

SAFETY DATA SHEETS

This SDS packet was issued with item:

073267911

The safety data sheets (SDS) in this packet apply to one or more components included in the items listed below. Items listed below may require one or more SDS. Please refer to invoice for specific item number(s).

073270014

MATERIAL SAFETY DATA SHEET

Product name: ZAP TOPICAL ANESTHETIC GEL
Last revised date: 6 December 2013
Print date: 18 December 2013

1. SUBSTANCE AND SUPPLIER IDENTIFICATION

PRODUCT NAME: Zap Topical Anesthetic Gel
DIN: 01930699

MANUFACTURER: Germiphene Corporation
ADDRESS: 1379 Colborne Street East, Brantford, Ontario N3T 5M1, Canada
PHONE: 519-759-7100
FAX: 519-759-1625

EMERGENCY PHONE: CANUTEC 613-996-6666

PRODUCT USE: For rapid and long lasting topical anesthesia.

2. COMPOSITION / INFORMATION ON INGREDIENTS

INGREDIENT: Tetracaine Hydrochloride
CAS No 136-47-0 % wt 2.0
HAZARDOUS: yes

INGREDIENT: Benzocaine
CAS No N/Av % wt 18.0
HAZARDOUS: yes

INGREDIENT: Propylene Glycol
CAS No 57-55-6 % wt 36 - 37.5
HAZARDOUS: yes

INGREDIENT: Polyethylene Glycol
CAS No 25322-68-3 % wt 35 - 38
HAZARDOUS: yes

3. HAZARD IDENTIFICATION

EYES: May cause irritation.
SKIN: May cause irritation.
INGESTION: May be harmful if swallowed.
INHALATION: N/Ap

4. FIRST AID MEASURES

EYES: Wash eyes with plenty of water for at least 15 minutes. If irritation persists, contact physician.
SKIN: Wash well with soap and water.
INGESTION: Immediately contact physician or poison control center.
INHALATION: N/Ap

MATERIAL SAFETY DATA SHEET

Product name: ZAP TOPICAL ANESTHETIC GEL
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5. FIREFIGHTING MEASURES

FLAMMABILITY: N/Av
COMBUSTIBLE: N/Av
HAZARDOUS COMBUSTION PRODUCTS: N/Av

6. ACCIDENTAL RELEASE MEASURES

Small spills can be wiped with absorbent paper. Large spills should be absorbed with sand, earth or similar material or mopped up and wash with water.

7. HANDLING AND STORAGE

Store below 25°C.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

VENTILATION: N/Av
RESPIRATORY PROTECTION: No
EYE PROTECTION: No
SKIN PROTECTION: No
OTHER PROTECTIVE CLOTHING OR EQUIPMENT: No

9. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE: Clear, viscous, colour characteristic of flavour
ODOUR: Characteristic of flavour
PHYSICAL STATE: Gel
pH: 3.00-5.00
BOILING POINT: N/Av
FREEZING POINT: N/Av
EVAPORATION RATE: N/Av
SPECIFIC GRAVITY @ 25 ± 1°C: 1.07 - 1.11 g/mL
VISCOSITY: 35000-120,000 cps
VAPOUR PRESSURE (mmHg): N/Av
SOLUBILITY: N/Av

10. STABILITY AND REACTIVITY

STABILITY: N/Av
CONDITIONS TO AVOID (STABILITY): N/Av
INCOMPATIBILITY (MATERIALS TO AVOID): N/Av
HAZARDOUS DECOMPOSITION PRODUCTS: N/Av

MATERIAL SAFETY DATA SHEET

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11. TOXICOLOGICAL INFORMATION

TETRACAINE HYDROCHLORIDE Oral mouse LD50 160 mg/kg
BENZOCAINE Oral rabbit LD50 1150 mg/kg
PROPYLENE GLYCOL Oral rat LD50 20 - 34 g/kg
POLYETHYLENE GLYCOL Oral rat LD50 16 g/kg

12. ECOLOGICAL INFORMATION

N/Av

13. DISPOSAL CONSIDERATIONS

WASTE DISPOSAL METHOD: Dispose of in accordance with local, provincial, and federal law.

14. TRANSPORT INFORMATION

Not regulated by TDG.

15. REGULATORY INFORMATION

WHMIS CATEGORY: Exempt - Drug Product

16. OTHER INFORMATION

Prepared by: Germiphene Technical Department

Disclaimer

No representations or warranties, either expressed or implied, of merchantability, fitness for a particular purpose, or of any nature are made with respect to the product or information contained in this Material Safety Data Sheet. All information contained herein is presented in good faith and is believed to be appropriate and accurate. However, neither the above named supplier, nor any of its subsidiaries assumes any liability whatsoever for the accuracy or completeness of the information contained herein. Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist. The buyer or user assumes all risks associated with the use, misuse or disposal of this product. The buyer or user is responsible to comply with all federal, state, provincial, or local regulations concerning the use, misuse, or disposal of these products.

