



## 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<br>Modemgatan 9<br>SE-235 39 Vellinge<br><a href="mailto:lab@chemotechnique.se">lab@chemotechnique.se</a> |
| Telephone      | +46 (0) 40 466 077 (Monday-Friday 8.00-16.00 GMT+1)  |
| Fax            | +46 (0) 40 466 700   |

### 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**

CO<sub>2</sub>, 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, CO<sub>2</sub> 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.