



BIO-PHARM Incorporated

CARBAMIDE PEROXIDE 6.5% EAR DROPS

Safety Data Sheet

Prepared according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

Revision date: 09/02/2015

Supersedes: N/A

Version: 1.0

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Product name : CARBAMIDE PEROXIDE 6.5% EAR DROPS
Product form : Mixture
Other means of identification : Pharmaceutical
Active Ingredient: 6.5% carbamide peroxide (w/v)

1.2. Relevant identified uses of the substance or mixture and uses advised against

Use of the substance/mixture : Softening, loosening, and removing the ear wax.

1.3. Details of the supplier of the safety data sheet

BIO-PHARM INC.
2091 HARTEL STREET
LEVITTOWN, PA 19057
PHONE: (215) 949-3711

1.4. Emergency telephone number

Emergency number : 1-866-845-1611

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

GHS-US classification

Skin Irrit. 2 H315
Eye Irrit. 2A H319

2.2. Label elements

GHS-US labelling

Hazard pictograms (GHS-US) :



GHS07

Signal word (GHS-US) : **Warning**

Hazard statements (GHS-US) : H315 - Causes skin irritation
H319 - Causes serious eye irritation

Precautionary statements (GHS-US) : P264 - Wash hands, forearms and face thoroughly after handling
P280 - Wear eye protection, face protection, protective clothing, protective gloves
P302+P352 - If on skin: Wash with plenty of soap and water
P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing
P321 - Specific treatment (see first aid instructions on this label)
P332+P313 - If skin irritation occurs: Get medical advice/attention
P337+P313 - If eye irritation persists: Get medical advice/attention
P362+P364 - Take off contaminated clothing and wash it before reuse

2.3. Other hazards

No additional information available

2.4. Unknown acute toxicity (GHS US)

No data available

SECTION 3: Composition/information on ingredients

3.1. Substance

Not applicable

3.2. Mixture

| Name | Product identifier | % |
|----------------------|--------------------|--------|
| Urea peroxide | (CAS No) 124-43-6 | 5 - 10 |
| 1,2-Propylene glycol | (CAS No) 57-55-6 | 3 - 7 |

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SECTION 4: First aid measures

4.1. Description of first aid measures

- First-aid measures general : If exposed or concerned, get medical attention/advice. Show this safety data sheet to the doctor in attendance. Wash contaminated clothing before re-use. Never give anything to an unconscious person.
- First-aid measures after inhalation : IF INHALED: Remove to fresh air and keep at rest in a position comfortable for breathing. Get medical attention if breathing is affected. If breathing is difficult, supply oxygen.
- First-aid measures after skin contact : IF ON SKIN (or clothing): Remove affected clothing and wash all exposed skin with water for at least 15 minutes. If irritation develops or persists, get medical attention.
- First-aid measures after eye contact : IF IN EYES: Immediately flush with plenty of water for at least 15 minutes. Remove contact lenses if present and easy to do so. If pain, blinking, or irritation develops or persists, get medical attention. Continue rinsing.
- First-aid measures after ingestion : IF SWALLOWED: rinse mouth thoroughly. Do not induce vomiting without advice from poison control center or medical professional. Get medical attention if you feel unwell.

4.2. Most important symptoms and effects, both acute and delayed

- Symptoms/injuries : Causes skin irritation. Causes serious eye irritation.
- Symptoms/injuries after inhalation : May cause respiratory irritation.
- Symptoms/injuries after skin contact : Causes skin irritation.
- Symptoms/injuries after eye contact : Causes serious eye irritation.
- Symptoms/injuries after ingestion : May cause gastrointestinal irritation.

4.3. Indication of any immediate medical attention and special treatment needed

No additional information available.

SECTION 5: Firefighting measures

5.1. Extinguishing media

- Suitable extinguishing media : Foam. Carbon dioxide. Dry powder. Water spray. Sand.

5.2. Special hazards arising from the substance or mixture

- Fire hazard : Not flammable.
- Explosion hazard : Product is not explosive.
- Reactivity : No dangerous reactions known under normal conditions of use.

5.3. Advice for firefighters

- Precautionary measures fire : Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
- Firefighting instructions : Use water spray or fog for cooling exposed containers. Exercise caution when fighting any chemical fire. Do not dispose of fire-fighting water in the environment.
- Protection during firefighting : Do not enter fire area without proper protective equipment, including respiratory protection.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

- General measures : Evacuate area. Ventilate area. Keep upwind. Spill should be handled by trained clean-up crews properly equipped with respiratory equipment and full chemical protective gear (see Section 8).

