Material Safety Data Sheet  Gelato Plus Topical Anesthetic Gel  Page 1 of 5

Section 1 – Identification

Product Name:  Gelato Plus 18% Benzocaine & 2% Tetracaine Topical Anesthetic Gel
Active Ingredient:  Benzocaine & Tetracaine
Manufacturer:  Keystone Industries
480 S Democrat Rd, Gibbstown, NJ 08027
Information Contacts:  (856) 663-4700
Toll Free:  (800) 333-3131
Emergency Phone Numbers:  (800) 535-5053

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Section 2 – Hazards Identification

EMERGENCY OVERVIEW
This information is based on findings from related or similar materials.

- Harmful if swallowed or inhaled.
- Irritating to skin, eyes, and respiratory system
- May cause allergic skin reaction
- Please read entire MSDS for additional information.

Potential Health Effects, Signs and Symptoms of Exposure:

Primary Route of Entry  Inhalation, skin, and ingestion.
Eye  May cause irritation, redness, and pain.
Skin  May cause skin irritation and redness. Has local anesthetic properties.
Ingestion  Rare cases of cyanosis have been reported. Central nervous excitement may occur.
Inhalation  May cause irritation to the respiratory tract. Symptoms may include coughing and shortness of breath.

NOTE: Refer to Section 11, Toxicological Information for Details

Section 3 – Composition/Information on Ingredients

<table>
<thead>
<tr>
<th>Chemical Identity</th>
<th>CAS Numbers</th>
<th>EINECS#</th>
<th>INCI Name</th>
<th>Exposure OSHA TWA/STEL</th>
<th>Limits ACGIH TWA/STEL</th>
<th>Carcinogen IARC/NTP/OSHA</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Benzocaine USP</td>
<td>94-09-7</td>
<td>202-303-5</td>
<td>4-Aminobenzoic acid and its esters, with the free amino group</td>
<td>N/E</td>
<td>N/E</td>
<td>No/No/No</td>
<td>15-23</td>
</tr>
<tr>
<td>Tetracaine USP</td>
<td>94-24-6</td>
<td>202-316-6</td>
<td>Tetracaine (INN) and its salts</td>
<td>N/E</td>
<td>N/E</td>
<td>No/No/No</td>
<td>0.5-2.7</td>
</tr>
</tbody>
</table>

N/E – None Established  N/R – Not Reviewed  N/DA – No Data  Available  N/A – Not Applicable

(items in parenthesis relate to 1999/45/EC)

Benzocaine:  Danger Symbol – GHS07 (Xi)  Hazard Statement – H319+335+315 (R36/37/38)  Precautionary Statement – P261 (S23), P305+334 (S26), P280 (S37/39)

Tetracaine:  Danger Symbol – GHS08 (Carc), GHS06 (T)  Hazard Statement – H301 (R25), H317 (R43), H351 (R40)  Precautionary Statement – P201 (S53), P202 (N/A), P261 (S23), P264 (S28), P270 (S20/21), P272 (N/A), P280 (S37/38/39), P301 +310 (S46), P302 + 352 (S28), P308 + 313 (N/A), P321 (N/A), P330 (S64), P333+313 (N/A), P363 (N/A), P405 (S1), P501 (S56)

See Section 16 for Hazard and Precautionary Statement Key.

Section 4 – First Aid Measures

First Aid for Eye  Immediately flush eyes with plenty of water for at least 15 minutes, lifting lower and upper eyelids occasionally. Get medical attention immediately.

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First Aid for Skin
Remove any contaminated clothing. Wash skin with soap or mild detergent and water for at least 15 minutes. Get medical attention if irritation develops or persists.

First Aid for Ingestion
Induce vomiting immediately as directed medical personnel. Never give anything by mouth to an unconscious person. Get medical attention.

First Aid for Inhalation
Remove to fresh air. Get medical attention for any breathing difficulty.

