



Lidocaine Ointment 5% USP

Safety Data Sheet

according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

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Date of issue: 08/07/2014

Version: 2.0

SECTION 1: Identification

1.1. Product identifier

Product form: Mixture

Product name: Lidocaine Ointment 5% USP

Synonyms: Octocaine

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

Use of the substance/mixture: Pharmaceutical for human use. For professional use only.

1.3. Name, Address, and Telephone of the Responsible Party

Company

Novocol Pharmaceutical of Canada, Inc.

25 Wolseley Court

Cambridge, ON N1R 6X3

519-623-4800

<http://www.septodont.com/>

1.4. Emergency telephone number

Emergency number : ChemTel LLC

(800)255-3924 (North America)

+1 (813)248-0585 (International)

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification (GHS-US)

Skin Sens. 1 H317

STOT SE 3 H335

2.2. Label elements

GHS-US labeling

Hazard pictograms (GHS-US) :



GHS07

Signal word (GHS-US) :

Warning

Hazard statements (GHS-US) :

H317 - May cause an allergic skin reaction

H335 - May cause respiratory irritation

Precautionary statements (GHS-US) :

P261 - Avoid breathing mist, spray, vapors

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

P272 - Contaminated work clothing should not be allowed out of the workplace

P280 - Wear eye protection, protective gloves, protective clothing

P302+P352 - IF ON SKIN: Wash with plenty of soap and water

P304+P340 - IF INHALED: Remove person to fresh air and keep at rest in a position comfortable for breathing

P312 - Call a POISON CENTER/doctor/physician if you feel unwell

P321 - Specific treatment (see Section 4)

P333+P313 - If skin irritation or rash occurs: Get medical advice/attention

P362+P364 - Take off contaminated clothing and wash it before reuse

P403+P233 - Store in a well-ventilated place. Keep container tightly closed

P405 - Store locked up

P501 - Dispose of contents/container according to local, regional, national, and international regulations

2.3. Other hazards

No additional information available

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2.4. Unknown acute toxicity (GHS-US)

No data available

SECTION 3: Composition/information on ingredients

3.1. Substance

Not applicable

3.2. Mixture

Name	Product identifier	%	Classification (GHS-US)
Polyethylene glycol	(CAS No) 25322-68-3	80 - 95	STOT SE 3, H335
Acetamide, 2-(diethylamino)-N-(2,6-dimethylphenyl)-	(CAS No) 137-58-6	5 - 10	Acute Tox. 4 (Oral), H302 Skin Sens. 1, H317
Oils, peppermint	(CAS No) 8006-90-4	0.1 - 1	Skin Irrit. 2, H315 Skin Sens. 1, H317 Aquatic Chronic 2, H411

Full text of H-phrases: see section 16

SECTION 4: First aid measures

4.1. Description of First Aid Measures

- First-aid measures general** : Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible).
- First-aid measures after inhalation** : When symptoms occur: go into open air and ventilate suspected area. If you feel unwell, seek medical advice.
- First-aid measures after skin contact** : Remove contaminated clothing. Drench affected area with water for at least 15 minutes. Wash contaminated clothing before reuse. Seek medical attention if ill effect or irritation develops.
- First-aid measures after eye contact** : Rinse cautiously with water for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Obtain medical attention.
- First-aid measures after ingestion** : Rinse mouth. Do NOT induce vomiting. Immediately call a POISON CENTER or doctor/physician.

4.2. Most Important Symptoms and Effects, Both Acute and Delayed

- Symptoms/injuries** : May cause an allergic skin reaction. May cause respiratory irritation.
- Symptoms/injuries after inhalation** : May cause respiratory irritation.
- Symptoms/injuries after skin contact** : Exposure may produce an allergic reaction.
- Symptoms/injuries after eye contact** : May cause minor eye irritation.
- Symptoms/injuries after ingestion** : May be harmful if swallowed.

4.3. Indication of Any Immediate Medical Attention and Special Treatment Needed

If exposed or concerned, get medical advice and attention.

SECTION 5: Fire-Fighting measures

5.1. Extinguishing media

- Suitable extinguishing media** : Use extinguishing media appropriate for surrounding fire.
- Unsuitable extinguishing media** : Do not use a heavy water stream. Use of heavy stream of water may spread fire.

5.2. Special hazards arising from the substance or mixture

- Fire hazard** : Not considered flammable but may burn at high temperatures.
- Explosion hazard** : Product is not explosive.
- Reactivity** : Polyethylene Glycol can form explosive peroxides. Reacts with strong oxidants causing fire and explosion hazard. May attack plastics and rubber.

5.3. Advice for firefighters

- Precautionary measures fire** : Exercise caution when fighting any chemical fire.
- Firefighting instructions** : Use water spray or fog for cooling exposed containers.
- Protection during firefighting** : Do not enter fire area without proper protective equipment, including respiratory protection.

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5.4. Other information

Refer to Section 9 for flammability properties.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General measures : Avoid all contact with skin, eyes, or clothing. Avoid breathing (vapor, mist, spray).

6.1.1. For non-emergency personnel

Protective equipment : Use appropriate personal protection equipment (PPE).

Emergency procedures : Evacuate unnecessary personnel.

6.1.2. For emergency responders

Protective equipment : Equip cleanup crew with proper protection.

Emergency procedures : Ventilate area.

6.2. Environmental precautions

Prevent entry to sewers and public waters.

6.3. Methods and material for containment and cleaning up

For containment : Absorb and/or contain spill with inert material, then place in suitable container.

Methods for cleaning up : Clear up spills immediately and dispose of waste safely.