6.1.1. For non-emergency personnel

- Protective equipment : Wear Protective equipment as described in Section 8.

6.1.2. For emergency responders

- Protective equipment : Wear suitable protective clothing, gloves and eye or face protection. Approved supplied-air respirator, in case of emergency.

6.2. Environmental precautions

Prevent entry to sewers and public waters. Avoid release to the environment.

6.3. Methods and material for containment and cleaning up

- For containment : Contain any spills with dikes or absorbents to prevent migration and entry into sewers or streams.
- Methods for cleaning up : Take up liquid spill into absorbent material. Place in a suitable container for disposal in accordance with the waste regulations (see Section 13).

6.4. Reference to other sections

See Sections 8 and 13.

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SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : Do not handle until all safety precautions have been read and understood. Avoid contact with skin and eyes. Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Keep the container tightly closed. Store in a dry, cool and well-ventilated place. Protect from light.

Storage temperature : 20 - 25 °C

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

| Urea peroxide (124-43-6) | |
|--------------------------------|----------------------|
| Remark (ACGIH) | OELs not established |
| Remark (OSHA) | OELs not established |
| 1,2-Propylene glycol (57-55-6) | |
| Remark (ACGIH) | OELs not established |
| Remark (OSHA) | OELs not established |

8.2. Exposure controls

Appropriate engineering controls : Provide adequate general and local exhaust ventilation. Use process enclosures, local exhaust ventilation, or other engineering controls to control airborne levels below recommended exposure limits. Use explosion-proof equipment with flammable materials. Ensure adequate ventilation, especially in confined areas.

Personal protective equipment : Gloves. Protective goggles. Wear chemically impervious apron over labcoat and full coverage clothing.



Hand protection : Use gloves chemically resistant to this material when prolonged or repeated contact could occur. Gloves should be classified under Standard EN 374 or ASTM F1296. Suggested glove materials are: Neoprene, Nitrile/butadiene rubber, Polyethylene, Ethyl vinyl alcohol laminate, PVC or vinyl. . Suitable gloves for this specific application can be recommended by the glove supplier.

Eye protection : Wear eye protection, including chemical splash goggles and a face shield when possibility exists for eye contact due to spraying liquid or airborne particles.

Skin and body protection : Wear long sleeves, and chemically impervious PPE/coveralls to minimize bodily exposure.

Respiratory protection : Use NIOSH-approved dust/particulate respirator. Where vapor, mist, or dust exceed PELs or other applicable OELs, use NIOSH-approved respiratory protective equipment.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state : Liquid

Color : Colorless. Pale yellow.

Odor : No data available

Odor Threshold : No data available

pH : 4 - 7.5

Relative evaporation rate (butylacetate=1) : No data available

Melting point : No data available

Freezing point : No data available

Boiling point : No data available

Flash point : No data available

Auto-ignition temperature : No data available

Decomposition temperature : No data available

Flammability (solid, gas) : No data available

Vapour pressure : No data available

Relative vapour density at 20 °C : No data available

Relative density : 1.245 - 1.272

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| | |
|----------------------|-----------------------------|
| Solubility | : No data available |
| Log Pow | : No data available |
| Log Kow | : No data available |
| Viscosity, kinematic | : No data available |
| Viscosity, dynamic | : No data available |
| Explosive properties | : Product is not explosive. |
| Oxidising properties | : No data available |
| Explosive limits | : No data available |

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

No dangerous reactions known under normal conditions of use.

10.2. Chemical stability

Stable under recommended handling and storage conditions (see section 7).

10.3. Possibility of hazardous reactions

None known.

10.4. Conditions to avoid

Excessive heat.

10.5. Incompatible materials

None known.

10.6. Hazardous decomposition products

Thermal decomposition generates : Carbon oxides (CO, CO₂).

