SAFETY DATA SHEET

Buparvaquone Formulation

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Buparvaquone Formulation

Manufacturer or supplier's details

Company name of supplier : MSD
Address : 2000 Galloping Hill Road
Kenilworth - New Jersey - U.S.A. 07033
Telephone : 908-740-4000
Emergency telephone : 1-908-423-6000
E-mail address : EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification

Skin irritation : Category 2
Eye irritation : Category 2A
Reproductive toxicity : Category 1B
Specific target organ toxicity - single exposure : Category 3

GHS label elements

Hazard pictograms : [Image of pictograms]

Signal Word : Danger

Hazard Statements : H315 Causes skin irritation.
H319 Causes serious eye irritation.
H335 May cause respiratory irritation.
H360D May damage the unborn child.

Precautionary Statements : Prevention:
P201 Obtain special instructions before use.
P202 Do not handle until all safety precautions have been read and understood.
P261 Avoid breathing mist or vapors.
P264 Wash skin thoroughly after handling.
P271 Use only outdoors or in a well-ventilated area.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response:
P302 + P352 IF ON SKIN: Wash with plenty of water.
P304 + P340 + P312 IF INHALED: Remove victim to fresh air.
and keep at rest in a position comfortable for breathing. Call a
POISON CENTER or doctor/physician if you feel unwell.
P305 + P351 + P338 IF IN EYES: Rinse cautiously with water
for several minutes. Remove contact lenses, if present and easy
to do. Continue rinsing.
P308 + P313 IF exposed or concerned: Get medical advice/
attention.
P332 + P313 If skin irritation occurs: Get medical advice/ atten-
tion.
P337 + P313 If eye irritation persists: Get medical advice/ atten-
tion.
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 dis-
posal plant.

SECTION 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>
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<tbody>
<tr>
<td>N-Methyl-2-pyrrolidone</td>
<td>872-50-4</td>
<td>&gt;= 50 - &lt; 70</td>
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<tr>
<td>Buparvaquone</td>
<td>88426-33-9</td>
<td>&gt;= 5 - &lt; 10</td>
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</table>

SECTION 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.

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 : In case of contact, immediately flush eyes with plenty of water
for at least 15 minutes.
If easy to do, remove contact lens, if worn.
Get medical attention.

If swallowed : If swallowed, DO NOT induce vomiting.
Get medical attention.
Rinse mouth thoroughly with water.

Most important symptoms and effects, both acute and delayed:
- Causes skin irritation.
- Causes serious eye irritation.
- May cause respiratory irritation.
- May damage the unborn child.

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.

SECTION 5. FIRE-FIGHTING 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 fire-fighters:
In the event of fire, wear self-contained breathing apparatus.
Use personal protective equipment.

SECTION 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 diking or other appropriate containment to keep material from spreading. If diked 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.

SECTION 7. HANDLING AND STORAGE

Technical measures: See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.
Local/Total ventilation: If sufficient ventilation is unavailable, use with local exhaust ventilation.
Advice on safe handling: Do not get on skin or clothing. Avoid breathing mist or vapors. Do not swallow. Do not get in 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. Keep container tightly closed. Already sensitized individuals should consult their physician regarding working with respiratory irritants or sensitizers. Take care to prevent spills, waste and minimize release to the environment.
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.
Conditions for safe storage: Keep in properly labeled containers. Store locked up. Keep tightly closed. Keep in a cool, well-ventilated place. Store in accordance with the particular national regulations.
Materials to avoid: Do not store with the following product types: Strong oxidizing agents Organic peroxides Explosives Gases

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients 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>
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<tbody>
<tr>
<td>Buparvaquone</td>
<td>88426-33-9</td>
<td>TWA</td>
<td>20 µg/m3 (OEB 3)</td>
<td>Internal</td>
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</table>
Further information: Skin

<table>
<thead>
<tr>
<th>Wipe limit</th>
<th>Internal</th>
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### Biological occupational exposure limits

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Control parameters</th>
<th>Biological specimen</th>
<th>Sampling time</th>
<th>Permissible concentration</th>
<th>Basis</th>
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<tr>
<td>N-Methyl-2-pyrrolidone</td>
<td>872-50-4</td>
<td>5-Hydroxy-N-methyl-2-pyrrolidone</td>
<td>Urine</td>
<td>End of shift</td>
<td>100 mg/l</td>
<td>MX BEI</td>
</tr>
<tr>
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<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>5-Hydroxy-N-methyl-2-pyrrolidone</td>
<td>Urine</td>
<td>End of shift (As soon as possible after exposure ceases)</td>
<td>100 mg/l</td>
<td>ACGIH BEI</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.

Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of the compound to uncontrolled areas (e.g., open-face containment devices).

Minimize open handling.

