

Safety Data Sheet

1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

| | |
|----------------|--|
| Product Name | "Deleted" Promethazine hydrochloride 1.0% pet |
| Article Number | P-017A |
| Applications | Diagnosis of contact allergy. |
| Manufacturer | Chemotechnique MB Diagnostics AB Modemgatan 9 SE-235 39 Vellinge lab@chemotechnique.se |
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2. HAZARD IDENTIFICATION

Health hazards

The objective of applying a hapten on the patient's skin is the diagnosis of contact allergy. Localized dermal allergic reaction may occur at test site.

Signs and symptom of exposure

Dermal irritation.

Medical conditions aggravated by exposure

Dermatitis.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Classification according to (EC) No. 1272/2008 [EU-GHS/CLP]

| Component | CAS-No. | Content | Classification |
|--------------------------------------|-----------|---------|--|
| Petrolatum | 8009-03-8 | 99.0% | - |
| "Deleted" Promethazine hydrochloride | 58-33-3 | 1.0% | Acute tox. Oral 4, Acute tox. Inhal. 4, Skin irrit. 2, Eye irrit. 2, Skin sensit. 1, Spec. targ. org. tox. - single exp. 3, Chron. aq. tox. 1; H302+H332, H315, H317, H319, H335, H411 |

Classification according to EU Directive 67/548/EEC and 1999/45/EC

| Component | CAS-No. | Content | Classification |
|------------------------|-----------|---------|---------------------------|
| Petrolatum | 8009-03-8 | 99.0% | - |
| "Deleted" Promethazine | 58-33-3 | 1.0% | Xn, N; R20/22, R36/37/38, |

4. FIRST AID MEASURES

Emergency and first aid procedures

Obtain medical attention.

5. FIRE-FIGHTING MEASURES*

Suitable extinguish media

CO₂, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.

For safety reasons unsuitable extinguishing agents

Water with full jet.

Special protective equipment for fire-fighters

Wear self-contained respiratory protective device. Wear fully protective suit.

*Data is shown for petrolatum only

6. ACCIDENTAL RELEASES MEASURES

Steps to be taken if material is released or spilled

Contain and place in a closed container.

7. HANDLING AND STORAGE

Precautions to be taken in handling and storage

Store dark at 5-8°C. Avoid extended exposure to light. FOR EXTERNAL USE ONLY.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Respiratory protection

Not required.

Ventilation

Local exhaust.

Protective gloves

Disposal gloves.

Eye protection

Not required with normal use.

Work/Hygienic practices

Wash hands after each use.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance

Ivory White Semi-solid

Odour

Odourless

| | |
|---------------------------------------|---|
| Melting point* | 50-55° C |
| Boiling point* | No data available |
| Flash point* | >100°C |
| Self ignition* | Product does not self ignite. |
| Danger of explosion* | Product does not present an explosion hazard. |
| Density* | No data available. |
| Solubility in/Miscibility with Water* | Insoluble |

*Data is shown for petrolatum only

10. STABILITY AND REACTIVITY

Incompability

May react with strong oxidizing agents.

Stability

Stable at recommended storage conditions.

Hazardous byproducts

Combustion may generate CO, CO₂ and other oxides.

Hazardous polymerization

Will not occur.

11. TOXICOLOGICAL INFORMATION

No data available.

12. ECOLOGICAL INFORMATION

No data available.

13. DISPOSAL CONSIDERATIONS

Waste disposal method

Comply with federal, state/provincial and local regulation.

14. TRANSPORT INFORMATION

Not dangerous goods.

15. REGULATORY INFORMATION

The classification is according to the latest editions of the EU lists, and extended by company and literature data.

16. OTHER INFORMATION

Text of H-statements and R-phrases mentioned in Section 3

| | |
|---------------------------------------|--|
| Acute tox. Oral 4 | Acute toxicity, Oral (Category 4) |
| Acute tox. Inhal. 4 | Acute toxicity, Inhalation (Category 4) |
| Skin irrit. 2 | Skin irritation (Category 2) |
| Eye irrit. 2 | Eye irritation (Category 2) |
| Skin sensit. 1 | Skin sensitization (Category 1) |
| Spec. targ. org. tox. - single exp. 3 | Specific target organ toxicity - single exposure (Category 3) |
| Chron. aq. tox. 1 | Chronic aquatic toxicity (Category 1) |
| H302+H332 | Harmful if swallowed or if inhaled |
| H315 | Causes skin irritation |
| H317 | May cause an allergic skin reaction |
| H319 | Causes serious eye irritation |
| H335 | May cause respiratory irritation |
| H411 | Toxic to aquatic life with long lasting effects |
| Xn | Harmful |
| N | Dangerous for the environment |
| R20/22 | Harmful by inhalation and if swallowed |
| R36/37/38 | Irritating to eyes, respiratory system and skin |
| R43 | May cause sensitisation by skin contact |
| R51/53 | Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment |

Pharmaceutical quality of tested hapten is confirmed by Chemotechnique Diagnostics according to validated analytical methods. Hapten passed test according to GMP standards.

Chemotechnique Diagnostics makes no representation as to the comprehensiveness or correctness of the information provided. It is intended only as a guide to a properly trained individual in the appropriate handling of the material.