SAFETY DATA SHEET

Diminazene / Phenazone Formulation

1. PRODUCT AND COMPANY IDENTIFICATION

Product name: Diminazene / Phenazone Formulation

Manufacturer or supplier’s details
Company: MSD
Address: Briahnager - Off Pune Nagar Road
           Wagholi - Pune - India 412 207
Telephone: +1-908-740-4000
Emergency telephone number: +1-908-423-6000
E-mail address: EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use
Recommended use: Veterinary product

2. HAZARDS IDENTIFICATION

Manufacture, Storage and Import of Hazardous Chemicals Rules 1989

Classification
Not classified as hazardous according to criteria laid down in Part I of Schedule-1.

GHS Classification
Skin corrosion/irritation: Category 2
Specific target organ toxicity - single exposure (Oral): Category 1 (Brain)
Specific target organ toxicity - repeated exposure (Oral): Category 1 (Brain)

GHS label elements
Hazard pictograms:

Signal word: Danger
Hazard statements:
H315 Causes skin irritation.
H370 Causes damage to organs (Brain) if swallowed.
H372 Causes damage to organs (Brain) through prolonged or repeated exposure if swallowed.

Precautionary statements:
Prevention:
P260 Do not breathe mist or vapours.
P264 Wash skin thoroughly after handling.
P270 Do not eat, drink or smoke when using this product.
P280 Wear protective gloves.

Response:
P302 + P352 IF ON SKIN: Wash with plenty of water.
P308 + P316 IF exposed or concerned: Get emergency medical help immediately.
P332 + P317 IF skin irritation occurs: Get medical help.
P362 + P364 Take off contaminated clothing and wash it before reuse.

Storage:
P405 Store locked up.

Disposal:
P501 Dispose of contents/ container to an approved waste disposal plant.

Other hazards which do not result in classification
None known.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diminazene</td>
<td>536-71-0</td>
<td>&gt;= 30 - &lt; 50</td>
</tr>
<tr>
<td>Phenazone</td>
<td>60-80-0</td>
<td>&gt;= 5 - &lt; 10</td>
</tr>
</tbody>
</table>

4. FIRST AID MEASURES

General advice : In the case of accident or if you feel unwell, seek medical advice immediately.
When symptoms persist or in all cases of doubt seek medical advice.

If inhaled : If inhaled, remove to fresh air.
Get medical attention if symptoms occur.

In case of skin contact : In case of contact, immediately flush skin with plenty of water for at least 15 minutes while removing contaminated clothing and shoes.
Get medical attention.
Wash clothing before reuse.
Thoroughly clean shoes before reuse.

In case of eye contact : Flush eyes with water as a precaution.
Get medical attention if irritation develops and persists.

If swallowed : If swallowed, DO NOT induce vomiting unless directed to do so by medical personnel.
Get medical attention.
Rinse mouth thoroughly with water.
Never give anything by mouth to an unconscious person.

Most important symptoms : Causes skin irritation.
and effects, both acute and delayed

Causes damage to organs if swallowed.
Causes damage to organs through prolonged or repeated exposure if swallowed.

Protection of first-aiders: First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).

Notes to physician: Treat symptomatically and supportively.

5. FIREFIGHTING MEASURES

Suitable extinguishing media: Water spray
Alcohol-resistant foam
Carbon dioxide (CO2)
Dry chemical

Unsuitable extinguishing media: None known.

Specific hazards during firefighting: Exposure to combustion products may be a hazard to health.

Hazardous combustion products: Carbon oxides
Nitrogen oxides (NOx)

Specific extinguishing methods: Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Use water spray to cool unopened containers.
Remove undamaged containers from fire area if it is safe to do so.
Evacuate area.

Special protective equipment for firefighters: In the event of fire, wear self-contained breathing apparatus.
Use personal protective equipment.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures: Use personal protective equipment.
Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

Environmental precautions: Avoid release to the environment.
Prevent further leakage or spillage if safe to do so.
Prevent spreading over a wide area (e.g. by containment or oil barriers).
Retain and dispose of contaminated wash water.
Local authorities should be advised if significant spillages cannot be contained.

Methods and materials for containment and cleaning up: Soak up with inert absorbent material.
For large spills, provide dyking or other appropriate containment to keep material from spreading. If dyked material can be pumped, store recovered material in appropriate container.
Clean up remaining materials from spill with suitable absorbent.
Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable.
Sections 13 and 15 of this SDS provide information regarding...
certain local or national requirements.

7. HANDLING AND STORAGE

Technical measures: See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.

Local/Total ventilation: Use only with adequate ventilation.

Advice on safe handling:
- Do not get on skin or clothing.
- Do not breathe mist or vapours.
- Do not swallow.
- Avoid contact with eyes.
- Wash skin thoroughly after handling.
- Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment.
- Do not eat, drink or smoke when using this product.
- Take care to prevent spills, waste and minimize release to the environment.

