SAFETY DATA SHEET

SECTION 1: PRODUCT IDENTIFICATION

PRODUCT NAME: TROCHE BASE
PRODUCT CODE: 2378
SUPPLIER:
MEDISCA Inc.
Tel.: 1.800.932.1039 | Fax.: 1.855.850.5855
661 Route 3, Unit C, Plattsburgh, NY, 12901
3955 W. Mesa Vista Ave., Unit A-10, Las Vegas, NV, 89118
6641 N. Belt Line Road, Suite 130, Irving, TX, 75063
MEDISCA Pharmaceutique Inc.
Tel.: 1.800.665.6334 | Fax.: 514.338.1693
4509 Rue Dobrin, St. Laurent, QC, H4R 2L8
21300 Gordon Way, Unit 153/158, Richmond, BC V6W 1M2
MEDISCA Australia Pty Ltd
Tel.: 1.300.786.392 | Fax.: 61.2.9700.9047
5-9 Ricketty Street, Mascot, NSW 2020
CHEMTREC Day or Night Within USA and Canada: 1-800-424-9300
NSW Poisons Information Centre: 131 126
EMERGENCY PHONE: Medicinal lozenge base

SECTION 2: HAZARDS IDENTIFICATION

GHS CLASSIFICATION: Based on available data, the classification criteria are not met.
PICTOGRAM: Not Applicable.
SIGNAL WORD: Not Applicable.
HAZARD STATEMENT(S): Not Applicable.
AUSTRALIA-ONLY HAZARDS: Not Applicable.
PRECAUTIONARY STATEMENT(S):
Prevention: Not Applicable.
Response: Not Applicable.
Storage: Not Applicable.
Disposal: Not Applicable.

HMIS CLASSIFICATION:
Health Hazard: 0
Flammability: 0
Reactivity: 0
Personal Protection: A

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

CHEMICAL NAME: Not applicable
BOTANICAL NAME: Not applicable
SYNONYM: Not applicable
CHEMICAL FORMULA: Not applicable
CAS NUMBER: Not applicable
ALTERNATE CAS NUMBER: Not applicable
**SAFETY DATA SHEET**

**MOLECULAR WEIGHT**
Not applicable

**COMPOSITION**

<table>
<thead>
<tr>
<th>CHEMICAL NAME</th>
<th>CAS NUMBER</th>
<th>% BY WEIGHT</th>
</tr>
</thead>
<tbody>
<tr>
<td>SACCHARIN SODIUM</td>
<td>6155-67-3</td>
<td>0.25</td>
</tr>
</tbody>
</table>

There are no additional ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified as health hazards and hence require reporting in this section.

**NOTES**
List of ingredients: Polyethylene Glycol 1450, Stevia powder, Gelatin, Polyethylene Glycol 400, Saccharin Sodium.

*Proprietary: Ingredients indicated as hazardous have been assessed under standards for workplace safety. In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as trade secret.

**SECTION 4: FIRST-AID MEASURES**

**IN CASE OF EYE CONTACT**
Not expected to be an eye hazard under normal use. Flush with copious amounts of water for 15 minutes, separating eyelids with fingers. If irritation persists seek medical aid.

**IN CASE OF SKIN CONTACT**
Not expected to be a skin hazard under normal use. Wash with soap and water if irritation occurs. Seek medical attention if irritation develops and persists.

**IF SWALLOWED**
No adverse effects expected.

**IF INHALED**
No adverse effects expected due to inhalation of vapours at ambient temperature.

**SYMPTOMS AND EFFECTS**
Not expected to present a significant hazard under anticipated conditions of normal use.

**SECTION 5: FIREFIGHTING MEASURES**

**SPECIFIC HAZARDS ARISING FROM THE CHEMICAL**
Not applicable

**FLAMMABLE PROPERTIES**
May be combustible at high temperature

**HAZARDOUS COMBUSTION PRODUCTS**
Under fire conditions, hazardous fumes will be present.

**EXTINGUISHING MEDIA**
Small fire: dry chemical, CO₂ or water spray. Large fire: dry chemical, CO₂, alcohol resistant foam or water spray. Do not get water inside containers.

