SAFETY DATA SHEET
according to the Globally Harmonized System

Buparvaquone Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
5.0	28.09.2024	2092243-00014	Date of first issue: 17.10.2017

1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Buparvaquone 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
Restrictions on use : Not applicable

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

Serious eye damage/eye irritation : Category 2A

Reproductive toxicity : Category 1B

Specific target organ toxicity - single exposure : Category 3

Short-term (acute) aquatic hazard : Category 1

Long-term (chronic) aquatic hazard : Category 1

GHS label elements

Hazard pictograms :

Signal word : Danger

Hazard statements : H315 + H319 Causes skin irritation and serious eye irritation.
H335 May cause respiratory irritation.
H360D May damage the unborn child.
H410 Very toxic to aquatic life with long lasting effects.

Precautionary statements :

Prevention:

P203 Obtain, read and follow all safety instructions before use.
P261 Avoid breathing mist or vapours.
P264 Wash hands thoroughly after handling.
P271 Use only outdoors or with adequate ventilation.
P273 Avoid release to the environment.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response:

P302 + P352 IF ON SKIN: Wash with plenty of water.
P304 + P340 + P319 IF INHALED: Remove person to fresh air and keep comfortable for breathing. Get medical help 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.
P318 IF exposed or concerned, get medical advice.
P332 + P317 If skin irritation occurs: Get medical help.
P337 + P317 If eye irritation persists: Get medical help.
P362 + P364 Take off contaminated clothing and wash it before reuse.
P391 Collect spillage.

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

Chemical name	CAS-No.	Concentration (% w/w)
N-Methyl-2-pyrrolidone	872-50-4	>= 50 - < 70

Buparvaquone	88426-33-9	>= 5 - < 10

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 and 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.

5. FIREFIGHTING 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	:	In the event of fire, wear self-contained breathing apparatus.

for firefighters	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	:	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 vapours. 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 sensitised individuals, and those susceptible to asthma, allergies, chronic or recurrent respiratory disease, should consult their physician regarding working with respiratory irritants or sensitisers. Take care to prevent spills, waste and minimize release to the environment.
Conditions for safe storage	:	Keep in properly labelled 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

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Buparvaquone	88426-33-9	TWA	40 µg/m3 (OEB 3)	Internal
		Wipe limit	400 µg/100 cm²	Internal

Biological occupational exposure limits

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

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 vapour 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.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	:	liquid
Colour	:	clear, red
Odour	:	No data available
Odour 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
Vapour pressure	:	No data available
Relative vapour density	:	No data available

Relative density	:	1 (20 °C)
Density	:	No data available
Solubility(ies)		
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.
Particle characteristics		
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:

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 sensitisation

Skin sensitisation

Not classified based on available information.

Respiratory sensitisation

Not classified based on available information.

Components:

N-Methyl-2-pyrrolidone:

Test Type	:	Local lymph node assay (LLNA)
Exposure routes	:	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 (vapour)
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 foetal development	:	Test Type: Embryo-foetal development Species: Rat Application Route: Ingestion Method: OECD Test Guideline 414 Result: positive Test Type: Fertility/early embryonic development Species: Rat Application Route: inhalation (vapour) Result: positive Test Type: Embryo-foetal 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

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	:	EC50 (Daphnia magna (Water flea)): > 1,000 mg/l

aquatic invertebrates		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 microorganisms	:	EC50: > 600 mg/l Exposure time: 30 min Method: ISO 8192
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	:	NOEC: 12.5 mg/l Exposure time: 21 d Species: Daphnia magna (Water flea) Method: OECD Test Guideline 211

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
M-Factor (Acute aquatic toxicity)	:	10
M-Factor (Chronic aquatic toxicity)	:	10

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

13. DISPOSAL CONSIDERATIONS

Disposal methods

Waste from residues	:	Do not dispose of waste into sewer. 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

UN number	:	UN 3082
Proper shipping name	:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Buparvaquone)
Class	:	9
Packing group	:	III
Labels	:	9
Environmentally hazardous	:	yes

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 IMO instruments

Not applicable for product as supplied.

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.

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

Revision Date	:	28.09.2024

Further information

Sources of key data used to compile the Safety Data Sheet	:	Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, http://echa.europa.eu/

Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

Date format	:	dd.mm.yyyy

Full text of other abbreviations

ACGIH BEI	:	ACGIH - Biological Exposure Indices (BEI)

AIIC - 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 System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International

Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

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