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity : Not classified

| 1,2-Propylene glycol (57-55-6) | |
|--------------------------------|----------------------------|
| LD50 oral rat | 20000 mg/kg |
| LD50 dermal rabbit | 20800 mg/kg |
| ATE CLP (oral) | 20000.000 mg/kg bodyweight |
| ATE CLP (dermal) | 20800.000 mg/kg bodyweight |

| | |
|--|---|
| Skin corrosion/irritation | : Causes skin irritation. pH: 4 - 7.5 |
| Serious eye damage/irritation | : Causes serious eye irritation. pH: 4 - 7.5 |
| Respiratory or skin sensitisation | : Not classified |
| Germ cell mutagenicity | : Not classified |
| Carcinogenicity | : Not classified |
| Reproductive toxicity | : Not classified |
| Specific target organ toxicity (single exposure) | : Not classified |
| Specific target organ toxicity (repeated exposure) | : Not classified |
| Aspiration hazard | : Not classified |
| Symptoms/injuries after inhalation | : May cause respiratory irritation. |
| Symptoms/injuries after skin contact | : Causes skin irritation. |
| Symptoms/injuries after eye contact | : Causes serious eye irritation. |
| Symptoms/injuries after ingestion | : May cause gastrointestinal irritation. |

SECTION 12: Ecological information

12.1. Toxicity

Ecology - general : No information available.

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12.2. Persistence and degradability

| CARBAMIDE PEROXIDE 6.5% EAR DROPS | |
|-----------------------------------|------------------------|
| Persistence and degradability | Readily biodegradable. |

12.3. Bioaccumulative potential

| CARBAMIDE PEROXIDE 6.5% EAR DROPS | |
|-----------------------------------|---------------------------|
| Bioaccumulative potential | No information available. |

12.4. Mobility in soil

| CARBAMIDE PEROXIDE 6.5% EAR DROPS | |
|-----------------------------------|---------------------------|
| Ecology - soil | No information available. |

12.5. Other adverse effects

Other adverse effects : No data available.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste treatment methods : Obtain the consent of pollution control authorities before discharging to wastewater treatment plants.

Waste disposal recommendations : Dispose in a safe manner in accordance with local/national regulations. Do not allow the product to be released into the environment.

SECTION 14: Transport information

In accordance with DOT

Not hazardous for transport

Additional information

Other information : No supplementary information available.

Transport by sea

No additional information available

Air transport

No additional information available

SECTION 15: Regulatory information

15.1. US Federal regulations

| CARBAMIDE PEROXIDE 6.5% EAR DROPS | |
|---|---------------------------------|
| All chemical substances in this product are listed in the EPA (Environment Protection Agency) TSCA (Toxic Substances Control Act) Inventory | |
| SARA Section 311/312 Hazard Classes | Immediate (acute) health hazard |

15.2. International regulations

No additional information available.

15.3. US State regulations

California Proposition 65

WARNING! This product contains chemicals known to the state of California to cause cancer, birth defects, or other reproductive harm.

| Diethanolamine (111-42-2) | | | | |
|---|---|---|---|-----------------------------------|
| U.S. - California - Proposition 65 - Carcinogens List | U.S. - California - Proposition 65 - Developmental Toxicity | U.S. - California - Proposition 65 - Reproductive Toxicity - Female | U.S. - California - Proposition 65 - Reproductive Toxicity - Male | No significance risk level (NSRL) |
| Yes | No | No | No | Not available |

Urea peroxide (124-43-6)

U.S. - New Jersey - Right to Know Hazardous Substance List

1,2-Propylene glycol (57-55-6)

U.S. - New Jersey - Right to Know Hazardous Substance List
U.S. - Pennsylvania - RTK (Right to Know) List

Glycerol (56-81-5)

U.S. - Massachusetts - Right To Know List
U.S. - New Jersey - Right to Know Hazardous Substance List
U.S. - Pennsylvania - RTK (Right to Know) List

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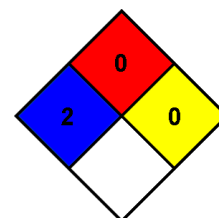
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SECTION 16: Other information

Indication of changes : Revision 1.0: New SDS Created.
Revision date : 09/02/2015
Other information : Author: BCS.

NFPA health hazard : 2 - Intense or continued exposure could cause temporary incapacitation or possible residual injury unless prompt medical attention is given.
NFPA fire hazard : 0 - Materials that will not burn.
NFPA reactivity : 0 - Normally stable, even under fire exposure conditions, and are not reactive with water.



HMIS III Rating

Health : 2
Flammability : 0
Physical : 0
Personal Protection : C

The information contained in this Safety Data Sheet has been compiled from reliable sources and is believed to be correct as of the date issued. It is the responsibility of the user to determine the appropriateness and applicability to their situation. BIO-PHARM INC. disclaims any expressed or implied warranty as to the accuracy of the above information and shall not be held liable for any direct, incidental, or consequential damages, from use or reliance on the above information.