**PROTECTIVE EQUIPMENT AND PRECAUTIONS FOR FIREFIGHTERS**
Wear self-contained breathing apparatus and protective clothing to prevent contact with skin and eyes.

**SECTION 6: ACCIDENTAL RELEASE MEASURES**

**PERSONAL PRECAUTIONS**
Wear respiratory protection. Avoid breathing vapours, mist or gas. Ensure adequate ventilation. Evacuate personnel to safe areas.

**METHODS & MATERIAL FOR CONTAINMENT**
On land, sweep or shovel into suitable containers.

**CLEANUP PROCEDURE**
Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Wear respirator, chemical safety goggles, rubber boots and heavy rubber gloves. Stop leak if you can do it without risk. Prevent entry into waterways, sewers, basements or confined areas. Shut off all sources of ignition. Evacuate the area. If necessary, employ water fog to disperse the vapors. Absorb the matter with compatible vermiculite or other absorbing material. Place in a suitable container and retain for disposal. Ventilate and clean the affected area. Do not flush into sewerage system or to drains.
SECTION 7: HANDLING AND STORAGE

PRECAUTIONS FOR SAFE HANDLING

Avoid contact with eyes. Store away from incompatible materials, in a well-ventilated area. Eliminate all sources of ignition. Store in accordance with local regulations. Do not store in unlabelled containers. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Use appropriate containment to avoid environmental contamination.

STORAGE CONDITIONS

Store in original container, tightly sealed, protected from direct sunlight and moisture. Controlled room temperature indicates a temperature 20° to 25°C (68° to 77°F); that results in a mean kinetic temperature calculated to be not more than 25°C; and that allows for excursions between 15° and 30°C (59° and 86°F) that are experienced in pharmacies, hospitals, and warehouses. Provided the mean kinetic temperature remains in the allowed range, transient spikes up to 40°C (104°F) are permitted as long as they do not exceed 24 hours. Keep in well-closed containers at controlled room temperature.

SECTION 8: EXPOSURE CONTROLS/ PERSONAL PROTECTION

Chemical Name: POLYETHYLENE GLYCOL  CAS #: 25322-68-3

<table>
<thead>
<tr>
<th></th>
<th>TWA</th>
<th>Ceiling</th>
<th>STEL</th>
<th>REL</th>
<th>IDLH</th>
<th>Remarks</th>
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<tbody>
<tr>
<td>NIOSH</td>
<td>N/L</td>
<td>N/L</td>
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<td>N/L</td>
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<tr>
<td>AIHA WEEL</td>
<td>10 mg/m³</td>
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<td>-</td>
<td>-</td>
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<tr>
<td>Safe Work Australia HSIS</td>
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<td>-</td>
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<tr>
<td>HSE</td>
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<td>N/L</td>
<td>N/L</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>OSHA PEL</td>
<td>N/L</td>
<td>N/L</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>ACGIH TLV</td>
<td>N/L</td>
<td>N/L</td>
<td>N/L</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>

N/L = Not Listed

EXPOSURE GUIDELINES
Consult local authorities for provincial or state exposure limits. Particulates not otherwise regulated, respirable fraction: 5 mg/m²

PERSONAL PROTECTIVE EQUIPMENT

Eyes: Not needed for normal use. Operate according to good working practices. Skin: No special precaution must be adopted for normal use. Operate according to good working practices. Clothing: Not needed for normal use. Operate according to good working practices. Respirators: Not needed for normal use. Operate according to good working practices.

SPECIFIC ENGINEERING CONTROLS
Not needed for normal use. Operate according to good working practices.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

PHYSICAL STATE
Solid

DESCRIPTION
White-translucent chunk or pellet at room temperature with mild polyethylene glycol odor.

