



Safety Data Sheet dated 18/6/2018, version 7

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Identification of the substance:

Trade name: ISOXSUPRINE HYDROCHLORIDE
Trade code: RGR 921
CAS number: 579-56-6
EC number: 209-443-6

Exempt from REACH regulation since this is API.

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

Recommended use:

Pharmaceutical use only.

Uses advised against:

Only those applications listed in the recommended uses.

1.3. Details of the supplier of the safety data sheet

Company:

ERREGIERRE S.p.A.
Via Francesco Baracca, 19
24060 San Paolo d'Argon (BG) Italia
Tel +39.035.958383
Fax +39.035.958165
(Mon-Fri 8:00 - 17:00)

Competent person responsible for the safety data sheet:

msds@erregierre.it



1.4. Emergency telephone number

Tel +39.035.958383
Fax +39.035.958165
(Mon-Fri 8:00 - 17:00)

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

EC regulation criteria 1272/2008 (CLP)

 Warning, Acute Tox. 4, Harmful if swallowed. Warning, STOT SE 3, May cause respiratory irritation.

Adverse physicochemical, human health and environmental effects:

No other hazards

2.2. Label elements

Hazard pictograms:



Warning

Hazard statements:

H302 Harmful if swallowed.
H335 May cause respiratory irritation.

Precautionary statements:

P261 Avoid breathing dust or mist.
P264 Wash hands thoroughly after handling.

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P270 Do not eat, drink or smoke when using this product.

P271 Use only outdoors or in a well-ventilated area.

P312 Call a POISON CENTER/doctor/... if you feel unwell.

P501 Dispose of contents/container in accordance with applicable regulations.

Special Provisions:

None

Contains

4-Hydroxy- α -[1-[(1-methyl-2-phenoxyethyl)amino]ethyl]benzenemethanol Hydrochloride

Special provisions according to Annex XVII of REACH and subsequent amendments:

None

2.3. Other hazards

vPvB Substances: None - PBT Substances: None

Other Hazards:

Finely dispersed powders form explosive atmospheres in the air. Evaporate the formation of dusty clouds.

SECTION 3: Composition/information on ingredients

3.1. Substances

Identification of the substance:

Chemical characterization:

4-Hydroxy- α -[1-[(1-methyl-2-phenoxyethyl)amino]ethyl]benzenemethanol Hydrochloride



Trade code: RGR 921

Pharmaceutical category: Peripheral vasodilator

Formula: $C_{18}H_{23}NO_3 \times HCl$

CAS number: 579-56-6

EC number: 209-443-6

Qty	Name	Ident. Number	Classification
>= 99%	4-Hydroxy- α -[1-[(1-methyl-2-phenoxyethyl)amino]ethyl]benzenemethanol Hydrochloride	CAS: 579-56-6 EC: 209-443-6	 3.1/4/Oral Acute Tox. 4 H302  3.8/3 STOT SE 3 H335

3.2. Mixtures

N.A.

SECTION 4: First aid measures

4.1. Description of first aid measures

In case of skin contact:

Wash with soap and water and contact a doctor if necessary.

In case of eyes contact:

Rinse thoroughly with plenty of water for at least 15 minutes and seek medical advice if necessary.

In case of Ingestion:

Give nothing to eat or drink.

Do not under any circumstances induce vomiting. OBTAIN A MEDICAL EXAMINATION IMMEDIATELY.

In case of Inhalation:

In case of inhalation remove the person to fresh air. If no breathing give artificial respiration. Consult a doctor.

4.2. Most important symptoms and effects, both acute and delayed

None

4.3. Indication of any immediate medical attention and special treatment needed

In case of accident or unwellness, seek medical advice immediately (show directions for use or safety data sheet if possible).

Treatment:

In the event of a medical consultation show this safety data sheet.

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SECTION 5: Firefighting measures

- 5.1. Extinguishing media
 - Suitable extinguishing media:
Use water, inert powder or foam.
Carbon dioxide (CO₂).
 - Extinguishing media which must not be used for safety reasons:
None in particular.
 - 5.2. Special hazards arising from the substance or mixture
 - Do not inhale explosion and combustion gases.
 - 5.3. Advice for firefighters
 - If necessary wear breath protection equipment with independent air supply.
 - Collect contaminated fire extinguishing water separately. This must not be discharged into drains.
 - Move undamaged containers from immediate hazard area if it can be done safely.
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SECTION 6: Accidental release measures

- 6.1. Personal precautions, protective equipment and emergency procedures
 - Wear personal protection equipment (mask with P3 universal filter, gloves and appropriate protective clothing).
 - See protective measures under point 7 and 8.
 - 6.2. Environmental precautions
 - Do not allow to enter into soil/subsoil. Do not allow to enter into surface water or drains.
 - Retain contaminated washing water and dispose it.
 - In case of gas escape or of entry into waterways, soil or drains, inform the responsible authorities.
 - Suitable material for taking up: Take up mechanically or by suction in a closed container and labeled, using appropriate means.
 - 6.3. Methods and material for containment and cleaning up
 - Wash with plenty of water.
 - 6.4. Reference to other sections
 - See also section 8 and 13
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SECTION 7: Handling and storage

