



Safety Data Sheet

Section 1: Identification

Product identifier

Product Name Ear Pain MD® / EAR PAIN MD® for KIDS
Product Code E009

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

Recommended use Temporary relief of minor pain
Restrictions on use No information available

Details of the supplier of the safety data sheet

Supplier Name Eosera Inc.
Supplier Address 5000 South Freeway
Fort Worth, TX 76115 US

Telephone (General) Phone: 844-732-7929

Emergency telephone number 1-800-222-1222 – In case of overdose, please call the poison control hotline.

Consumer product: This safety data sheet is written to provide health, safety and environmental information for people handling this formulated product in the workplace. It is not intended to provide information relevant to consumer use of the product.

Section 2: Hazard Identification

Hazard Classification: Not Classified

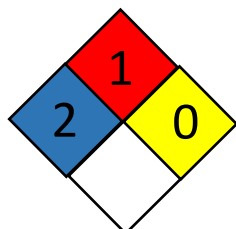
This product is exempt from the requirements of the OSHA Hazard Classification Communication Standard according to US OSHA Standard (29 CFR Part 1910.1200)

Emergency Overview

Adverse Effects: Adverse effects may include numbness, burning, stinging or swelling of skin, drowsiness or excitement, nervousness, dizziness, blurred vision, tremors, convulsions, unconsciousness and possible cardiac arrest. When improperly used and ingested, lidocaine may cause nausea, vomiting or abdominal discomfort. Possible allergic reaction to material if inhaled, ingested, or in contact with skin.

Potential Health Effects:

Inhalation: May cause irritation and numbness.
 Eye Contact: May cause irritation and numbness.
 Skin Contact: May cause irritation and numbness.
 Ingestion: May cause irritation, numbness and toxicity.

**National Fire Protection Association (NFPA)**

(estimated)

Health-2

Flammability-1

Reactivity-0

Section 3: Composition/ Information on Ingredients

Composition		
Chemical Name	CAS Number	%
Lidocaine HCL Monohydrate	73-78-9	4
Aloe Barbadensis Extract	85507-69-3	*
Hypromellose	37353-59-6	*
Benzyl Alcohol	100-51-6	*
Benzalkonium Chloride	8001-54-5	*
Water	7732-18-5	*

* Designates that a specific chemical identity and/or percentage of composition has been withheld.

Listed Carcinogens: The following components, present at the concentrations of $0 \geq 0.1\%$ are listed as carcinogens or potential carcinogens by either the National Toxicology Program (NTP), the International agency for Research on Cancer, OSHA or ACGIH: **NONE**.

Section 4: First- Aid Measures**Description of first aid measures:**

Inhalation – Remove to fresh air and keep patient at rest. Seek medical attention immediately.

Skin – For excess exposure to large amounts of skin, remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.

Eye – For excess exposure to large amounts of skin or direct exposure to eye(s), flush with water while holding eyelids open for at least 15 minutes. If eye irritation persists: Get medical advice/attention.

Ingestion – Never give anything by mouth to anyone. Wash out mouth with water. Do NOT induce vomiting unless directed by medical personnel. Seek medical attention immediately.

Section 5: Fire-Fighting Measures

Flammable Properties:	Not flammable. However, during fire, gases hazardous to health may be formed.
Extinguishing Media:	CO ₂ , alcohol-resistant foam, water spray or dry chemical. Do not use direct water system.
Special Fire Fighting Procedures:	Self-contained breathing apparatus and full protective clothing should be worn when fighting chemical fires.

Section 6: Accidental Release Measures

Personal precautions, protective equipment and emergency procedures

Spill - Use the appropriate personal protective equipment. Small spills may be absorbed with a disposable towel; larger spills may require use of an appropriate vacuum cleaner designed for drug disposal. Carefully collect with a non-combustible absorbent material and transfer to a suitable, properly labeled container for disposal. Clean area using soap and water.

Release to air - If aerosolized, reduce exposures by ventilating area. Do not breathe mist.

Release to water - Refer to local water authority. Drain disposal is not recommended; refer to local, state, and federal disposal guidelines.

Environmental protections - Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release. Refer to specific member state legislation for requirements under community environmental legislation.

Environmental precautions - Prevent spilled material from entering storm sewers or drains, waterways, and contact with soil.

Section 7: Handling and Storage

Precautions for safe handling

Handling – Handle in accordance with good industrial hygiene and safety practices. Avoid contact with skin, eyes or clothing. Do not eat, drink or smoke when using product.

Conditions for safe storage, including any incompatibilities

Storage – Keep containers tightly closed in a dry, cool and well-ventilated place.

Section 8: Exposure Controls/ Personal Protection

Exposure Limits/ Guidelines - Refer to the occupational exposure limits / guidelines for the individual product components.

Compound	Issuer	Type	Exposure Limit
Lidocaine HCl Monohydrate	OSHA	PEL	N/E
	ACGIH	TLV	N/E

Exposure controls

Engineering Measures/Controls – General room ventilation is adequate unless the process generates dust, mist or fumes.

