

Product Name: Pramoxine Hydrochloride
Issued: Dec-21-2012

SAFETY DATA SHEET

Section 1. Identification of the substance/mixture and of the company/undertaking

1.1 Product Identifier

Product Name: Pramoxine Hydrochloride
Synonyms: Pramoxine Hydrochloride, USP: 4-n-Butoxyphenyl gamma-Morpholinopropyl Ether
Hydrochloride: Pramoxine Hydrochloride USP
List Number: 5106: 5416: 5300
Drug Code Number: 58701: 72847: 72683: 77863

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

Recommended use: Pharmaceuticals

1.3 Details of the supplier of the safety data sheet

Supplier: AbbVie Inc.
North Chicago, IL 60064
U.S.A.
1-800-255-5162
+1-847-937-7433
Customer Service Telephone: 1-800-255-5162 (US and Canada only)
+1-847-937-7433
E-mail Address: AbbVie.SDS@abbvie.com

1.4 Emergency telephone number

Emergency Telephone: CHEMTREC: 1(800) 424-9300 (in USA and Canada)
or +1-703-527-3887 (international)

Section 2. Hazards identification

2.1 Classification of the substance or mixture

Regulation (EC) No 1272/2008

Acute oral toxicity	Category 4
Skin corrosion/irritation	Category 2
Serious eye damage/eye irritation	Category 2
Specific target organ systemic toxicity (single exposure)	Category 3

Classification according to EU Directives 67/548/EEC or 1999/45/EC

Indication of danger: Xn - Harmful
Xi - Irritant
Risk Phrases: R22 - Harmful if swallowed
R36 - Irritating to eyes
R37 - Irritating to respiratory system
R38 - Irritating to skin

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Section 2. Hazards identification

2.2 Label elements



Signal Word: Warning

Hazard Statements:

- H302 - Harmful if swallowed
- H315 - Causes skin irritation
- H319 - Causes serious eye irritation
- H335 - May cause respiratory irritation

P337 + P313 - If eye irritation persists: Get medical advice/attention
P280 - Wear protective gloves/protective clothing/eye protection/face protection
P332 + P313 - If skin irritation occurs: Get medical advice/attention
P304 + P340 - IF INHALED: Remove to fresh air and keep at rest in a position comfortable for breathing
P312 - Call a POISON CENTER or doctor/physician if you feel unwell
P403 + P233 - Store in a well-ventilated place. Keep container tightly closed

2.3 Other hazards

Not determined

Section 3. Composition/information on ingredients

Chemical Name	Percent	EINECS/ELINCS Number	EEC Classification	EU - GHS Substance Classification	REACH No.
Pramoxine Hydrochloride 637-58-1	100	211-293-1	Xn; R22 Xi; R36/37/38	STOT SE 3 (H335) Skin Irrit. 2 (H315) Eye Irrit. 2 (H319) Acute Tox. 4 (H302)	No data available

For the full text of the R-phrases mentioned in this Section, see Section 16
For the full text of the H-Statements mentioned in this Section, see Section 16

Section 4. First aid measures

4.1 Description of first aid measures

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Eye Contact: Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Skin Contact: Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Inhalation: Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Ingestion: Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Protection of First-aiders: Use personal protective equipment

4.2 Most important symptoms and effects, both acute and delayed

Signs and Symptoms: Clinical data suggests the following: numbness, stinging, edema.

Medical Conditions Aggravated by Exposure: Data suggest any pre-existing ailments in the following organs: eyes, skin, respiratory system. Hypersensitivity to the material and/or similar materials.

4.3 Indication of any immediate medical attention and special treatment needed

Notes To Physician: Treat symptomatically

Section 5. Firefighting measures

5.1 Extinguishing Media

Suitable Extinguishing Media: Use extinguishing agent suitable for type of surrounding fire

Unsuitable Extinguishing Media: Not determined

5.2 Special hazards arising from the substance or mixture

Special Exposure Hazards: This material is capable of forming explosive dust clouds in air, therefore, measures must be taken to avoid ignition. This material is particularly sensitive to ignition by electrostatic discharge.

5.3 Advice for firefighters

Protective Equipment and Precautions for Firefighters: As in any fire, wear self-contained breathing apparatus and full protective gear

Section 6. Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Personal Precautions: For personal protection see section 8.