- 7.1. Precautions for safe handling
 - Avoid contact with skin and eyes, inhalation of dust and any vapors or mists.
 - Don't use empty container before they have been cleaned.
 - Before making transfer operations, assure that there aren't any incompatible material residuals in the containers.
 - Do not eat or drink while working. Wash thoroughly after handling.
 - See also section 8 for recommended protective equipment.
- 7.2. Conditions for safe storage, including any incompatibilities
 - Keep away from food, drink and feed.
 - Incompatible materials:
None in particular.
 - Instructions as regards storage premises:
Adequately ventilated premises.
Store at room temperature in well-closed containers.
- 7.3. Specific end use(s)
 - None in particular

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SECTION 8: Exposure controls/personal protection

8.1. Control parameters

No occupational exposure limit available

DNEL Exposure Limit Values

N.A.

PNEC Exposure Limit Values

N.A.

8.2. Exposure controls

Eye protection:

Wear safety goggles in accordance with EN 166.

Protection for skin:

Wear protective clothing according to EN 13982-1.

Protection for hands:

Wear protective gloves according to EN 374.

Respiratory protection:

Use PPE for respiratory protection in case of formation of dust according to EN 529/2005 EC.

Thermal Hazards:

None

Environmental exposure controls:

None

Appropriate engineering controls:

None

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Properties	Value	Method:	Notes
Appearance:	Crystalline powder	--	--
Colour:	White	--	--
Odour:	N.A.	--	--
Odour threshold:	N.A.	--	--
pH:	N.A.	--	--
Melting point / freezing point:	200 ° C	--	--
Initial boiling point and boiling range:	N.A.	--	--
Flash point:	N.A.	--	--
Evaporation rate:	N.A.	--	--
Solid/gas flammability:	N.A.	--	--
Upper/lower flammability or explosive limits:	30 mg/l	--	Lower limit
Vapour pressure:	N.A.	--	--
Vapour density:	N.A.	--	--
Relative density:	0.5 g/ml	--	--
Solubility in water:	Slightly soluble in water	--	--
Solubility in oil:	N.A.	--	--
Partition coefficient (n-octanol/water):	N.A.	--	--
Auto-ignition temperature:	520 °C	--	--

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Decomposition temperature:	N.A.	--	--
Viscosity:	N.A.	--	--
Explosive properties:	kSt=34.85	--	--
Oxidizing properties:	N.A.	--	--

9.2. Other information

Properties	Value	Method:	Notes
Miscibility:	N.A.	--	--
Fat Solubility:	N.A.	--	--
Conductivity:	N.A.	--	--
Substance Groups relevant properties	N.A.	--	--

SECTION 10: Stability and reactivity

10.1. Reactivity

Material is stable from a safety point of view. No decomposition occurs when stored and handled correctly.

10.2. Chemical stability

Stable under normal conditions

10.3. Possibility of hazardous reactions

No hazardous reaction occurs when correctly used.

10.4. Conditions to avoid

Stable under normal conditions, when stored and handled correctly.

10.5. Incompatible materials

No information available.

10.6. Hazardous decomposition products

When heated to decomposition very toxic fumes of NO_x and HCl are produced

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Toxicological information of the product:

4-Hydroxy-a-[1-[(1-methyl-2-phenoxyethyl)amino]ethyl]benzenemethanol Hydrochloride -
CAS: 579-56-6

a) acute toxicity

The product is classified: Acute Tox. 4 H302

b) skin corrosion/irritation

Not classified

Based on available data, the classification criteria are not met

c) serious eye damage/irritation

Not classified

Based on available data, the classification criteria are not met

d) respiratory or skin sensitisation

Not classified

Based on available data, the classification criteria are not met

e) germ cell mutagenicity

Not classified

Based on available data, the classification criteria are not met

f) carcinogenicity

Not classified

Based on available data, the classification criteria are not met

g) reproductive toxicity

Not classified

Based on available data, the classification criteria are not met

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h) STOT-single exposure

The product is classified: STOT SE 3 H335

i) STOT-repeated exposure

Not classified

Based on available data, the classification criteria are not met

j) aspiration hazard

Not classified

Based on available data, the classification criteria are not met

Toxicological information of the main substances found in the product:

4-Hydroxy-a-[1-[(1-methyl-2-phenoxyethyl)amino]ethyl]benzenemethanol Hydrochloride -

CAS: 579-56-6

a) acute toxicity:

Test: LD50 - Route: Oral - Species: Rat = 1750 mg/kg

SECTION 12: Ecological information

12.1. Toxicity

Adopt good working practices, so that the product is not released into the environment.

4-Hydroxy-a-[1-[(1-methyl-2-phenoxyethyl)amino]ethyl]benzenemethanol Hydrochloride - CAS: 579-56-6

Not classified for environmental hazards

Based on available data, the classification criteria are not met

12.2. Persistence and degradability

N.A.

12.3. Bioaccumulative potential

N.A.

12.4. Mobility in soil

N.A.

