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SAFETY DATA SHEET

1. Identification

Product identifier Emla Cream

Other means of identification None.

Recommended use Topical anaesthetic.

Recommended restrictions None known.

Manufacturer/Importer/Supplier/Distributor information

Company name

Aspen Global Incorporated

Address GBS Plaza, Cnr La Salette et Royal Road

Grand Bay, Mauritius

Telephone N/A

E-mail SDSRequest@aspengl.com
Emergency telephone Toll free access: 1 866 519 4752

Emergency telephone

number

(US, Canada, Mexico) (+) 1 760 476 3962

Access Code: 333974

2. Hazard identification

Physical hazards Not classified.

Health hazards Serious eye damage/eye irritation

Category 2

Environmental hazards Not classified.

Label elements



Signal word Warning

Hazard statement Causes serious eye irritation.

Precautionary statements

Prevention Wash thoroughly after handling. Wear eye/face protection.

Response IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present

and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.

Storage Store away from incompatible materials.

Disposal Dispose of contents/container in accordance with local/regional/national/international regulations.

Other hazards None known.

Supplemental information None.

3. Composition/information on ingredients

Mixtures

Chemical name	CAS number	%
Lidocaine	137-58-6	1 - <10
Prilocaine	721-50-6	2.5 - <3

Composition comments All concentrations are in percent by weight unless ingredient is a gas. Gas concentrations are in

percent by volume.

4. First-aid measures

Inhalation Remove victim from source of exposure. Get medical attention for any breathing difficulty.

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Wash skin with soap and water. Remove contaminated clothing and shoes. If skin irritation or rash Skin contact

occurs: Get medical advice/attention. For minor skin contact, avoid spreading material on

unaffected skin.

Flush thoroughly with water for at least 15 minutes. Remove contact lenses, if present and easy to Eye contact

do. Get medical attention if irritation develops and persists.

Rinse mouth and then drink 200-300 ml of water. Do not induce vomiting without advice from Ingestion

medical personnel. Get medical attention.

Most important

symptoms/effects, acute and

delayed

Direct contact with eyes may cause temporary irritation. May produce a reduced heart rate and

reduction in blood pressure with a resulting feeling of dizziness.

Indication of immediate medical attention and special

treatment needed

Provide general supportive measures and treat symptomatically. Symptoms may be delayed.

Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves.

5. Fire-fighting measures

Suitable extinguishing media

Unsuitable extinguishing

General information

media

the chemical

Specific hazards arising from

Special protective equipment

Use fire-extinguishing media appropriate for surrounding materials.

During fire, gases hazardous to health may be formed.

Water fog. Foam. Dry chemical powder. Carbon dioxide (CO2).

and precautions for firefighters

Use water spray to cool unopened containers.

Fire fighting equipment/instructions

Specific methods

Use standard firefighting procedures and consider the hazards of other involved materials.

Self-contained breathing apparatus and full protective clothing must be worn in case of fire.

General fire hazards No unusual fire or explosion hazards noted.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

Keep unnecessary personnel away. For personal protection, see section 8 of the SDS.

Methods and materials for containment and cleaning up

Stop the flow of material, if this is without risk. Sweep or shovel up material and place in a clearly labeled container for waste. Following product recovery, flush area with water. For waste disposal, see section 13 of the SDS.

Environmental precautions

Avoid discharge into drains, water courses or onto the ground.

7. Handling and storage

Precautions for safe handling

Avoid contact with eyes. Observe good industrial hygiene practices.

Conditions for safe storage. including any incompatibilities Store in original tightly closed container. Store away from incompatible materials (see section 10 of

the SDS). Do not freeze. Store temperature: <30°C

8. Exposure controls/personal protection

Occupational exposure limits No exposure limits noted for ingredient(s).

Biological limit values No biological exposure limits noted for the ingredient(s).

Exposure guidelines No exposure standards allocated.

Appropriate engineering

controls

Good general ventilation should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been

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established, maintain airborne levels to an acceptable level.

Individual protection measures, such as personal protective equipment

Eye/face protection Wear safety glasses with side shields (or goggles).

Skin protection

Hand protection Wear appropriate chemical resistant gloves.

Other Wear suitable protective clothing.

No personal respiratory protective equipment normally required. Respiratory protection Thermal hazards Wear appropriate thermal protective clothing, when necessary.

Emla Cream SDS Canada General hygiene considerations

Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants.

9. Physical and chemical properties

Appearance

Physical state Liquid.

Form Cream. Emulsion.

White. Colour

No data available. Odour **Odour threshold** Not applicable.

Not available. Melting point/freezing point Initial boiling point and boiling Not available.

range

Not applicable. Flash point **Evaporation rate** Not applicable. Not applicable. Flammability (solid, gas) Upper/lower flammability or explosive limits

Flammability limit - lower

Not available.

8.7 - 9.7

(%)

Flammability limit - upper

Not available.

(%)

Vapour pressure Not applicable. Vapour density Not applicable. Not available. Relative density

Solubility(ies)

Solubility (water) Miscible in water. Partition coefficient Not available.

(n-octanol/water)

Auto-ignition temperature Not available. **Decomposition temperature** Not available. **Viscosity** Not applicable.

Other information

Explosive properties Not explosive. Oxidising properties Not oxidising.

10. Stability and reactivity

The product is stable and non-reactive under normal conditions of use, storage and transport. Reactivity

Chemical stability Material is stable under normal conditions.

Possibility of hazardous

reactions

No dangerous reaction known under conditions of normal use.