SAFETY DATA SHEET

Revision #0

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1. SUBSTANCE AND SUPPLIER IDENTIFICATION

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EMERGENCY PHONE: CANUTEC 613-996-6666

PRODUCT USE: For rapid and long lasting topical anesthesia.

2. HAZARD IDENTIFICATION

EMERGENCY OVERVIEW: May cause serious eye damage. Prolonged contact with skin may cause irritation. Possible Allergen. Contact with eyes may cause irritation or other effects. May be harmful if swallowed. This product is a Non-flammable liquid with a flash point of >250 °F.

SYMBOLS:



SIGNAL WORD: Warning

GHS Classification:

| | Health | Environmental | Physical |
|------------------|-------------|------------------------------------|----------|
| Skin Irritant: | Category 3 | Acute Aquatic Toxicity: Category 3 | |
| Eye Irritant: | Category 2A | Chronic Toxicity: None Known | |
| Skin Sensitizer: | Category 1 | | |

| <u>Hazard Statements</u> | <u>Precautionary Statements</u> |
|---|---|
| H320: Causes eye irritation | P261: Avoid breathing mist/vapors/spray |
| H317: May cause allergic skin reaction | P264: Wash hands thoroughly after handling |
| H336: May cause drowsiness or dizziness | P273: Avoid release to the environment |
| H402: Harmful to aquatic life | P280: Wear appropriate protective gloves/eye protection |

| <u>Risk Phrases</u> | <u>Safety Phrases</u> |
|---|---|
| R21/22: Harmful in contact with skin and if swallowed | S26: In case of contact with eyes, rinse immediately with plenty of water and seek medical advice |
| R26/27/28: Irritating to eye, respiratory system and skin | S36/37: Wear suitable protective clothing and gloves |
| R43: May cause sensitization by skin contact | S45: In case of an accident or if you feel unwell, seek medical advice immediately |
| R51: Toxic to aquatic organisms | S61: Avoid release to the environment |
| R67: Vapors may cause drowsiness and dizziness | |

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HEALTH HAZARDS OR RISKS FROM EXPOSURE:

Inhalation: Inhalation of vapors may cause irritation of the upper respiratory system

Contact with Skin: Topical anesthetic. Contact with skin may cause irritation and allergen.

Eye Contact: Contact with the eyes can cause irritation and/or redness. Will anesthetize mucous membranes and may act as an allergen.

Ingestion: Not expected to be a normal route of entry. Topical anesthetic. May induce CNS depression, drowsiness and possible respiratory depression.

Chronic: Anesthetic. Tetracaine hydrochloride may cause sensitization and allergic reaction.

Target Organs: **Acute:** Skin, eyes, respiratory tract **Chronic:** Skin

3. COMPOSITION / INFORMATION ON INGREDIENTS

| INGREDIENT: | CAS No: | % wt: | HAZARDOUS: |
|--------------------------|------------|-----------|------------|
| Tetracaine Hydrochloride | 136-47-0 | 2.0 | yes |
| Benzocaine | N/Av | 18.0 | yes |
| Propylene Glycol | 57-55-6 | 36 - 37.5 | yes |
| Polyethylene Glycol | 25322-68-3 | 35 - 38 | yes |

4. FIRST AID MEASURES

EYES: Wash eyes with plenty of water for at least 15 minutes. Remove contact lenses if present. If irritation persists or blurred vision continues, contact physician.

SKIN: Wash skin thoroughly after handling. Seek medical attention if irritation persists. Remove contaminated clothing. Launder before re-use.

INGESTION: If product is swallowed, call physician or poison control center for most current information. If professional advice is not available, do not induce vomiting. Never induce vomiting or give diluents (milk or water) to someone who is unconscious, having convulsions, or who cannot swallow. Seek medical advice. Take a copy of the label and/or SDS with the victim to the health professional.

INHALATION: N/Av

MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE: Pre-existing skin problems may be aggravated by prolonged exposure to this product.

RECOMMENDATIONS TO PHYSICIANS: Treat symptoms and reduce over-exposure.

5. FIREFIGHTING MEASURES

FLASH POINT: > 250 °F

AUTOIGNITION TEMPERATURE: Not established

FLAMMABLE LIMITS (in air, by volume, %): Lower (LOL): Not Established
Upper (UEL): Not Established

UNUSUAL FIRE AND EXPLOSION HAZARDS: This product may produce hazardous combustion by-products.