Personal Protective Equipment

Respiratory – Aerosol formation is extremely unlikely. If exposure to mist is possible, wear a NIOSH approved half-face respirator equipped with a dust/mist filter. Respiratory protection should be adjunct to and not a substitute for engineering controls.

Eye/Face - None required during normal administration of Ear Itch MD. Avoid contact with eyes, and do not ingest.

Hands/Skin/Body - None required during normal administration of Ear Itch MD. If prolonged exposure to skin is expected, wear protective gloves. Do not use on large areas of skin.

General Industrial Hygiene Considerations - Handle in accordance with good industrial hygiene and safety practices.

Section 9: Physical and Chemical Properties**Information on Physical and Chemical Properties**

1.	Appearance	Colorless, clear liquid
2.	Odor	Bland
3.	Odor Threshold	NA
4.	pH	4.5 – 6.5
5.	Melting point	NA
6.	Initial boiling point	NA

7.	Flash point	NA
8.	Evaporation point	NA
9.	Flammability	NA
10.	Upper lower flammability or explosion limits	NA
11.	Vapor pressure	NA
12.	Vapor density	NA
13.	Relative density	NA
14.	Solubility	NA
15.	Partition coefficient: n-octanol/water	NA
16.	Auto-ignition temperature	NA
17.	Decomposition temperature	NA
18.	Viscosity	~1.00 cps – similar to water

Section 10: Stability and Reactivity

Reactivity – No data available

Chemical stability – Stable under recommended storage conditions

Possibility of hazardous reactions – When heated to decomposition, product may emit oxides of carbon, nitrogen and sulfur.

Conditions to avoid – Keep away from strong oxidizers, extreme heat or cold.

Incompatible materials – As a precaution, keep away from strong oxidizers.

Section 11: Toxicological Information

Component	Type	Route	Species	Dosage
Lidocaine HCl	LD ₅₀	Oral	Rat	317 mg/kg
Lidocaine HCl	LD ₅₀	Subcutaneous	Mouse	285 mg/kg
Lidocaine HCl	LD ₅₀	Oral	Mouse	220, 292 mg/kg
Lidocaine HCl	LD ₅₀	Subcutaneous	Rat	570 mg/kg
Lidocaine HCl	LD ₅₀	Intramuscular	Mouse	260 mg/kg
Lidocaine HCl	LD ₅₀	Intravenous	Mouse	22 mg/kg
Lidocaine HCl	LD ₅₀	Intraperioteneal	Mouse	119 mg/kg

Hazardous Chemical Listings

NTP: No

IARC: No

OSHA: No

Section 12: Ecological Information

(a)	Ecotoxicity	NA
(b)	Persistence and degradability	NA
(c)	Bioaccumulative potential	NA
(d)	Mobility in soil	NA
(e)	Other adverse effects	NA

Section 13: Disposal Considerations

Waste Treatment Methods

Disposal methods - This material, as supplied, is not a hazardous waste according to Federal Regulation (40 CFR 261). Dispose of content and/or container in accordance with local, regional, national, and/or international regulations.

Contaminated Packaging - Dispose of content and/or container in accordance with local,

Section 14: Transport Information

regional, national, and/or international regulations.

(a)	UN Number	NA
(b)	UN Proper Shipping Name	NA
(c)	Transport Hazard Class	NA
(d)	Packing Group	NA
(e)	Environmental Hazards	NA
(f)	Transport in bulk (according to Annex II of MARPOL 73/78 and the IBC Code)	NA
(g)	Special Precautions	NA

DOT: Not Regulated

ICAO/IA TA: Not Regulated

IMO: Not Regulated

Section 15: Regulatory Information

Below is selected regulatory information chosen primarily for possible Eosera usage. This section is not a complete analysis or reference to all applicable regulatory information. Please consider all applicable laws and regulations for your country/state.

TSCA: No

DSL: Not determined

TSCA (United States Toxic Substances Control Act Section 8(b) Inventory)
DSL/NDSL (Canadian Domestic Substances List/Non-Domestic Substances List)

US Federal Regulations

Sara 313 - Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product does not contain any chemicals that are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372.

CWA (Clean Water Act) – This product does not contain any substances regulated as pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42).

CERCLA – This material, as supplied, does not contain any substances regulated as hazardous substances under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302) or the Superfund Amendment and Reauthorization Act (SARA) (40 CFR 355). There may be specific reporting requirements at the local, regional or state level pertaining to releases of this material.

US State Regulations

California Proposition 65 – This product does not contain any Proposition 65 chemicals.

Section 16: Other Information

As of the date of issuance, we are providing available information relevant to the handling of this material in the workplace. All information contained herein is offered with the good faith belief that it is accurate. THIS SAFETY DATA SHEET SHALL NOT BE DEEMED TO CREATE ANY WARRANTY OF ANY KIND (INCLUDING WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE). In the event of an adverse incident associated with this material, this safety data sheet is not intended to be a substitute for consultation with appropriately trained personnel. Nor is this safety data sheet intended to be a substitute for product literature which may accompany the finished product.

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End of Safety Data Sheet