### 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**

Combined particulates and organic vapor type

**Hand protection**

**Material**

Chemical-resistant gloves

**Remarks**

Consider double gloving.

**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.

Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces.

Use appropriate degowning techniques to remove potentially contaminated clothing.

### SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES
### Appearance
Liquid

### Color
Clear, red

### Odor
No data available

### Odor Threshold
No data available

### pH
No data available

### 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

### Vapor pressure
No data available

### Relative vapor density
No data available

### Relative density
1 (20 °C)

### Density
No data available

### Solubility(ies)

<table>
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<th>Water solubility</th>
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</table>

### Partition coefficient: n-octanol/water
Not applicable

### Autoignition temperature
No data available

### Decomposition temperature
No data available

### Viscosity

<table>
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<tr>
<th>Viscosity, kinematic</th>
<th>No data available</th>
</tr>
</thead>
</table>

### Explosive properties
Not explosive

### Oxidizing properties
The substance or mixture is not classified as oxidizing.

### Particle size
Not applicable
SECTION 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.

SECTION 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:
N-Methyl-2-pyrrolidone:
Acute oral toxicity : LD50 (Rat): 4,150 mg/kg
Acute inhalation toxicity : LC50 (Rat): > 5.1 mg/l
   Exposure time: 4 h
   Test atmosphere: dust/mist
   Method: OECD Test Guideline 403
Acute dermal toxicity : LD50 (Rat): > 5,000 mg/kg

Buparvaquone:
Acute oral toxicity : LD50 (Rat): > 8,000 mg/kg
   LD50 (Mouse): > 50 mg/kg
   Remarks: No mortality observed at this dose.
Acute toxicity (other routes of administration) : LD50: 2.5 mg/kg
   Application Route: Intravenous

Skin corrosion/irritation
Causes skin irritation.
Components:

N-Methyl-2-pyrrolidone:
Result: Skin irritation

Buparvaquone:
Species: Mouse
Result: Mild skin irritation

Serious eye damage/eye irritation
Causes serious eye irritation.

Components:

N-Methyl-2-pyrrolidone:
Species: Rabbit
Result: Irritation to eyes, reversing within 21 days

Buparvaquone:
Result: Mild eye irritation

Respiratory or skin sensitization

Skin sensitization
Not classified based on available information.

Respiratory sensitization
Not classified based on available information.

Components:

N-Methyl-2-pyrrolidone:
Test Type: Local lymph node assay (LLNA)
Routes of exposure: Skin contact
Species: Mouse
Method: OECD Test Guideline 429
Result: negative
Remarks: Based on data from similar materials

Germ cell mutagenicity
Not classified based on available information.

Components:

N-Methyl-2-pyrrolidone:
Genotoxicity in vitro: Test Type: Bacterial reverse mutation assay (AMES)
Method: OECD Test Guideline 471
Result: negative

Test Type: In vitro mammalian cell gene mutation test
Method: OECD Test Guideline 476
Result: negative
Test Type: DNA damage and repair, unscheduled DNA synthesis in mammalian cells (in vitro)
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: Hamster
Application Route: Ingestion
Method: OECD Test Guideline 475
Result: negative

Carcinogenicity
Not classified based on available information.

Components:

N-Methyl-2-pyrrolidone:
Species: Rat
Application Route: Ingestion
Exposure time: 2 Years
Result: negative

Species: Rat
Application Route: inhalation (vapor)
Exposure time: 2 Years
Result: negative

Reproductive toxicity
May damage the unborn child.

Components:

N-Methyl-2-pyrrolidone:
Effects on fertility:
Test Type: Two-generation reproduction toxicity study
Species: Rat
Application Route: Ingestion
Method: OECD Test Guideline 416
Result: negative

Effects on fetal development:
Test Type: Embryo-fetal development
Species: Rat
Application Route: Ingestion
Method: OECD Test Guideline 414
Result: positive

Test Type: Fertility/early embryonic development
Species: Rat
Application Route: inhalation (vapor)
Result: positive

Test Type: Embryo-fetal development
Species: Rabbit
Application Route: Ingestion
Result: positive

Reproductive toxicity - Assessment: Clear evidence of adverse effects on development, based on animal experiments.

STOT-single exposure
May cause respiratory irritation.

Components:

N-Methyl-2-pyrrolidone:
Assessment: May cause respiratory irritation.

STOT-repeated exposure
Not classified based on available information.

