

Safety Data Sheet

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

Product Name	N-Ethyl-N-(2-hydroxyethyl)-2-methyl-1,4-phenylenediamine sulfate salt 1.0% pet
Article Number	E-011
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%	-
N-Ethyl-N-(2-hydroxyethyl)-2-methyl-1,4-phenylenediamine sulfate salt	25646-77-9	1.0%	Acute tox. Oral 3, Spec. targ. org.tox. - rep. exp. 2, Skin sensit. 1, Acute aq. tox. 1, Chron. aq. tox. 1; H301, H317, H373, H410

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

Component	CAS-No.	Content	Classification
Petrolatum	8009-03-8	99.0%	-
N-Ethyl-N-(2-hydroxyethyl)-2-methyl-1,4-phenylenediamine sulfate salt	25646-77-9	1.0%	T, N; R25, R43, R48/22, R50/53

-2-methyl-1,4-phenylenedi
amine sulfate salt

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

Beige to Grey 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 3	Acute toxicity, Oral (Category 3)
Spec. targ. org. tox. - rep. exp. 2	Specific target organ toxicity - repeated exposure (Category 2)
Skin sensit. 1	Skin sensitization (Category 1)
Acute aq. tox. 1	Acute aquatic toxicity (Category 1)
Chron. aq. tox. 1	Chronic aquatic toxicity (Category 1)
H301	Toxic if swallowed.
H317	May cause an allergic skin reaction.
H373	May cause damage to organs through prolonged or repeated exposure.
H410	Very toxic to aquatic life with long lasting effects.
T	Toxic
N	Dangerous for the environment
R25	Toxic if swallowed.
R43	May cause sensitization by skin contact.
R48/22	Harmful: danger of serious damage to health by prolonged exposure if swallowed.
R50/53	Very 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.