Conditions to avoid Contact with incompatible materials. Keep from freezing.

Incompatible materials Strong oxidising agents.

Hazardous decomposition

products

No hazardous decomposition products are known.

11. Toxicological information

Information on likely routes of exposure

Inhalation No adverse effects due to inhalation are expected.

Skin contact Mild skin irritation. May cause numbness.

Eye contact Direct contact with eyes may cause temporary irritation.

Ingestion Expected to be a low ingestion hazard. However, ingestion is not likely to be a primary route of

occupational exposure.

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Symptoms related to the physical, chemical and toxicological characteristics Direct contact with eyes may cause temporary irritation. May produce a reduced heart rate and reduction in blood pressure with a resulting feeling of dizziness.

Information on toxicological effects

May cause discomfort if swallowed. Acute toxicity

Components **Species Test Results**

Lidocaine (CAS 137-58-6)

Acute Oral

Rat LD50 317 mg/kg

Prilocaine (CAS 721-50-6)

Acute

Oral

LD50

Rat 317 mg/kg

Skin corrosion/irritation Serious eye damage/eye

Germ cell mutagenicity

Causes mild skin irritation. Causes serious eye irritation.

irritation

Respiratory or skin sensitisation

Respiratory sensitisation

Not a respiratory sensitiser.

Skin sensitisation This product is not expected to cause skin sensitisation.

> Prolonged or repeated contact may cause skin sensitisation in susceptible individuals. No data available to indicate product or any components present at greater than 0.1% are

mutagenic or genotoxic.

Carcinogenicity Not classifiable as to carcinogenicity to humans.

Reproductive toxicity This product is not expected to cause reproductive or developmental effects.

Specific target organ toxicity -

single exposure

Not classified.

Specific target organ toxicity -

repeated exposure

Not classified.

Not an aspiration hazard. **Aspiration hazard**

Further information None known.

12. Ecological information

The product is not classified as environmentally hazardous. However, this does not exclude the **Ecotoxicity** possibility that large or frequent spills can have a harmful or damaging effect on the environment.

Components		Species	Test Results
Lidocaine (CAS 137-5	58-6)		
Aquatic			
Algae	EC50	Green algae	780 mg/l, 72 hours
Crustacea	EC50	Daphnia	112 mg/l, 48 hours
Fish	LC50	Danio rerio	106 mg/l, 96 hours OECD Test Guideline 203
Prilocaine (CAS 721-5	50-6)		
Aquatic			
Acute			
Algae	EC50	Green algae	154 mg/l, 72 hours OECD Test Guideline 201
Crustacea	EC50	Daphnia magna	61 mg/l, 48 hours OECD Test Guideline 202
Fish	LC50	Zebrafish	188 mg/l, 96 hours OECD Test

Persistence and degradability

Bioaccumulative potential

No data is available on the degradability of this product.

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Guideline 203

Partition coefficient n-octanol / water (log Kow)

Prilocaine (CAS 721-50-6)

Mobility in soil No data available.

Other adverse effects No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation

2.11

potential, endocrine disruption, global warming potential) are expected from this component.

13. Disposal considerations

Disposal instructionsCollect and reclaim or dispose in sealed containers at licensed waste disposal site.

Local disposal regulations Dispose in accordance with all applicable regulations.

Hazardous waste code

The waste code should be assigned in discussion between the user, the producer and the waste

disposal company.

Waste from residues / unused

products

Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see:

Disposal instructions).

Contaminated packaging Since emptied containers may retain product residue, follow label warnings even after container is

emptied. Empty containers should be taken to an approved waste handling site for recycling or

disposal.

Not applicable.

14. Transport information

TDG

Not regulated as dangerous goods.

IATA

Not regulated as dangerous goods.

IMDG

Not regulated as dangerous goods.

Transport in bulk according to

Annex II of MARPOL 73/78 and

the IBC Code

15. Regulatory information

Canadian regulations This product has been classified in accordance with the hazard criteria of the HPR and the SDS

contains all the information required by the HPR.

Controlled Drugs and Substances Act

Not regulated.

Export Control List (CEPA 1999, Schedule 3)

Not listed.

Greenhouse Gases

Not listed.

Precursor Control Regulations

Not regulated.

International regulations

Stockholm Convention

Not applicable.

Rotterdam Convention

Not applicable.

Kyoto Protocol

Not applicable.

Montreal Protocol

Not applicable.

Basel Convention

Not applicable.

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	No
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	No

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Country(s) or region	inventory name	On inventory (yes/no)
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	No
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	No
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No

Taiwan Taiwan Chemical Substance Inventory (TCSI) No Toxic Substances Control Act (TSCA) Inventory United States & Puerto Rico No

Inventory name

16. Other information

Country(s) or region

01-June-2018 Issue date

Revision date Version No. 01

List of abbreviations LD50: Lethal Dose 50%.

EC50: Effective Concentration 50%. LC50: Lethal Concentration 50%.

References Supplier's SDS

Disclaimer While the information and recommendations contained in this safety data sheet are believed to be

correct at the time of issue, liability for its accuracy, adequacy or completeness is excluded to the maximum extent permissible by law and no express or implied warranty is given. This exclusion extends to liability for any statement, opinion or conclusion contained in or any omission from this safety data sheet (including its annexes and references) and for any other related written or oral communication. No representations or warranties are made for these statements, opinions or conclusions and the user must determine the correct and proper use of the material described in

On inventory (yes/no)*

this safety data sheet.

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^{*}A "Yes" indicates this product complies with the inventory requirements administered by the governing country(s).

A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).