Conditions for safe storage:
- Keep in properly labelled containers.
- Store locked up.
- Store in accordance with the particular national regulations.

Materials to avoid:
- Do not store with the following product types:
  - Strong oxidizing agents

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diminazene</td>
<td>536-71-0</td>
<td>TWA</td>
<td>200 µg/m³ (OEB 2)</td>
<td>Internal</td>
</tr>
</tbody>
</table>

**Engineering measures**
- Use appropriate engineering controls and manufacturing technologies to control airborne concentrations (e.g., drip-less quick connections).
- All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.
- Laboratory operations do not require special containment.

**Personal protective equipment**

Respiratory protection:
- If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.

Filter type:
- Particulates type

Hand protection:
- Material: Chemical-resistant gloves

Eye protection:
- Wear safety glasses with side shields or goggles.
  - If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles.
Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.

Skin and body protection:
- Work uniform or laboratory coat.

Hygiene measures:
- If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place.
- When using do not eat, drink or smoke.
- Wash contaminated clothing before re-use.
- The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

9. PHYSICAL AND CHEMICAL PROPERTIES

**Appearance**: liquid

**Colour**: yellow-orange

**Odour**: No data available

**Odour Threshold**: No data available

**pH**: 5.0 - 7.0

**Melting point/freezing point**: No data available

**Initial boiling point and boiling range**: No data available

**Flash point**: No data available

**Evaporation rate**: No data available

**Flammability (solid, gas)**: Not applicable

**Flammability (liquids)**: No data available

**Upper explosion limit / Upper flammability limit**: No data available

**Lower explosion limit / Lower flammability limit**: No data available

**Vapour pressure**: No data available

**Relative vapour density**: No data available

**Relative density**: No data available

**Density**: No data available

**Solubility(ies)**
SAFETY DATA SHEET

Diminazene / Phenazone Formulation

Water solubility : No data available
Partition coefficient: n-octanol/water : Not applicable
Auto-ignition temperature : No data available
Decomposition temperature : No data available
Viscosity
   Viscosity, kinematic : No data available
Explosive properties : Not explosive
Oxidizing properties : The substance or mixture is not classified as oxidizing.
Molecular weight : No data available
Particle size : Not applicable

10. STABILITY AND REACTIVITY

Reactivity : Not classified as a reactivity hazard.
Chemical stability : Stable under normal conditions.
Possibility of hazardous reactions : Can react with strong oxidizing agents.
Conditions to avoid : None known.
Incompatible materials : Oxidizing agents
Hazardous decomposition products : No hazardous decomposition products are known.

11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure : Inhalation
   Skin contact
   Ingestion
   Eye contact

Acute toxicity
Not classified based on available information.

Product:
Acute oral toxicity : Acute toxicity estimate: > 5,000 mg/kg
   Method: Calculation method

Components:

Diminazene:
Acute toxicity (other routes of administration) : LD50 (Rat): 663 mg/kg
   Application Route: Subcutaneous
   LD50 (Mouse): 258 mg/kg
   Application Route: Subcutaneous
LDLo (Dog): 20 mg/kg
Application Route: Intramuscular

**Phenazone:**
Acute oral toxicity : LD50 (Cat): 1,250 mg/kg

**Skin corrosion/irritation**
Causes skin irritation.

**Components:**

**Diminazene:**
Species : Rabbit
Result : Skin irritation

**Serious eye damage/eye irritation**
Not classified based on available information.

**Respiratory or skin sensitisation**

**Skin sensitisation**
Not classified based on available information.

**Respiratory sensitisation**
Not classified based on available information.

**Germ cell mutagenicity**
Not classified based on available information.

**Components:**

**Diminazene:**
Genotoxicity in vitro : Test Type: Microbial mutagenesis assay (Ames test)
Test system: Salmonella typhimurium
Method: Mutagenicity (Salmonella typhimurium - reverse mutation assay)
Result: negative

Test Type: Micronucleus test
Test system: Mouse
Result: negative

Test Type: In vitro mammalian cell gene mutation test
Test system: Chinese hamster cells
Result: negative

Genotoxicity in vivo : Test Type: Micronucleus test
Species: Mouse
Result: negative

Germ cell mutagenicity - Assessment : Weight of evidence does not support classification as a germ cell mutagen.
Genotoxicity in vitro :
- Test Type: Bacterial reverse mutation assay (AMES)
- Result: negative

Genotoxicity in vivo :
- Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
  - Species: Mouse
  - Application Route: Ingestion
  - Method: OECD Test Guideline 474
  - Result: negative

- Test Type: Mutagenicity (in vivo mammalian bone-marrow cytogenetic test, chromosomal analysis)
  - Species: Rat
  - Application Route: Ingestion
  - Result: negative

Carcinogenicity
Not classified based on available information.

