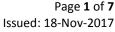
# **SAFETY DATA SHEETS**

# This SDS packet was issued with item:

074841466

The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).

071150010 071150028 071150036 071150044



Revision No. 06



# SAFETY DATA SHEET BENZOCAINE 18%/TETRACAINE HYDROCHLORIDE 2% GEL

#### **SECTION 1: IDENTIFICATION**

## **Product Identifier**

Product Name: BENZOCAINE 18%/TETRACAINE HYDROCHLORIDE 2% GEL

Other Means of Identification

Product Item Code(s): 10039-BG, 10039-CH, 10039-M, 10039-ST, 10039-RB

Recommended use of the chemical and restriction on use

Recommended Use: Topical Anesthetic

Restrictions on Use: Do not swallow. For professional use only

Name, address, telephone number of the supplier:

Company Address: AMD Medicom Inc.

2555 Chemin de l'Aviation

Pointe-Claire (Montreal), Quebec, H9P 2Z2

Canada

<u>Information Telephone Number</u>: 514-636-6262 Emergency Telephone Number: 1-800-361-2862

## **SECTION 2: HAZARD(S) IDENTIFICATION**

## **GHS Classification**

- Skin sensitization Category 1
- Eye Irritation Category 2

## **GHS Label Elements, including Precautionary Statements**

Signal Word: Warning Hazard Statements:

- Causes eye irritation
- May be harmful if swallowed
- May cause an allergic skin reaction

### Pictograms:



## **Precautionary Statements:**



Issued: 18-Nov-2017 Revision No. 06

# SAFETY DATA SHEET BENZOCAINE 18%/TETRACAINE HYDROCHLORIDE 2% GEL

- Keep out of reach of children
- Keep container tightly closed
- Wash hands thoroughly after handling

Hazards not otherwise classified: None

**Unknown Acute Toxicity**: No ingredients with unknown toxicity

#### **SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS**

Ingredients	CAS No./ EINECS No.	Weight Percent
Benzocaine	94-09-7/202-303-5	18%
Tetracaine hydrochloride	136-47-0/N/A	2%
Carbomer Polymer	9003-01-4/N/A	1-5%

#### **SECTION 4: FIRST AID MEASURES**

Eye Contact: Flush eyes with large quantities of water for at least 15 minutes, holding the eyelids apart. Get medical attention if irritation develops or persists

Skin Contact: Wash skin with plenty of soap and water. Get medical attention if irritation or allergic reaction occurs

Ingestion: Do not induce vomiting. Rinse out mouth with water. If symptoms persist, get immediate medical attention

**Inhalation:** Move victim to fresh air. Get medical attention if irritation persists

Most Important symptoms/effects, acute and delayed: May cause skin sensitization

Indication of immediate medical attention and special treatment needed

Notes to Physician: Treat symptomatically. May cause sensitization of skin for susceptible persons

#### **SECTION 5: FIRE FIGHTING MEASURES**

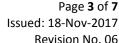
Suitable Extinguishing Media: Use media appropriate for the surrounding fire

**Unsuitable Extinguishing Media**: None known

Specific hazards arising from the chemical: May cause sensitization by skin contact

Special Protective equipment and precautions for firefighters: Firefighters should wear full

emergency equipment and positive pressure self-contained breathing apparatus



# SAFETY DATA SHEET BENZOCAINE 18%/TETRACAINE HYDROCHLORIDE 2% GEL

Unusual Fire/Explosion Hazards: None known

Known or Anticipated Hazardous Products of Combustion: Carbon monoxide, carbon dioxide

#### **SECTION 6: ACCIDENTAL RELEASE MEASURES**

<u>Personal precautions, protective equipment and emergency procedures</u>: Avoid contact with eyes, skin and clothing. Use appropriate protective equipment as described in Section 8. Wash thoroughly with soap and water after handling. Keep containers closed when not in use

**Environmental Precautions:** Prevent spill from entering waterways

<u>Methods and materials for containment and cleaning up</u>: Prevent further leakage or spillage if safe to do so. Wipe up or collect using an inert absorbent material and place in appropriate containers for disposal. Rinse spill area with water. Prevent spill from entering sewers and water courses. Report releases as required by local, state and federal authorities

#### **SECTION 7: HANDLING AND STORAGE**

<u>Precautions for safe handling</u>: Avoid contact with the eyes, skin and clothing. Wear protective clothing and equipment as described in Section 8. Wash thoroughly with soap and water after handling. Keep containers tightly closed when not in use

Do not reuse containers. Empty containers retain product residues that can be hazardous. Follow all safety precautions when handling empty containers

<u>Conditions for safe storage including any incompatibilities</u>: Store at room temperature away from excessive heat over 40°C or 104°F. Keep out of reach of children. Keep container tightly closed

#### SECTION 8: EXPOSURE CONTROLS/ PERSONAL PROTECTION

**Exposure Control Parameters**: The parameters are not provided for the product itself. This product, as supplied, does not contain hazardous substances with occupational exposure limit values

<u>Occupational Exposure Limits</u>: No limits are established for the product. No ingredients with occupational exposure limit values

<u>Appropriate Engineering Controls</u>: No special ventilation normally required. For bulk handling, use ventilation that is adequate to maintain exposure levels below the occupational exposure limits

#### **Individual Protection Measures:**

Personal Protective Equipment

Revision No. 06



SAFETY DATA SHEET
BENZOCAINE 18%/TETRACAINE HYDROCHLORIDE 2% GEL

Eye Protection: Safety glasses recommended, if splash is likely to occur. None required for

normal use

**Skin Protection:** Wear impervious gloves

<u>Respiratory Protection:</u> None should be needed for normal use. If the exposure limits are exceeded an approved respirator with particulate cartridges or air respirator appropriate for the form and concentration of the contaminants should be used. Selection and use of respiratory equipment must be in accordance with applicable regulations and good industrial hygiene practice