Section 5 – Fire Fighting Measures

<table>
<thead>
<tr>
<th>Flash Point (°F/°C)</th>
<th>Flammable Limit (vol%)</th>
<th>Auto-ignition Temperature (vol%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
</tr>
</tbody>
</table>

Method:
Extinguishing Media: “Alcohol” foam, Carbon dioxide, dry chemical foam, water. Water can be used to cool fire exposed containers.

Fire Fighting Instructions:
Wear full protective clothing and NIOSH approved self contained breathing apparatus with full face piece operated in the pressure demand or other positive pressure mode.

Unusual Hazards: N/A

Section 6 – Accidental Release Measures

Spill or Release Procedures
Minor spills – Clean up immediately, avoid contact with skin and eyes. Ensure adequate ventilation. Wipe area and clean with soapy water.

Major spills – Clear area of personnel. Restrict access to area. Avoid contact with skin and eyes. Ensure adequate ventilation. Depending on the size of the spill absorb or wipe up with inert material, such as sand, dry lime, or soda ash, and dispose of properly. Clean area with soapy water. See section 8 & section 12.

Section 7 – Handling and Storage

Handling
Limit all unnecessary personal contact. Avoid breathing vapors. Wear appropriate PPE.

Storage
Store in a cool, well ventilated area away from heat. Keep containers closed when not in use. Keep in original container provided by manufacturer.

Explosion Hazard
None.

Section 8 – Exposure Controls / Personal Protection

Engineering
Mechanical exhaust is recommended when handling large quantities. Safety shower, eye bath, and fire equipment (spill response) should be accessible.

Personal Protective Equipment

General
To identify additional Personal Protective Equipment (PPE) requirements, it is recommended that a hazard assessment in accordance with the OSHA PPE Standard (29CFR1910.132), or European Standard EN166 be conducted before using this product.

Eye/ Face Protection
Chemical safety glasses / goggles are required when handling. Ensure eye bath is on hand.

Skin Protection
Use impermeable clothing to prevent ANY contact with this product, such as gloves, apron, boots, or whole body suit.

Respiratory Protection
In case of insufficient ventilation, wear suitable respiratory equipment with correct respiratory cartridge. If the respirator is the sole means of protection, use a full face supplied air respirator.

Section 9 – Physical and Chemical Properties

<table>
<thead>
<tr>
<th>Appearance</th>
<th>Odor &amp; Odor Threshold</th>
<th>pH</th>
<th>Specific Gravity</th>
<th>Viscosity</th>
<th>% Volatile</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gel</td>
<td>Odor characteristic of flavor</td>
<td>N/A</td>
<td>(H2O = 1): N/A</td>
<td>N/A</td>
<td>N/A</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Boiling Point/ Freezing Point</th>
<th>Decomposition Temperature</th>
<th>Octanol/Water Partitioning Coefficient</th>
<th>Vapor Pressure</th>
<th>Vapor Density</th>
<th>Evaporation Rate</th>
<th>Ignition</th>
<th>Solubility In Water (20°C)</th>
</tr>
</thead>
<tbody>
<tr>
<td>N/A</td>
<td>N/DA</td>
<td>N/DA</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
</tr>
</tbody>
</table>

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Material Safety Data Sheet

Gelato Plus Topical Anesthetic Gel

Flash Point (°F/°C) | Flammable Limit (vol%) | Auto-ignition Temperature (vol%)
---|---|---
N/A | N/A | N/A

**Section 10 – Stability and Reactivity**

**Stability:**
Stable

**Hazardous Decomposition Products:**
Carbon dioxide and monoxide, possible nitrous oxide fumes

**Incompatibility (Materials to Avoid):**
Strong Oxidizers, Silver salts

**Hazardous Polymerization:**
Will not occur

**Conditions to Avoid:**
Heat and incompatible materials

**Section 11 – Toxicological Information**

| Acute Oral Toxicity | Acute Dermal Toxicity | Acute Inhalation Toxicity | Irritation – skin | Irritation – Eye |
---|---|---|---|---|
N/DA | N/DA | N/DA | N/DA | N/DA |

| Sensitization | Mutagenicity | Sub-chronic Toxicity |
---|---|---|
N/DA | N/DA | N/DA |