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SPECIAL FIRE-FIGHTING PROCEDURES: Incipient fire responders should wear eye protection. Structural firefighters must wear self-contained breathing apparatus and full protective equipment. Isolate materials not yet involved in the fire and protect personnel. Move containers from fire area if this can be done without risk; otherwise, cool with carefully applied water spray. If possible, prevent runoff water from entering storm drains, bodies of water, or other environmentally sensitive areas.

FLAMMABILITY: N/Av
COMBUSTIBLE: N/Av
HAZARDOUS COMBUSTION PRODUCTS: N/Av

6. ACCIDENTAL RELEASE MEASURES

SPILL AND LEAK RESPONSE: Personnel should be trained for spill response operations.
SPILLS: Contain spill if safe to do so. Soak up with an absorbent material and place in an appropriate closed container for disposal. Dispose of in accordance with applicable Federal, State, and local procedures (see Section 13, Disposal Considerations). Small spills can be wiped with absorbent paper. Large spills should be absorbed with sand, earth or similar material or mopped up and wash with water.

7. HANDLING AND STORAGE

WORK PRACTICES AND HYGIENE PRACTICES: As with all chemicals, avoid getting this product on you or in you. Wash thoroughly after handling this product. Do not eat, drink, smoke, or apply cosmetics while handling this product. Avoid breathing vapors/mists/sprays generated by this product. Use in a well-ventilated location. Remove contaminated clothing immediately.

STORAGE AND HANDLING PROCEDURES: Containers of this product must be properly labeled. Store containers in a cool, dry location (below 25 °C) away from heat and sources of ignition. Keep container tightly closed when not in use. Store away from incompatible materials.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

VENTILATION AND ENGINEERING CONTROLS: Use with adequate ventilation to ensure exposure levels are maintained below the limits provided below. Use local exhaust ventilation to control airborne mist/vapor/dust. Ensure eyewash/safety shower stations are available near areas where this product is used.

RESPIRATORY PROTECTION: Not normally required when using this product. Maintain airborne contaminant concentrations below guidelines listed above, if applicable. If necessary, use only respiratory protection authorized in the US Federal OSHA Respiratory Protection Standards (29 CFR 1910.134), equivalent US State Standards, Canadian CSA Standard

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EYE PROTECTION: Z94.4-93, the European Standard EN149, or EU member states.
Although eye protection is not normally required when using this product, splash goggles or safety glasses with side shields are recommended where splashing is possible. If necessary, refer to US OSHA 29 CFR 1910.133, Canadian Standards, and the European Standard EN166, Australian Standards, or relevant Japanese Standards.

HAND PROTECTION: Compatible protective gloves recommended as appropriate for task. Wash hands after removing gloves. If necessary, refer to US OSHA 29 CFR 1910.138, the European Standard DIN EN 374, the appropriate standards of Canada, Australian Standards, or relevant Japanese Standards.

BODY PROTECTION: Not normally required when using this product. Use body protection appropriate to prevent contact (e.g. lab coat, overalls). If necessary, refer to appropriate Standards of Canada, or appropriate Standards of the EU, Australian Standards, or relevant Japanese Standards.

9. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE: Clear, viscous, colour characteristic of flavour
ODOUR: Characteristic of flavour
PHYSICAL STATE: Gel
pH: 3.00-5.00
BOILING POINT: N/Av
FREEZING POINT: N/Av
EVAPORATION RATE: N/Av
SPECIFIC GRAVITY @ 25 ± 1°C: 1.07 - 1.11 g/mL
VISCOSITY: 35000-120,000 cps
VAPOUR PRESSURE (mmHg): N/Av
SOLUBILITY: N/Av

10. STABILITY AND REACTIVITY

STABILITY: Product is stable.
CONDITIONS TO AVOID (STABILITY): Avoid with incompatible materials.
INCOMPATIBILITY (MATERIALS TO AVOID): Strong oxidizing agents.
HAZARDOUS DECOMPOSITION PRODUCTS: When heated to decomposition this product may contain carbon dioxide, carbon monoxide and unidentified toxic and/or irritating compounds.

11. TOXICOLOGICAL INFORMATION

TETRACAINE HYDROCHLORIDE Oral mouse LD50 160 mg/kg
BENZOCAINE Oral rabbit LD50 1150 mg/kg
PROPYLENE GLYCOL Oral rat LD50 20 - 34 g/kg
POLYETHYLENE GLYCOL Oral rat LD50 16 g/kg

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IRRITANCY OF PRODUCT: Contact with this product can be irritating to exposed skin, eyes, and respiratory system.
SENSITIZATION OF PRODUCT: An ingredient in this product is considered a skin sensitizer.
REPRODUCTIVE TOXICITY INFORMATION: None available.