Repeated dose toxicity

Components:

N-Methyl-2-pyrrolidone:
Species: Rat, male
NOAEL: 169 mg/kg
LOAEL: 433 mg/kg
Application Route: Ingestion
Exposure time: 90 Days
Method: OECD Test Guideline 408

Species: Rat
NOAEL: 0.5 mg/l
LOAEL: 1 mg/l
Application Route: inhalation (dust/mist/fume)
Exposure time: 96 Days
Method: OECD Test Guideline 413

Species: Rabbit
NOAEL: 826 mg/kg
LOAEL: 1,653 mg/kg
Application Route: Skin contact
Exposure time: 20 Days

Buparvaquone:
Species: Cat
NOAEL: 10 mg/kg
Application Route: Intramuscular
Exposure time: 5 d
Remarks: No significant adverse effects were reported
NOAEL: 5 mg/kg
Application Route: Intravenous
Exposure time: 4 d
Remarks: No significant adverse effects were reported

Species: Mouse
NOAEL: 50 mg/kg
Application Route: Oral
Exposure time: 6 d
Remarks: No significant adverse effects were reported

Aspiration toxicity
Not classified based on available information.

Experience with human exposure

Components:

N-Methyl-2-pyrrolidone:
Skin contact: Symptoms: Skin irritation

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

N-Methyl-2-pyrrolidone:
Toxicity to fish: LC50 (Oncorhynchus mykiss (rainbow trout)): > 500 mg/l
Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates: EC50 (Daphnia magna (Water flea)): > 1,000 mg/l
Exposure time: 24 h
Method: DIN 38412

Toxicity to algae/aquatic plants: ErC50 (Desmodesmus subspicatus (green algae)): 600.5 mg/l
Exposure time: 72 h
EC10 (Desmodesmus subspicatus (green algae)): 92.6 mg/l
Exposure time: 72 h

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity): NOEC (Daphnia magna (Water flea)): 12.5 mg/l
Exposure time: 21 d
Method: OECD Test Guideline 211

Toxicity to microorganisms: EC50: > 600 mg/l
Exposure time: 30 min
Method: ISO 8192

Buparvaquone:
Toxicity to fish: LC50 (Brachydanio rerio (zebrafish)): 0.484 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 203
Toxicity to daphnia and other aquatic invertebrates:
EC50 (Daphnia magna (Water flea)): 0.013 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 202

Persistence and degradability

Components:

N-Methyl-2-pyrrolidone:
Biodegradability: Result: Readily biodegradable.
Biodegradation: 73 %
Exposure time: 28 d
Method: OECD Test Guideline 301C

Bioaccumulative potential

Components:

N-Methyl-2-pyrrolidone:
Partition coefficient: n-octanol/water
log Pow: -0.46
Method: OECD Test Guideline 107

Buparvaquone:
Partition coefficient: n-octanol/water
log Pow: 6.5

Mobility in soil
No data available

Other adverse effects
No data available

SECTION 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.

SECTION 14. TRANSPORT INFORMATION

International Regulations

UNRTDG
UN number: UN 3082
Proper shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Buparvaquone)

Class: 9
Packing group: III
Labels: 9

IATA-DGR
UN/ID No. : UN 3082
Proper shipping name : Environmentally hazardous substance, liquid, n.o.s. (Buparvaquone)
Class : 9
Packing group : III
Labels : Miscellaneous
Packing instruction (cargo aircraft) : 964
Packing instruction (passenger aircraft) : 964
Environmentally hazardous : yes

IMDG-Code
UN number : UN 3082
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Buparvaquone)
Class : 9
Packing group : III
Labels : 9
EmS Code : F-A, S-F
Marine pollutant : yes

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code
Not applicable for product as supplied.

Domestic regulation

NOM-002-SCT
UN number : UN 3082
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Buparvaquone)
Class : 9
Packing group : III
Labels : 9

Special precautions for user
The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

SECTION 15. REGULATORY INFORMATION

Safety, health and environmental regulations/legislation specific for the substance or mixture
Federal Law for the control of chemical precursors, essential chemical products and machinery for producing capsules, tablets and pills. : Not applicable

The ingredients of this product are reported in the following inventories:
AICS : not determined
DSL : not determined
SAFETY DATA SHEET

Buparvaquone Formulation

SECTION 16. OTHER INFORMATION

Full text of other abbreviations
ACGIH BEI : ACGIH - Biological Exposure Indices (BEI)
MX BEI : Official Mexican Norm NOM-047-SSA1-2011, Environmental Health - Biological exposure indices for workers occupationally exposed to chemical agents


Revision Date : 27.08.2021

The information is considered as correct, but not exhaustive, and will be used only as a guide, which is based in the current knowledge of the substance or mixture, and is applicable to proper safety precautions for the product.
SAFETY DATA SHEET

Buparvaquone Formulation

<table>
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<th>Version</th>
<th>Revision Date:</th>
<th>SDS Number:</th>
<th>Date of last issue:</th>
<th>Date of first issue:</th>
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<td>27.08.2021</td>
<td>2091129-00008</td>
<td>10.10.2020</td>
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MX / Z8