**Section 12 – Ecological Information**

**Ecotoxicological Information**

| Acute Toxicity to Fish | Acute Toxicity to Invertebrates | Acute Toxicity to Algae | Bioconcentration | Toxicity to Sewage Bacteria |
---|---|---|---|---|
N/DA | N/DA | N/DA | N/DA | N/DA |

**Chemical Fate Information**

| Biodegradability | Chemical Oxygen Demand |
---|---|
N/DA. This material is not expected to significantly bio-accumulate. | N/DA |

**Section 13 – Disposal Considerations**

Dispose of in compliance with governmental regulation (state and federal).

Dispose of container and unused contents in accordance with federal, state and local requirements. For EU Member States, please refer to any relevant Community provisions relating to waste. In their absence, it is useful to remind the user that national or regional provisions may be in force.

**Section 14 – Transport Information**

| DOT (49 CFR 172) | IATA (DGR): |
---|---|
Proper Shipping Name: Non-regulated material | Proper Shipping Name: Non-regulated material |
Identification Number: N/A | Class or Division: N/A |
Marine Pollutant: No | UN or ID Number: N/A |
Special Provisions: N/A | Packaging Instructions: N/A |
Emergency Response Guidebook (ERG) #: N/A | Emergency Response Guidance (ICAO)#: N/A |

| IMO (IMDG): |
---|
Proper Shipping Name: Non-regulated material | Proper Shipping Name: Non-regulated material |
Class or Division: N/A | Class or Division: N/A |
UN or ID Number: N/A | UN or ID Number: N/A |
Special Provisions & Stowage/Segregation: N/A | Special Provisions & Stowage/Segregation: N/A |
Emergency Schedule (EmS)#: N/A | Other Information: N/A |

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# Section 15 – Regulatory Information

## US Federal Regulations

| Clean Air Act: HAP/ODS | This product contains the following HAP’s or ODS:  
- NONE |
|------------------------|-------------------------------------------------|
| Clean Water Act: Priority Pollutant | This product contains the following chemicals listed under the U. S. Clean Water Act Priority Pollutant and Hazardous Substance List:  
- None |
| FDA: Food Packaging Status | This product has not been cleared by the FDA for use in food packaging and / or other applications as an indirect food-packaging additive. |
| Occupational Safety and Health Act | This product is considered to be hazardous under the OSHA Hazard Communication Standard. It’s hazards are:  
- Tetracaine – CAS# 94-24-6 (Toxic by ingestion, skin sensitizer, Carcinogen)  
- Benzocaine – CAS #94-09-7 (Acute Health Hazard) |
| RCRA | This product does not contain any chemicals that are considered to be hazardous waste under RCRA (40 CFR 261) |
| SARA Title III: Section 302 (RQ) | This product contains no chemicals regulated under Section 302 as extremely hazardous substances. |
| SARA Title III: Section 302 (TPQ) | This product does not contain chemicals regulated under Section 304 as extremely hazardous chemicals for emergency release notification (“CERCLA” List). |
| SARA Title III: Section 311-312: | This product is considered to be hazardous under the OSHA Hazard Communication Standard and is regulated under Section 311-312 (40 CFR 370). It’s hazards are:  
- Tetracaine – CAS# 94-24-6 (Toxic by ingestion, skin sensitizer, Carcinogen)  
- Benzocaine – CAS #94-09-7 (Acute Health Hazard) |
| SARA Title III: Section 313: | This product does not contain any chemicals which are subject to the reporting requirements of Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 and 40 CFR Part 372. |
| TSCA Section 8(b): Inventory: | This product does contain chemicals listed on the TSCA inventory or otherwise complies with TSCA pre-manufacture notification requirements.  
- Tetracaine – CAS# 94-24-6  
- Benzocaine – CAS #94-09-7  
None of the chemicals in this material have a SNUR under TSCA. |
| TSCA Significant New Use Rule: | |