12.5. Results of PBT and vPvB assessment

vPvB Substances: None - PBT Substances: None

12.6. Other adverse effects

None

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Product: Comply with all federal, state and local regulations on environmental protection. To dispose this product, contact an authorized company for waste disposal.

Containers contaminated: Dispose as unused product.

SECTION 14: Transport information

14.1. UN number

Not classified as dangerous in the meaning of transport regulations.

14.2. UN proper shipping name

N.A.

14.3. Transport hazard class(es)

N.A.

14.4. Packing group

N.A.

14.5. Environmental hazards

ADR-Environmental Pollutant: No

IMDG-Marine pollutant: No

14.6. Special precautions for user

N.A.

14.7. Transport in bulk according to Annex II of Marpol and the IBC Code

N.A.

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SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture
 Dir. 98/24/EC (Risks related to chemical agents at work)
 Dir. 2000/39/EC (Occupational exposure limit values)
 Regulation (EC) n. 1907/2006 (REACH)
 Regulation (EC) n. 1272/2008 (CLP)
 Regulation (EC) n. 790/2009 (ATP 1 CLP) and (EU) n. 758/2013
 Regulation (EU) 2015/830
 Regulation (EU) n. 286/2011 (ATP 2 CLP)
 Regulation (EU) n. 618/2012 (ATP 3 CLP)
 Regulation (EU) n. 487/2013 (ATP 4 CLP)
 Regulation (EU) n. 944/2013 (ATP 5 CLP)
 Regulation (EU) n. 605/2014 (ATP 6 CLP)
 Regulation (EU) n. 2015/1221 (ATP 7 CLP)
 Regulation (EU) n. 2016/918 (ATP 8 CLP)
 Regulation (EU) n. 2016/1179 (ATP 9 CLP)

Restrictions related to the product or the substances contained according to Annex XVII Regulation (EC) 1907/2006 (REACH) and subsequent modifications:

Restrictions related to the product:

No restriction.

Restrictions related to the substances contained:

No restriction.

Where applicable, refer to the following regulatory provisions :

Directive 2012/18/EU (Seveso III)

Regulation (EC) nr 648/2004 (detergents).

Dir. 2004/42/EC (VOC directive)

Provisions related to directive EU 2012/18 (Seveso III):

Seveso III category according to Annex 1, part 1

None

15.2. Chemical safety assessment

Was not carried out the chemical safety assessment of this substance.

A Chemical Safety Assessment has been carried out for the mixture.

SECTION 16: Other information

Full text of phrases referred to in Section 3:

H302 Harmful if swallowed.

H335 May cause respiratory irritation.

Hazard class and hazard category	Code	Description
Acute Tox. 4	3.1/4/Oral	Acute toxicity (oral), Category 4
STOT SE 3	3.8/3	Specific target organ toxicity - single exposure, Category 3

Classification and procedure used to derive the classification for mixtures according to Regulation (EC) 1272/2008 [CLP]:

Classification according to Regulation (EC) Nr. 1272/2008	Classification procedure
Acute Tox. 4, H302	Calculation method
STOT SE 3, H335	Calculation method

This document was prepared by a competent person who has received appropriate training.

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Main bibliographic sources:

ECDIN - Environmental Chemicals Data and Information Network - Joint Research Centre,
Commission of the European Communities
SAX's DANGEROUS PROPERTIES OF INDUSTRIAL MATERIALS - Eight Edition - Van
Nostrand Reinold

The information contained herein is based on our state of knowledge at the above-specified date. It refers solely to the product indicated and constitutes no guarantee of particular quality.

It is the duty of the user to ensure that this information is appropriate and complete with respect to the specific use intended.

This MSDS cancels and replaces any preceding release.

ADR:	European Agreement concerning the International Carriage of Dangerous Goods by Road.
CAS:	Chemical Abstracts Service (division of the American Chemical Society).
CLP:	Classification, Labeling, Packaging.
DNEL:	Derived No Effect Level.
EINECS:	European Inventory of Existing Commercial Chemical Substances.
GefStoffVO:	Ordinance on Hazardous Substances, Germany.
GHS:	Globally Harmonized System of Classification and Labeling of Chemicals.
IATA:	International Air Transport Association.
IATA-DGR:	Dangerous Goods Regulation by the "International Air Transport Association" (IATA).
ICAO:	International Civil Aviation Organization.
ICAO-TI:	Technical Instructions by the "International Civil Aviation Organization" (ICAO).
IMDG:	International Maritime Code for Dangerous Goods.
INCI:	International Nomenclature of Cosmetic Ingredients.
KSt:	Explosion coefficient.
LC50:	Lethal concentration, for 50 percent of test population.
LD50:	Lethal dose, for 50 percent of test population.
PNEC:	Predicted No Effect Concentration.
RID:	Regulation Concerning the International Transport of Dangerous Goods by Rail.
STEL:	Short Term Exposure limit.
STOT:	Specific Target Organ Toxicity.
TLV:	Threshold Limiting Value.
TWA:	Time-weighted average
WGK:	German Water Hazard Class.