 Other Protective Clothing or Equipment: None needed for normal use. Impervious clothing as needed to avoid contamination of personal clothing for bulk handling

#### **SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES**

**Appearance**: Gel of various colors

Odor: Characteristic

Odor Threshold: Not available

pH: Not available

<u>Melting point</u>: Not available <u>Freezing Point</u>: Not available

**Boiling Point/Range:** Not available

Flashpoint: Not available

**Evaporation Rate:** Not available

**Flammability (solid, gas)**: Not available

**Upper/lower flammability or explosive limits**:

LEL: Not available
UEL: Not available

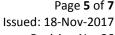
Vapor Pressure: Not available Vapor Density: Not available Relative Density: Not available Solubility in water: Not available

**Partition coefficient** 

(n-octanol/water): Not available

<u>Autoignition Temperature</u>: Not available <u>Decomposition Temperature</u>: Not available

Viscosity: Not available



Medicom<sup>®</sup>

Revision No. 06

# SAFETY DATA SHEET BENZOCAINE 18%/TETRACAINE HYDROCHLORIDE 2% GEL

#### **SECTION 10: STABILITY AND REACTIVITY**

**Reactivity:** No data available

**Chemical Stability:** Stable under recommended storage conditions.

Possibility of Hazardous Reactions: None under normal conditions of processing

Conditions to Avoid: None known

**Incompatible Materials:** Avoid oxidizing agent

Hazardous Decomposition Products: May produce carbon monoxide, carbon dioxide

#### SECTION 11: TOXICOLOGICAL INFORMATION

# **Information on Toxicological Effects:**

Toxicological data not available for the product itself. The data provided are for the ingredients listed

below

Benzocaine: Oral Rabbit LD<sub>50</sub>: 1150mg/kg

Oral Rat LD<sub>50</sub>: 3042mg/kg

Tetracaine hydrochloride: Oral Mouse LD<sub>50</sub>: 160mg/kg Carbomer Polymer: Oral Rat LD<sub>50</sub>: >10,000 mg/kg

# Likely Routes of Exposure and the Symptoms related to the Physical, Chemical and Toxicological **Characteristics:**

**Eyes**: Direct contact causes eye irritation

Skin: May cause sensitization for a susceptible person

Inhalation: No adverse effects expected under normal conditions of use

Ingestion: May be irritating to mouth, throat and stomach

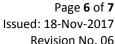
Chronic Health Effects: Not expected under normal conditions of use. May cause sensitization for a

susceptible person

Mutagenicity: No data available

Carcinogenicity: Not known to be as carcinogen or potential carcinogen by NTP (National Toxicological Program), IARC (International Agency for the Research of Cancer) or OSHA (Occupational Safety and Health Administration) or ACGIH (American Conference of Governmental Industrial Hygienists)

Medical Conditions Aggravated by Exposure: Individuals with pre-existing skin disorders may be at increased risk from exposure



# SAFETY DATA SHEET BENZOCAINE 18%/TETRACAINE HYDROCHLORIDE 2% GEL

#### **SECTION 12: ECOLOGICAL INFORMATION**

## **Ecotoxicity**:

Ecological data not available for the product itself. The data provided are for the ingredients listed

below:

Benzocaine: 96 hrs. LC<sub>50</sub> Rainbow Trout: 7.2mg/L

Persistence and degradability: No information available

**Bio-accumulative Potential**: No data available

Mobility in soil: No data available

Other adverse effects: No information available

#### **SECTION 13: DISPOSAL CONSIDERATIONS**

Dispose in accordance with national and local regulations

#### **SECTION 14: TRANSPORT INFORMATION**

**<u>DOT (US)</u>**: This is not a DOT controlled material **<u>Proper Shipping Name</u>**: Not a regulated material

Hazard Class: N/A
UN Number: N/A
Packing Group: N/A

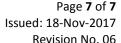
<u>Air (IATA/ICAO)</u>: This is not a regulated material <u>Proper Shipping Name</u>: Not a regulated material

Hazard Class: N/A
UN Number: N/A
Packing Group: N/A

**IMO/IMDG**: This is not a regulated material

**Proper Shipping Name**: Not a regulated material

Hazard Class: N/A
UN Number: N/A
Packing Group: N/A





# SAFETY DATA SHEET BENZOCAINE 18%/TETRACAINE HYDROCHLORIDE 2% GEL

#### SECTION 15: REGULATORY INFORMATION

#### **U.S. FEDERAL REGULATIONS**:

**SARA TITLE III:** 

Hazard Category for Section 311/312: Acute health hazard

<u>Section 313 Toxic Chemicals</u>: This product contains the following chemicals subject to Annual Release Reporting Requirements under SARA Title III, Section 313 (40 CFR 372): None at or above reportable quantity

Section 302 extremely hazardous Substances (TPQ): None at or above reportable quantity

**EPA Toxic Substances Control Act (TSCA) Status**: This product complies with TSCA inventory requirements

**Note**: The regulatory information given above only indicates the principal regulations specifically applicable to the product described in the safety data sheet. The user's attention is drawn to the possible existence of additional provisions which complete these regulations. Refer to all applicable national, international and local regulations or provisions

## **SECTION 16: OTHER INFORMATION**

**Risk phrases used in Section 2**: Not applicable

**Date of preparation of SDS**: November 18, 2017

**Legal disclaimer**: The above information is believed to be correct but does not purport

to be all inclusive and shall be used only as a guide. This company shall not be held liable for any damage resulting from handling or

from contact with the above product