## State Regulations

| CA Right-to-Know Law: California No Significant Risk Rule: | N/E |
| MA Right-to-Know Law: | N/E |
| NJ Right-to-Know Law: | Benzocaine – CAS #94-09-7  
Tetracaine – CAS # 94-24-6 |
| PA Right-to-Know Law: | Tetracaine – CAS # 94-24-6  
Benzocaine – CAS #94-09-7 |
| FL Right-to-Know Law: | N/E |
| MN Right-to-Know Law: | N/E |

## International Regulations

| CDSL: Canadian Inventory (on Canadian Transitional List) | Benzocaine – CAS #94-09-7  
Tetracaine – CAS # 94-24-6 |

## Labeling according to EC directives – 1272/2008 (CLP) AND 1999/45/EC (items in parenthesis relate to 1999/45/EC)

### European Community:

| European Community: | For Gelato Plus Topical Anesthetic Gel (finished product):  
- DANGER SYMBOLS: GHS07 (XI) – Irritant / Warning.  

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Section 16 – Other Information

EU Classes and Risk / Safety Phrases for Referenced Ingredients (See Section 2):

(items in parenthesis relate to 1999/45/EC)

Danger Symbols:
GHS07 (Xi) – Irritant. GHS06 (T) – Toxic. GHS08 (Carc) – Health hazard (Organ Toxicity). GHS07 (Xn) - Harmful

Hazard Statement: H302 (R22), Harmful if swallowed. H317 (R43), Causes skin sensitization. H319+335+315 (R36/37/38), Irritating to eyes, respiratory system, and skin. H301 (R25), Toxic if swallowed. H317 (R43), May cause an allergic reaction. H351 (R40), Suspected of causing cancer. H332 (R20), Harmful if swallowed. H315 (R38), Causes skin irritation. H319 (R36), Serious eye damage / irritation. H335 (R37), May cause respiratory irritation.

Precautionary Statement: P102 (S1 or S2), Keep out of reach of children. P210 (S15 or S16), Keep away from heat/sparks/open flames/hot surfaces. P280 (S36/37/39), Wear protective gloves/eye protection/face protection. P305+334 (S26), In case of contact with eyes, rinse immediately with water. P309+314 (S45), If exposed or you feel unwell, get medical advice/attention. P404 (S7), Store in a closed container. P403 (S9), Store in a well ventilated place. P261 (S24), Avoid breathing dust/fume/gas/mist/vapors. P201 (S53), Obtain special instructions before use. P202 (N/A), Do not handle until all safety precautions have been read and understood. P264 (S28), Wash skin thoroughly after handling. P270 (S20/21), Do not eat, drink, or smoke when using this product. P272 (N/A), Contaminated work clothing should not be allowed out of the workplace. P301 + 310 (S46), If swallowed, immediately all a poison center or doctor / physician. P302 +352 (S28), If on skin wash with plenty of soap and water. P308 + 313 (N/A), If exposed or concerned, get medical attention. P321 (N/A), Specific treatment (see first aid section). P330 (S64), Rinse Mouth. P333 + 313 (N/A), If skin irritation or rash occurs, get medical attention. P363 (N/A), Wash contaminated clothing before reuse. P405 (S1), Store locked up. P501 (S56), Dispose of contents properly.

Hazard Rating System (Pictograms)

NFPA:

<table>
<thead>
<tr>
<th>Flammability</th>
<th>Reactivity</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

HMIS:

Health

| 2 |

Flammability

| 0 |

 Reactivity

| 0 |

MSDS Prepared by: WME

Revision History: 03/23/11 Initial

05/01/13 Changed manufacturer from Deepak to Keystone, changed address and telephone number SWR

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