Reproductive toxicity
Not classified based on available information.

Components:

**Diminazene:**
Effects on foetal development :
- Test Type: reproductive and developmental toxicity study
  - Species: Rat
  - Application Route: Oral
  - General Toxicity Maternal: LOAEL: 800 mg/kg body weight
  - Developmental Toxicity: LOAEL: 800 mg/kg body weight
  - Symptoms: Skeletal malformations, Embryo-foetal toxicity

- Test Type: reproductive and developmental toxicity study
  - Species: Rat
  - Application Route: Oral
  - General Toxicity Maternal: NOAEL: 400 mg/kg body weight
  - Developmental Toxicity: NOAEL: 400 mg/kg body weight

Reproductive toxicity - Assessment :
- Experiments have shown reproductive toxicity effects on laboratory animals.

**Phenazone:**
Effects on fertility :
- Test Type: Two-generation reproduction toxicity study
  - Species: Rat
  - Application Route: Ingestion
  - Result: negative

**STOT - single exposure**
Causes damage to organs (Brain) if swallowed.

Components:

**Diminazene:**
Exposure routes :
- Oral
Target Organs: Brain
Assessment: Shown to produce significant health effects in animals at concentrations of 1000 mg/kg bw or less.

**STOT - repeated exposure**
Causes damage to organs (Brain) through prolonged or repeated exposure if swallowed.

**Components:**

**Diminazene:**
- Exposure routes: Oral
- Target Organs: Brain
- Assessment: Causes damage to organs through prolonged or repeated exposure.

**Repeated dose toxicity**

**Components:**

**Diminazene:**
- Species: Rat
- NOAEL: 63 mg/kg
- Application Route: Oral
- Exposure time: 3 Months

- Species: Rat
- NOAEL: 300 mg/kg
- Application Route: Oral
- Exposure time: 9 Months

- Species: Dog
- LOAEL: 60 mg/kg
- Application Route: Oral
- Exposure time: 9 Months
- Target Organs: Brain, Testis
- Symptoms: Disorder

**Phenazone:**
- Species: Dog
- NOAEL: 63 mg/kg
- Application Route: Ingestion
- Exposure time: 6 Months

**Aspiration toxicity**
Not classified based on available information.

**Experience with human exposure**

**Components:**

**Diminazene:**
- Ingestion: Target Organs: Stomach
  Symptoms: Vomiting
  Target Organs: Central nervous system
Symptoms: paralysis
Target Organs: Immune system
Symptoms: Fever

12. ECOLOGICAL INFORMATION

Ecotoxicity

**Components:**

**Phenazone:**

**Toxicity to fish**

: LC50 (Oryzias latipes (Japanese medaka)): > 100 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 203

**Toxicity to daphnia and other aquatic invertebrates**

: EC50 (Daphnia magna (Water flea)): >= 1,000 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 202

**Toxicity to algae/aquatic plants**

: ErC50 (Selenastrum capricornutum (green algae)): > 1,000 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

NOEC (Selenastrum capricornutum (green algae)): 10 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

**Toxicity to microorganisms**

: EC50: 16,900 mg/l
Exposure time: 48 h

**Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)**

: NOEC: 100 mg/l
Exposure time: 21 d
Species: Daphnia magna (Water flea)
Method: OECD Test Guideline 211

Persistence and degradability

**Components:**

**Phenazone:**

**Biodegradability**

: Result: Not inherently biodegradable.
Biodegradation: 50 %
Exposure time: 20 d

Bioaccumulative potential

**Components:**

**Phenazone:**

**Partition coefficient: n-octanol/water**

: log Pow: 0.38
SAFETY DATA SHEET

Diminazene / Phenazone Formulation

Version 2.2
Revision Date: 10.10.2020
SDS Number: 4834918-00004
Date of last issue: 23.03.2020
Date of first issue: 10.09.2019

13. DISPOSAL CONSIDERATIONS

Disposal methods
Waste from residues: Dispose of in accordance with local regulations.
Contaminated packaging: Empty containers should be taken to an approved waste handling site for recycling or disposal.
If not otherwise specified: Dispose of as unused product.

14. TRANSPORT INFORMATION

International Regulations
UNRTDG
Not regulated as a dangerous good
IATA-DGR
Not regulated as a dangerous good
IMDG-Code
Not regulated as a dangerous good
Transport in bulk according to IMO instruments
Not applicable for product as supplied.

15. REGULATORY INFORMATION

Safety, health and environmental regulations/legislation specific for the substance or mixture

The components of this product are reported in the following inventories:
AICS : not determined
DSL : not determined
IECSC : not determined

16. OTHER INFORMATION

Further information

Date format: dd.mm.yyyy

Full text of other abbreviations

Mobility in soil
No data available

Other adverse effects
No data available
The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user’s end product, if applicable.

IN / EN