



Lidocaine Ointment 5% USP

Safety Data Sheet

according to Regulation (EC) No. 453/2010

Revision date: 07/08/2014 Date of issue: 07/08/2014

Version: 1.0

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

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

1.2.1. Relevant identified uses

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

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

Septodont, Inc.
416 S. Taylor Ave.
Louisville, CO 80027
T 303-665-7535
email: usregulatoryaffairs@septodont.com
www.septodontusa.com

1.4. Emergency Telephone Number

Emergency Number : 800-424-9300 CHEMTREC; 1-703-527-3887 CHEMTREC - Outside USA

SECTION 2: Hazards identification

2.1. Classification of the Substance or Mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP]

Skin Sens. 1 H317

STOT SE 3 H335

Full text of H-phrases: see section 16

Classification according to Directive 67/548/EEC or 1999/45/EC

Xi; R37

R43

Full text of R-phrases: see section 16

Adverse physicochemical, human health and environmental effects

No additional information available

2.2. Label Elements

Labelling according to Regulation (EC) No. 1272/2008 [CLP]

Hazard pictograms (CLP) :



GHS07

Signal word (CLP) :

Warning

Hazardous ingredients :

Acetamide, 2-(diethylamino)-N-(2,6-dimethylphenyl)-, Oils, peppermint

Hazard statements (CLP) :

H317 - May cause an allergic skin reaction

H335 - May cause respiratory irritation

Precautionary statements (CLP) :

P261 - Avoid breathing mist, spray, vapours

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 clothing, protective gloves

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

Lidocaine Ointment 5% USP

Safety Data Sheet

according to Regulation (EC) No. 453/2010

P304+P340 - IF INHALED: Remove person to fresh air and keep comfortable for breathing

P312 - Call a POISON CENTER or doctor if you feel unwell

P321 - Specific treatment (see Section 4 on this label)

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

SECTION 3: Composition/information on ingredients

3.1. Substance

Not applicable

3.2. Mixture

Name	Product Identifier	%	Classification according to Directive 67/548/EEC
Polyethylene glycol	(CAS No) 25322-68-3 (EC no) 500-038-2	80 - 95	Not classified
Acetamide, 2-(diethylamino)-N-(2,6-dimethylphenyl)-	(CAS No) 137-58-6 (EC no) 205-302-8	5 - 10	R43 Xn; R22
Oils, peppermint	(CAS No) 8006-90-4 (EC no) 616-900-7	0,1 - 1	Xi; R38 R43 N; R51/53
Name	Product Identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Polyethylene glycol	(CAS No) 25322-68-3 (EC no) 500-038-2	80 - 95	STOT SE 3, H335
Acetamide, 2-(diethylamino)-N-(2,6-dimethylphenyl)-	(CAS No) 137-58-6 (EC no) 205-302-8	5 - 10	Acute Tox. 4 (Oral), H302 Skin Sens. 1, H317
Oils, peppermint	(CAS No) 8006-90-4 (EC no) 616-900-7	0,1 - 1	Skin Irrit. 2, H315 Skin Sens. 1, H317 Aquatic Chronic 2, H411

Full text of R- and 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.

Lidocaine Ointment 5% USP

Safety Data Sheet

according to Regulation (EC) No. 453/2010

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: Firefighting 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.

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 section 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.

Lidocaine Ointment 5% USP

Safety Data Sheet

according to Regulation (EC) No. 453/2010

7.3. Specific end use(s)

Pharmaceutical for human use. For professional use only.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Polyethylene glycol (25322-68-3)		
Austria	MAK (mg/m ³)	1000 mg/m ³ (average molecular weight 200-400)
Austria	MAK Short time value (mg/m ³)	4000 mg/m ³ (average molecular weight 200-400)
Germany	TRGS 900 Occupational exposure limit value (mg/m ³)	1000 mg/m ³ (The risk of damage to the embryo or fetus can be excluded when AGW and BGW values are observed, average molecular weight 200-400)
Slovakia	NPHV (priemerná) (mg/m ³)	1000 mg/m ³
Slovakia	NPHV (Hraničná) (mg/m ³)	8000 mg/m ³

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.

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.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Liquid
Colour	: No data available
Odour	: No data available
Odour threshold	: No data available
pH	: No data available
Relative evaporation rate (butylacetate=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
Vapour pressure	: No data available
Relative vapour 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, kinematic	: No data available

Lidocaine Ointment 5% USP

Safety Data Sheet

according to Regulation (EC) No. 453/2010

Viscosity, dynamic	: No data available
Explosive properties	: No data available
Oxidising properties	: No data available
Explosive limits	: Not applicable

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 CLP (oral)	500,000 mg/kg bodyweight
----------------	--------------------------

Oils, peppermint (8006-90-4)

LD50 oral rat	2426 mg/kg
---------------	------------

Skin corrosion/irritation	: Not classified
Serious eye damage/irritation	: Not classified
Respiratory or skin sensitisation	: 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

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

Lidocaine Ointment 5% USP

Safety Data Sheet

according to Regulation (EC) No. 453/2010

12.5. Results of PBT and vPvB assessment

No additional information available

12.6. 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 ADR / RID / IMDG / IATA / ADN

14.1. UN number

No dangerous good in sense of transport regulations

14.2. UN proper shipping name

Not applicable

14.3. Transport hazard class(es)

Not applicable

14.4. Packing group

Not applicable

14.5. Environmental hazards

Other information : No supplementary information available.

14.6. Special precautions for user

14.6.1. Overland transport

No additional information available

14.6.2. Transport by sea

No additional information available

14.6.3. Air transport

No additional information available

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

15.1.1. EU-Regulations

The following restrictions are applicable according to Annex XVII of the REACH Regulation (EC) No 1907/2006:

3. Liquid substances or mixtures which are regarded as dangerous in accordance with Directive 1999/45/EC or are fulfilling the criteria for any of the following hazard classes or categories set out in Annex I to Regulation (EC) No 1272/2008	Lidocaine Ointment 5% USP - Oils, peppermint
--	--

Contains no REACH candidate substance

VOC content : < 1 %

Other information, restriction and prohibition regulations : This substance is for use in medicinal products, and as such, is exempt from REACH registration requirements.

15.1.2. National regulations

No additional information available

15.2. Chemical safety assessment

No chemical safety assessment has been carried out

SECTION 16: Other information

Revision date : 07/08/2014

Data sources : REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006

Lidocaine Ointment 5% USP

Safety Data Sheet

according to Regulation (EC) No. 453/2010

Full text of R-, H- and EUH-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	Sensitisation — Skin, category 1
STOT SE 3	Specific target organ toxicity — Single exposure, Category 3, Respiratory tract irritation
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
R22	Harmful if swallowed
R37	Irritating to respiratory system
R38	Irritating to skin
R43	May cause sensitisation by skin contact
R51/53	Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment
N	Dangerous for the environment
Xi	Irritant
Xn	Harmful

SDS EU (REACH Annex II)

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.