP: Classification, Labelling and Packaging
- CMR: Carcinogens, Mutagens, Toxic for re production substances
- EINECS: European Inventory of existing Commercial Substances
- EPA: US Environmental Protection Agency
- GHS: Globally Harmonised System
- IARC: International Agency for Research on Cancer
- IATA: International Air Transport Association Code
- IMDG: International Maritime Dangerous Goods Code
- IUPAC: International Union of Pure and Applied Chemistry
- LOEL: Lowest Observed Effect Level
- N.A.: Not Applicable
- N.A.: Not Available
- NOAEL: No Observed Adverse Effect Level)
- NTP: National Toxicology Program
- OEL: Occupational Exposure Limit
- OSHA: Occupational Safety and Health Administration
- PPE : Personal protective Equipment



- PBT: Persistent, Bioaccumulative and Toxic substances
- RID: Regulation concerning the International carriage of Dangerous goods by rail
- TLV/TWA: Threshold Limit Value/Threshold Weighted Average
- vPvB: very Persistent, very Bioaccumulative
- DNEL: Derived No-Effect Level (REACH)
- PNEC: Predicted No-Effect Concentration (REACH)
- LD₅₀: Lethal Dose, 50 percent
- EC₅₀: Half maximal Effective Concentration

Bibliography:

RTECS, (10/99) (1) reference standard USP Conv MSDS.

Information related to the regulation CE/1272/2008

H302	Harmful if swallowed
P264	Wash hands thoroughly after handling.
P270	Do not eat, drink or smoke when using this product.
P301 + P312	IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell
P330 P501	Rinse mouth Dispose of content in accordance to local, regional and national regulation

Information on workers training

Follow criteria of Directive 98/24/CE, its amendments and National reinforcements

Restriction of use : none

Substance under authorisation : no

DISCLAIMER

This document aims to provide guidance for appropriate handling and precaution of this product by qualified personnel or operating under the supervision of personnel trained in handling chemicals. The product should not be used for purposes other than those mentioned in section 1, unless they are given adequate written information received on how to handle the material. The provider of this document can not provide any warnings about the dangers of ' use or interaction with other chemicals or materials. And 'the user's safe use of the product, the product suitability for the purpose for which it is applied and proper disposal. The information below should not be considered a declaration or guarantee, either expressed or implied, of merchantability, fitness for a particular purpose, quality, or any other. The information contained in this SDS are in accordance with Regulation (EC) 1907/2006, as modified by Regulation (EU) 2015/830