6.4. Reference to other sections

See heading 8, Exposure Controls and Personal Protection. Concerning disposal elimination after cleaning, see item 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Hygiene measures : Handle in accordance with good industrial hygiene and safety procedures. Wash hands and other exposed areas with mild soap and water before eating, drinking, or smoking and again when leaving work.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Store in a dry, cool and well-ventilated place. Keep container closed when not in use.

Incompatible products : Strong acids. Strong bases. Strong oxidizers.

7.3. Specific end use(s)

Pharmaceutical for human use. For professional use only.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

No Occupational Exposure Limits (OELs) have been established for this product or its chemical components.

8.2. Exposure controls

Appropriate engineering controls : Emergency eye wash fountains and safety showers should be available in the immediate vicinity of any potential exposure. Ensure adequate ventilation, especially in confined areas.

Personal protective equipment : Safety glasses. Gloves. Protective clothing. Insufficient ventilation: wear respiratory protection.



Hand protection : Wear chemically resistant protective gloves.

Eye protection : Chemical goggles or safety glasses.

Skin and body protection : Wear suitable protective clothing to prevent skin exposure.

Respiratory protection : Use a NIOSH-approved respirator or self-contained breathing apparatus whenever exposure may exceed established Occupational Exposure Limits.

Other information : When using, do not eat, drink or smoke.

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SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Liquid
Appearance	: No data available
Color	: No data available
Odor	: No data available
Odor threshold	: No data available
pH	: No data available
Relative evaporation rate (butyl acetate=1)	: No data available
Melting point	: No data available
Freezing point	: No data available
Boiling point	: No data available
Flash point	: No data available
Auto-ignition Temperature	: No data available
Decomposition temperature	: No data available
Flammability (solid, gas)	: No data available
Vapor pressure	: No data available
Relative vapor density at 20 °C	: No data available
Relative density	: No data available
Solubility	: No data available
Partition coefficient: n-octanol/water	: No data available
Viscosity	: No data available

9.2. Other information

VOC content : < 1 %

SECTION 10: Stability and reactivity

10.1. Reactivity

Polyethylene Glycol can form explosive peroxides. Reacts with strong oxidants causing fire and explosion hazard. May attack plastics and rubber.

10.2. Chemical stability

Product is stable.

10.3. Possibility of hazardous reactions

Hazardous polymerization will not occur.

10.4. Conditions to avoid

Direct sunlight. Extremely high or low temperatures.

10.5. Incompatible materials

Strong acids. Strong bases. Strong oxidizers.

10.6. Hazardous decomposition products

Hydrocarbons. Carbon oxides (CO, CO₂). Nitrogen compounds.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity : Not classified

Polyethylene glycol (25322-68-3)	
LD50 dermal rabbit	> 20 ml/kg
Acetamide, 2-(diethylamino)-N-(2,6-dimethylphenyl)- (137-58-6)	
ATE (oral)	500.000 mg/kg body weight
Oils, peppermint (8006-90-4)	
LD50 oral rat	2426 mg/kg

Skin corrosion/irritation : Not classified

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Serious eye damage/irritation	: Not classified
Respiratory or skin sensitization	: May cause an allergic skin reaction.
Germ cell mutagenicity	: Not classified
Carcinogenicity	: Not classified
Reproductive toxicity	: Not classified
Specific target organ toxicity (single exposure)	: May cause respiratory irritation.
Specific target organ toxicity (repeated exposure)	: Not classified
Aspiration hazard	: Not classified
Symptoms/injuries after inhalation	: May cause respiratory irritation.
Symptoms/injuries after skin contact	: Exposure may produce an allergic reaction.
Symptoms/injuries after eye contact	: May cause minor eye irritation.
Symptoms/injuries after ingestion	: May be harmful if swallowed.

SECTION 12: Ecological information

12.1. Toxicity

No additional information available

12.2. Persistence and degradability

No additional information available

12.3. Bioaccumulative potential

No additional information available

12.4. Mobility in soil

No additional information available

12.5. Other adverse effects

Other information : Avoid release to the environment.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste disposal recommendations : Dispose of waste material in accordance with all local, regional, national, and international regulations.

SECTION 14: Transport information

In accordance with DOT / IMDG / IATA

14.1. UN number

Not applicable

14.2. UN proper shipping name

Not applicable

14.3. Additional information

Other information : No supplementary information available.

Transport by Sea

No additional information available

Air Transport

No additional information available

SECTION 15: Regulatory information

15.1. US Federal regulations

Lidocaine Ointment 5% USP	
SARA Section 311/312 Hazard Classes	Immediate (acute) health hazard
Polyethylene glycol (25322-68-3)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
Acetamide, 2-(diethylamino)-N-(2,6-dimethylphenyl)- (137-58-6)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	

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Oils, peppermint (8006-90-4)

Listed on the United States TSCA (Toxic Substances Control Act) inventory

15.2. US State regulations

Not applicable

SECTION 16: Other information, including date of preparation or last revision

Revision date : 07/19/2021

Other information : This document has been prepared in accordance with the SDS requirements of the OSHA Hazard Communication Standard 29 CFR 1910.1200.

Full text of H-phrases:

Acute Tox. 4 (Oral)	Acute toxicity (oral) Category 4
Aquatic Chronic 2	Hazardous to the aquatic environment - Chronic Hazard Category 2
Skin Irrit. 2	Skin corrosion/irritation Category 2
Skin Sens. 1	Skin sensitization Category 1
STOT SE 3	Specific target organ toxicity (single exposure) Category 3
H302	Harmful if swallowed
H315	Causes skin irritation
H317	May cause an allergic skin reaction
H335	May cause respiratory irritation
H411	Toxic to aquatic life with long lasting effects

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.