12. ECOLOGICAL INFORMATION

ALL WORK PRACTICES MUST BE AIMED AT ELIMINATING ENVIRONMENTAL CONTAMINATION.
ENVIRONMENTAL STABILITY: No data available at this time.
EFFECT OF MATERIAL ON PLANTS OR ANIMALS: No data available at this time.
EFFECT OF MATERIAL ON AQUATIC LIFE: No data available at this time.

13. DISPOSAL CONSIDERATIONS

WASTE DISPOSAL METHOD: Dispose of in accordance with local, provincial, and federal law.

14. TRANSPORT INFORMATION

US DOT; IATA; IMO; ADR: This product is not hazardous as defined by 49 CFR 172.101 by the US Department of Transportation.
PROPER SHIPPING NAME: Non-Regulated Material
HAZARD CLASS NUMBER AND DESCRIPTION: None
UN IDENTIFICATION NUMBER: None
PACKING GROUP: None
DOT LABEL(S) REQUIRED: None
NORTH AMERICAN EMERGENCY RESPONSE GUIDEBOOK NUMBER (2004): None
MARINE POLLUTANT: None of the ingredients are classified by the DOT as a Marine Pollutant (as defined by 49 CFR 172.101, Appendix B)

US DEPARTMENT OF TRANSPORTATION (DOT) SHIPPING REGULATIONS:
This product is not classified as dangerous goods, per US DOT Regulations, under 49 CFR 172.101.

TRANSPORT CANADA, TRANSPORTATION OF DANGEROUS GOOD REGULATIONS:
This product is not classified as Dangerous Goods, per regulations of Transport Canada.

INTERNATIONAL AIR TRANSPORT ASSOCIATION (IATA):
This product is not classified as Dangerous Goods, by rules of IATA.

INTERNATIONAL MARITIME ORGANIZATION (IMO) DESIGNATION:
This product is not classified as Dangerous Goods by the International Maritime Organization.

EUROPEAN AGREEMENT CONCERNING THE INTERNATIONAL CARRIAGE OF DANGEROUS GOODS BY ROAD (ADR):
This product is not classified by the United Nations Economic Commission for Europe to be dangerous goods.

15. REGULATORY INFORMATION

UNITED STATES REGULATIONS

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SARA reporting requirements: This product is subject to the reporting requirements of sections 302, 304, and 313 of Title III of the Superfund Amendments and Reauthorization Act., as follows: None

TSCA: All components in this product are listed on the US Toxic Substances Control Act (TSCA) inventory of chemicals.

SARA 311/312: Acute Health: Yes Chronic Health: Yes Fire: No Reactivity: No

US SARA Threshold Planning quantity: There are no specific Threshold Planning Quantities for this product. The default Federal MSDS submission and inventory requirement threshold of 10,000 lb (4, 540 kg) may apply, per 40 CFR 370.20.

US Cercla reportable quantity (RQ): Saccharin Insoluble (CAS#81-07-2): 100 Lbs.

California safe drinking water and toxic enforcement act (proposition 65): This product does not contain ingredient(s) that are on the California Proposition 65 list.

CANADIAN REGULATIONS:

Canadian DSL/NDSL inventory status: all of the components of this product are on the DSL Inventory

Canadian environmental protect act (CEPA) priorities substances lists: No component of this product is on the CEPA First Priorities Substance Lists

Canadian WHMIS classification and symbols: This product is categorized as a Class D Division 2B materials causing other toxic effects, as per the Controlled Product Regulations

EUROPEAN ECONOMIC COMMUNITY INFORMATION:

EU labelling and classification: Classification of the mixture according to Regulation (EC) No1272/2008. See section 2 for details.

Australian information for product:

Australian inventory of chemical substances (AICS) status: All components of this product are listed on the AICS.

Standard for the uniform scheduling of drugs and poison: Not applicable.

JAPANESE INFORMATION FOR PRODUCT:

Japanese Minister of international trade and industry (MITI) Status: The components of this product are not listed as Class I Specified Chemical Substances, Class II Specified Chemical Substances, or Designated Chemical Substances by the Japanese MITI.

INTERNATIONAL CHEMICAL INVENTORIES:

Listing of the components on individual country Chemical Inventories is as follows:

| | |
|---|--------|
| Asia-Pac: | Listed |
| Australian Inventory of Chemical Substances (AICS): | Listed |
| Korean Existing Chemicals List (ECL): | Listed |
| Japanese Existing National Inventory of Chemical Substances (ENCS): | Listed |
| Philippines Inventory of Chemicals and Chemical Substances (PICCS): | Listed |
| Swiss Giftliste List of Toxic Substances: | Listed |
| US TSCA: | Listed |

WHMIS CATEGORY: Exempt - Drug Product

16. OTHER INFORMATION

Prepared by: Germiphene Technical Department

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