SAFETY DATA SHEET
Buparvaquone Formulation

Version 4.7  Revision Date: 04/04/2023  SDS Number: 2091185-00013  Date of last issue: 07/22/2022  Date of first issue: 10/17/2017

SECTION 1. IDENTIFICATION

Product name: Buparvaquone Formulation
Other means of identification: No data available

Manufacturer or supplier's details
Company name of supplier: Merck & Co., Inc
Address: 126 E. Lincoln Avenue, Rahway, New Jersey U.S.A. 07065
Telephone: 908-740-4000
Emergency telephone: 1-908-423-6000
E-mail address: EHSDATASTEWARD@merck.com

Recommended use of the chemical and restrictions on use
Recommended use: Veterinary product
Restrictions on use: Not applicable

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with the Hazardous Products Regulations
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: 

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.
and face protection.

Response:
P302 + P352 IF ON SKIN: Wash with plenty of water.
P304 + P340 + P312 IF INHALED: Remove person to fresh air and keep comfortable for breathing. Call a doctor 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 attention.
P332 + P313 IF skin irritation occurs: Get medical attention.
P337 + P313 IF eye irritation persists: Get medical attention.
P362 + P364 Take off contaminated clothing and wash it before reuse.

Storage:
P405 Store locked up.

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

Other hazards
None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Mixture</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Components</th>
<th>Chemical name</th>
<th>Common Name/Synonym</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>N-Methyl-2-pyrrolidone</td>
<td>1-Methylpyrrolidone</td>
<td>872-50-4</td>
<td>&gt;= 30 - &lt; 60 *</td>
<td></td>
</tr>
<tr>
<td>Coconut Oil</td>
<td>Cococ nucifera (coconut) oil</td>
<td>8001-31-8</td>
<td>&gt;= 30 - &lt; 60 *</td>
<td></td>
</tr>
<tr>
<td>Buparvaquone</td>
<td>No data available</td>
<td>88426-33-9</td>
<td>&gt;= 5 - &lt; 10 *</td>
<td></td>
</tr>
</tbody>
</table>

* Actual concentration or concentration range is withheld as a trade secret

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 fire fighting: 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/PERSOAL 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, and those susceptible to asthma, allergies, chronic or recurrent respiratory disease, should consult their physician regarding working with respiratory irritants or sensitizers.
- Take care to prevent spills, waste and minimize release to the environment.

**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
  - Self-reactive substances and mixtures
  - Organic peroxides
  - Explosives
  - Gases

### SECTION 8. EXPOSURE CONTROLS/PERSOAL 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>
</tr>
</thead>
</table>
Buparvaquone Formulation

Components

<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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<tbody>
<tr>
<td>N-Methyl-2-pyrrolidone</td>
<td>872-50-4</td>
<td></td>
<td></td>
<td>TWA</td>
<td>400 mg/m³</td>
<td>CA ON OEL</td>
</tr>
<tr>
<td>Coconut Oil</td>
<td>8001-31-8</td>
<td></td>
<td></td>
<td>TWAEV (Mist)</td>
<td>10 mg/m³</td>
<td>CA QC OEL</td>
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<tr>
<td>Buparvaquone</td>
<td>88426-33-9</td>
<td></td>
<td></td>
<td>TWA</td>
<td>40 µg/m³ (OEB 3)</td>
<td>Internal</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Wipe limit</td>
<td>400 µg/100 cm²</td>
<td>Internal</td>
</tr>
</tbody>
</table>

Engineering measures:

Use appropriate engineering controls and manufacturing technologies to control airborne concentrations (e.g., dripless 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.

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.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
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<tbody>
<tr>
<td>Appearance</td>
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<td>Color</td>
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<td>Odor Threshold</td>
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<tr>
<td>pH</td>
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<tr>
<td>Melting point/freezing point</td>
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<tr>
<td>Initial boiling point and boiling range</td>
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<tr>
<td>Flash point</td>
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<tr>
<td>Evaporation rate</td>
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<tr>
<td>Flammability (solid, gas)</td>
<td>Not applicable</td>
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<tr>
<td>Flammability (liquids)</td>
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<tr>
<td>Upper explosion limit / Upper flammability limit</td>
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<tr>
<td>Lower explosion limit / Lower flammability limit</td>
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<td>Vapor pressure</td>
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<tr>
<td>Density</td>
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<tr>
<td>Solubility(ies)</td>
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<tr>
<td>Water solubility</td>
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<td>Partition coefficient: n-octanol/water</td>
<td>Not applicable</td>
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<td>Autoignition temperature</td>
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</tr>
<tr>
<td>Decomposition temperature</td>
<td>No data available</td>
</tr>
</tbody>
</table>
Viscosity
  Viscosity, kinematic : No data available
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: > 2,000 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

Coconut Oil:
Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg
Acute dermal toxicity : LD50 (Guinea pig): > 3,000 mg/kg
Remarks: Based on data from similar materials

**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

**Coconut Oil:**
- Species: Rabbit
- Result: No 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

**Coconut Oil:**
- Species: Rabbit
- Result: No eye irritation

**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

Coconut Oil:
Test Type : Maximization Test
Routes of exposure : Skin contact
Species : Guinea pig
Result : negative

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

Coconut Oil:
Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)
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
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: log Pow: -0.46
octanol/water 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. Do not dispose of waste into sewer.
- **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

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

Class : 9
Packing group : III
Labels : 9
ERG Code : 171
Marine pollutant : yes (Buparvaquone)

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

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

SECTION 16. OTHER INFORMATION

Full text of other abbreviations
ACGIH BEI : ACGIH - Biological Exposure Indices (BEI)
CA ON OEL : Ontario Table of Occupational Exposure Limits made under the Occupational Health and Safety Act.
CA QC OEL : Québec. Regulation respecting occupational health and safety, Schedule 1, Part 1: Permissible exposure values for airborne contaminants
CA ON OEL / TWA : Time-Weighted Average Limit (TWA)
CA QC OEL / TWAEV : Time-weighted average exposure value

AIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized Sys-
SAFETY DATA SHEET

Buparvaquone Formulation

Sources of key data used to compile the Material Safety Data Sheet:

Revision Date: 04/04/2023
Date format: mm/dd/yyyy

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.

CA / Z8