6.2. Environmental precautions

Environmental Precautions: Should not be released into the environment.

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6.3. Methods and material for containment and cleaning up

Methods for Cleaning Up: Recover product and place in an appropriate container for disposal.

6.4. Reference to other sections

Refer to Sections 8, 12, and 13 for further information.

Section 7. Handling and storage

7.1. Precautions for safe handling

Handle in accordance with good industrial hygiene and safety practice.

7.2. Conditions for safe storage, including any incompatibilities

Store according to label instructions.

7.3. Specific end use(s)

Recommended use: Pharmaceuticals

Section 8. Exposure controls/personal protection

8.1. Control parameters

Exposure limits:

Chemical Name	Employee Exposure Limit	Skin Notation
Pramoxine Hydrochloride 637-58-1	0.1 mg/m ³ TWA	None

8.2. Exposure controls

Engineering Controls: Use inside a hood, glovebox or process enclosure.

Respiratory Protection: An approved respirator (i.e. NIOSH, etc.) should be worn when exposures are expected to exceed the applicable limits.

Eyes: Wear eye protection appropriate to handling activities.

Gloves: Impervious gloves.

Other PPE Data: Wear appropriate body coverings if contact may occur.

Environmental Exposure Controls: Do not allow material to contaminate ground water system

Section 9. Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance: White Crystalline Powder
Odor: Odorless.

Product Name:	Pramoxine Hydrochloride
Issued:	Dec-21-2012
Odor Threshold:	Not determined
pH:	4.5 as a 1% solution.
Boiling Pt. @ 760 mm Hg (°C):	Not determined.
Melting/Freezing Point (°C):	170-174
Flash Point (°C):	Not determined.
Evaporation Rate at 20°C:	Not determined.
Flammability (Solid):	Not determined.
Lower Explosive Limit:	Not determined.
Upper Explosive Limit:	Not determined.
Vapor Pressure (mm Hg):	Not determined.
Vapor Density (Air = 1):	Not determined.
Specific Gravity:	Not determined.
Solubility(ies):	Soluble in: water, alcohol, chloroform.
Partition coefficient: n-octanol/water	Not determined.
Autoignition Temp. (°C):	Not determined.
Decomposition temperature (°C):	Not determined.
Viscosity (centipoise):	Not determined.
Explosion Severity:	Not determined.
Oxidizer Properties:	Not determined.

9.2. Other information

Not determined	
Volume Resistivity (ohm.m):	5.6 x 10 ⁸
Max. rate of pressure rise (bar/sec):	1018
Min. Ignition Energy-Cloud (mJ):	10
Min. Ignit. Temp. Dust Cloud (°C):	450
Min. Explosive Conc. (g/m³):	30

Section 10. Stability and reactivity

10.1. Reactivity

Not determined

10.2. Chemical stability

Stable under normal conditions

10.3. Possibility of hazardous reactions

Hazardous reactions:	None under normal processing
Self-Heating Tendency:	Decomposes exothermically above 200 deg C in DSC and TGA testing.

10.4. Conditions to avoid

Not determined.

10.5 Incompatible materials

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Not determined

10.6 Hazardous decomposition products

Not determined.

Section 11. Toxicological information

11.1. Information on toxicological effects

Routes of Exposure:

Oral: Yes
Dermal: Yes
Inhalation: Yes

Acute Toxicity - Oral: Data for component (s) given below.

Chemical Name	Acute Test	Value	Units	Species
Pramoxine Hydrochloride 637-58-1	LD50 =	1050	mg/kg	Mice

Acute Toxicity - Dermal: Not determined.

Acute Toxicity - Inhalation: Not determined.

Other Toxicology Data: Data for component (s) given below:

Chemical Name	Test Type	Value	Units	Species	Comments
Pramoxine Hydrochloride 637-58-1	LD50 (iv) =	39 79.5	mg/kg	Rabbits Mice	None.

Corrosivity: Not determined.

Dermal Irritation: Not determined.

Eye Irritation: May be an eye irritant.

Sensitization: Not determined.

Toxicokinetics/Metabolism: Not determined.

Target Organ Effects: In clinical use target organ effects include: nervous system.
Data for component (s) given below.