SOLUBILITY
Not available

ODOR
Mild polyethylene glycol odor

FLAMMABILITY
May be combustible at high temperature

ODOR THRESHOLD
Not available

PH
Not available

MELTING POINT
45 - 51 °C

BOILING POINT
Not available

FREEZING POINT
Not available

FLASH POINT
Not available
SAFETY DATA SHEET

SPECIFIC GRAVITY: Not available
EVAPORATION RATE: Not available
EXPLOSIVE LIMIT: Not available

UPPER FLAMMABLE/EXPLOSIVE LIMIT(S): Not available
LOWER FLAMMABLE/EXPLOSIVE LIMIT(S): Not available
VAPOR PRESSURE: Not available

VAPOR DENSITY (AIR = 1): Not available
RELATIVE DENSITY (WATER = 1): Not available
log P (OCTANOL-WATER): Not available

AUTO-IGNITION TEMPERATURE: Not available
DECOMPOSITION TEMPERATURE: Not available
VISCOSITY: Not available

NOTES: The physical data presented above are typical values and should not be construed as a specification.

SECTION 10: STABILITY AND REACTIVITY

REACTIVITY: Not established

STABILITY: Stable under recommended storage conditions

MATERIALS TO AVOID: Strong oxidants

HAZARDOUS DECOMPOSITION PRODUCTS: Toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides and other gases may occur

HAZARDOUS POLYMERIZATION: Will not occur

POSSIBILITY OF HAZARDOUS REACTION: Not established

CONDITIONS TO AVOID: Moisture, sunlight and extreme temperatures

SECTION 11: TOXICOLOGICAL INFORMATION

ACUTE TOXICITY: Oral: Rat: LD50: (mg/kg): Not available
Dermal: Rabbit LD50: (mg/kg): Not available
Inhalation: Rat: LC50: (mg/L/4hr): Not available

SKIN CORROSION/IRRITATION: Due to lack of data the classification is not possible.

SERIOUS EYE DAMAGE/EYE IRRITATION: Due to lack of data the classification is not possible.

RESPIRATORY OR SKIN SENSITIZATION: Due to lack of data the classification is not possible.

GERM CELL MUTAGENICITY: Due to lack of data the classification is not possible.

CARCINOGENICITY: OSHA: SACCHARIN SODIUM is listed.
NTP: No component of this product, present at ≥0.1%, is listed.
IARC: SACCHARIN SODIUM is listed in group 3 (not classifiable as to its carcinogenicity to humans).

California Proposition 65: No component of this product, present at ≥0.1% is known to the State of California to cause cancer, birth defects, or any other reproductive harm.

ADDITIONAL CARCINOGENICITY INFORMATION: Due to lack of data the classification is not possible.

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**REPRODUCTIVE TOXICITY**  
Due to lack of data the classification is not possible.

**SPECIFIC TARGET ORGAN TOXICITY - SINGLE EXPOSURE**  
Due to lack of data the classification is not possible.

**SPECIFIC TARGET ORGAN TOXICITY - REPEATED EXPOSURE**  
Due to lack of data the classification is not possible.

**ASPIRATION HAZARDS**  
Based on available data, the classification criteria are not met.

**SIGNS AND SYMPTOMS OF EXPOSURE**

<table>
<thead>
<tr>
<th>Potential Health Effects</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inhalation</td>
<td>Not expected to present a significant hazard.</td>
</tr>
<tr>
<td>Ingestion</td>
<td>Edible, not expected to be harmful if swallowed.</td>
</tr>
<tr>
<td>Skin</td>
<td>Not expected to present a significant hazard. May cause skin irritation.</td>
</tr>
<tr>
<td>Eyes</td>
<td>May cause eye irritation.</td>
</tr>
</tbody>
</table>

**SECTION 12: ECOLOGICAL INFORMATION**

**TOXICITY**

- **EC50:** 48 Hr: Crustacea: (mg/L): Not available
- **LC50:** 96 Hr: Fish: (mg/L): Not available  
- **EC50:** 72 or 96 Hr: Algae (or other aqua plants): (mg/L): Not available

**PERSISTENCE AND DEGRADABILITY**

- Not available

**BIOACCUMULATIVE POTENTIAL**

- Not available

**MOBILITY IN SOIL**

- Not available

**OTHER ADVERSE EFFECTS**

- This product is not intended to be released into the environment

**SECTION 13: DISPOSAL CONSIDERATIONS**

**WASTE DISPOSAL**

Dispose of in accordance with federal / local laws and regulations. Avoid release into the environment.

**SECTION 14: TRANSPORT INFORMATION**

**UNITED STATES & CANADA**

- **UN PROPER SHIPPING NAME**: Not dangerous good
- **UN NUMBER**: Not applicable
- **CLASS**: Not applicable
- **PACKING GROUP**: Not applicable

**AUSTRALIA**

- **UN PROPER SHIPPING NAME**: Not dangerous good
- **UN NUMBER**: Not applicable
- **CLASS**: Not applicable
- **PACKING GROUP**: Not applicable
- **HAZCHEM**: Not applicable
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ENVIRONMENTAL HAZARDS
Not available

SPECIAL SHIPPING INFORMATION
Not applicable

SECTION 15: REGULATORY INFORMATION

<table>
<thead>
<tr>
<th></th>
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<th></th>
<th></th>
<th></th>
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</tr>
</thead>
<tbody>
<tr>
<td>SACCHARIN SODIUM</td>
<td>N/L</td>
<td>N/L</td>
<td>N/L</td>
<td>N/L</td>
<td>X</td>
<td>N/L</td>
<td>X</td>
<td>N/L</td>
</tr>
</tbody>
</table>

N/L = Not Listed; X = Listed

AUSTRALIAN REGULATIONS

<table>
<thead>
<tr>
<th>Chemical Name &amp; CAS</th>
<th>Poisons and Therapeutic Goods Regulation</th>
<th>Therapeutic Goods Act</th>
<th>Code of Practices - Illicit Drug Precursors</th>
</tr>
</thead>
<tbody>
<tr>
<td>SACCHARIN SODIUM</td>
<td>N/L</td>
<td>N/L</td>
<td>N/L</td>
</tr>
</tbody>
</table>

SECTION 16: OTHER INFORMATION

REFERENCES
Available upon request

ABBREVIATIONS AND ACRONYMS
- CAS – Chemical Abstract Service; GHS – Global Harmonized System; OSHA PEL – Occupational Safety & Health Administration Permissible Exposure Limits; TWA – Time Weighted Average; HSIS – Hazardous Substances Information System; STEL – Short Term Exposure Limit; AIHA WEEL – American Industrial Hygiene Association Workplace Environment Exposure Levels; LD50 – Lethal Dose, 50%; IARC – International Agency for Research on Cancer; NTP – National Toxicology Program; WHMIS – Workplace Hazardous Materials Information System; SARA – Superfund Amendments and Reauthorization Act; EPA – Environmental Protection Agency; CERCLA – Comprehensive Environmental Response, Compensation, and Liability Act; HMIS – Hazardous Materials Information System; NIOSH – National Institute for Occupational Safety and Health; MSHA – Mine Safety and Health Administration; ACGIH – American Conference of Governmental Industrial Hygienists; IDHL – Immediately Dangerous to Health or Life; TLV – Threshold Limit Value; HSE – Health and Safety Executive; REL - Recommended Exposure Limit

LAST REVISION
04/2019

SUPERSEDES
11/2016

DISCLAIMER
This document was created in accordance with OSHA, Safe Work Australia and WHMIS regulations. The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions. It does not represent any guarantee of the properties of the product. MEDISCA® shall not be held liable for any damage resulting from handling or from contact with the above product. Recipients of the product must take responsibility for observing existing laws and regulations.