Chemical Name	Target Organs:	Species	Dosage	Units	Route	Duration
Pramoxine Hydrochloride 637-58-1	Central Nervous System	Rabbits Mice	39 79.5	mg/kg	Intravenous	

Reproductive Effects: Not determined.

Carcinogenicity: Not determined.

Mutagenicity: Not determined.

Aspiration hazard: Not determined

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Notes:

1. ALD: Approximate lethal dosage
2. LC50: Concentration in air that produces 50% mortality
3. LD50: Oral or dermal dosage that produces 50% mortality

Section 12. Ecological information

12.1. Toxicity

Not determined.

12.2. Persistence and degradability

Not determined.

12.3. Bioaccumulative potential

Not determined

12.4. Mobility in soil

Not determined.

12.5. Results of PBT or vPvB assessment

Chemical safety report is not required for this substance/product.

12.6. Other adverse effects

Do not allow undiluted material or large quantities to reach groundwater, bodies of water or sewer system.

Notes:

1. EC50: Concentration in water that produces 50% mortality in *Daphnia* sp.
2. LC50: Concentration in water that produces 50% mortality in fish.
3. EbC50/ErC50: Concentration in water that produces 50% inhibition of growth and in algae.

Section 13. Disposal considerations

13.1 Waste treatment methods

Waste Disposal Methods: Disposal should be made in accordance with country, federal, state and local regulations.

Section 14. Transport information

ADR, DOT, ICAO/IATA, IMDG/IMO

Status: Not regulated

- | | |
|------------------------------------|----------------|
| 14.1. UN Number: | Not applicable |
| 14.2. Proper shipping name: | Not applicable |
| 14.3. Hazard class: | Not applicable |
| 14.4. Packing group: | Not applicable |
| 14.5. Environmental hazard: | Not applicable |
| 14.6. Special Provisions: | Not applicable |

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14.7. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code: Not applicable

Section 15. Regulatory Information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

International Inventories

Chemical Name	EINECS/ ELINCS	TSCA	DSL	NDSL	PICCS
Pramoxine Hydrochloride 637-58-1	211-293-1	-	X	Not listed.	-

Chemical Name	ENCS	ISHL	IECSC	AICS	KECL	New Zealand
Pramoxine Hydrochloride 637-58-1	-	-	-	-	-	

Legend

EINECS/ELINCS - European Inventory of Existing Commercial Chemical Substances/EU List of Notified Chemical Substances

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory

DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List

PICCS - Philippines Inventory of Chemicals and Chemical Substances

ENCS - Japan Existing and New Chemical Substances

ISHL - Japan Industrial Safety and Health Law

IECSC - China Inventory of Existing Chemical Substances

AICS - Australian Inventory of Chemical Substances

KECL - Korean Existing and Evaluated Chemical Substances

Carcinogenicity Rating:

Chemical Name	Percent	NTP:	IARC:	ACGIH:
Pramoxine Hydrochloride	100	Not Listed	Not Listed	Not Listed

SARA 313 Information

Chemical Name	Percent	SARA 313 Chemical:	CERCLA RQ/SARA EHS RQ (lbs):	SARA EHS TPQ (lbs):
Pramoxine Hydrochloride	100	No	Not Applicable	Not applicable

Immediate Health: Yes

Delayed Health: No

Fire: No

Sudden Pressure: No

Reactivity: No

RCRA Status: Not determined.

Proposition 65 Status: Does not contain chemicals known to the state of California to cause cancer or reproductive harm.

WHMIS Hazard Class: Not determined.

NFPA Rating:

Health: 1

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Fire: 1
Reactivity: 0

Notes:

1. SARA = Superfund Amendments and the Reauthorization Act.
2. CERCLA = Comprehensive Environmental Response, Compensation and Liability Act.
3. FIFRA = Federal Insecticide, Fungicide and Rodenticide Act.
4. TSCA = Toxic Substances Control Act.
5. EC = European Community.
6. WHMIS = Canadian Workplace Hazardous Materials Information System.
7. UN GHS = United Nations Globally Harmonized System for Hazard Identification.

15.2. Chemical safety assessment

Chemical safety assessment has not been conducted on the substance/product.

Section 16. Other information

Risk Phrases: R22 - Harmful if swallowed, R36 - Irritating to eyes, R37 - Irritating to respiratory system, R38 - Irritating to skin

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