according to the Globally Harmonized System



# **Butorphanol Formulation**

**Revision Date:** Date of last issue: 06.07.2024 Version SDS Number: 4.0 28.09.2024 918977-00019 Date of first issue: 03.10.2016

#### 1. PRODUCT AND COMPANY IDENTIFICATION

Product name **Butorphanol Formulation** 

Other means of identification Dolorex® (A006877)

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

Veterinary product Recommended use Not applicable Restrictions on use

### 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** 

single exposure (Oral)

Specific target organ toxicity - : Category 2 (Central nervous system)

repeated exposure (Oral)

Specific target organ toxicity - : Category 2 (Blood, Central nervous system)

**GHS** label elements

Hazard pictograms

Signal word

Hazard statements H371 May cause damage to organs (Central nervous system) if

H373 May cause damage to organs (Blood, Central nervous system) through prolonged or repeated exposure if swallowed.

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Precautionary statements : Prevention:

P260 Do not breathe mist or vapours. P264 Wash hands thoroughly after handling.

P270 Do not eat, drink or smoke when using this product.

Response:

P308 + P316 IF exposed or concerned: Get emergency medi-

cal help immediately.

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)
17-(cyclobutylmethyl)morphinan-3,14-diyl [S-(R*,R*)]-2,3-dihydroxysuccinate	58786-99-5	>= 1 - < 2.5

## 4. FIRST AID MEASURES

General advice : In the case of accident or if you feel unwell, seek medical ad-

vice 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 soap and plenty

of water.

Remove contaminated clothing and shoes.

Get medical attention. Wash clothing before reuse.

Thoroughly clean shoes before reuse. Flush eyes with water as a precaution.

Get medical attention if irritation develops and persists.

If swallowed, DO NOT induce vomiting.

Get medical attention.

Rinse mouth thoroughly with water.

Never give anything by mouth to an unconscious person.

Most important symptoms and effects, both acute and

In case of eye contact

: May cause damage to organs if swallowed.

May cause damage to organs it swallowed.

May cause damage to organs through prolonged or repeated

delayed

exposure if swallowed

exposure if swallowed.

Protection of first-aiders : First Aid responders should pay attention to self-protection,

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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 prod: :

ucts

Carbon oxides

Specific extinguishing meth-

ods

Use extinguishing measures that are appropriate to local cir-

cumstances 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 emer-

gency procedures

Use personal protective equipment.

Follow safe handling advice (see section 7) and personal pro-

tective 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 absor-

bent.

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 deter-

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mine 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 breathe mist or vapours.

Do not swallow.

Avoid contact with eyes.

Avoid prolonged or repeated contact with skin.

Wash skin thoroughly after handling.

Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure as-

sessment

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

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
17- (cyclobutylmethyl)morphinan- 3,14-diyl [S-(R*,R*)]-2,3- dihydroxysuccinate	58786-99-5	TWA	3 μg/m3 (OEB 4)	Internal
		Wipe limit	30 μg/100 cm <sup>2</sup>	Internal
		STEL	25 μg/m3	Internal

**Engineering measures** : All engineering controls should be implemented by facility

design and operated in accordance with GMP principles to

protect products, workers, and the environment.

Essentially no open handling permitted.

Use closed processing systems or containment technologies. If handled in a laboratory, use a properly designed biosafety cabinet, fume hood, or other containment device if the potential exists for aerosolization. If this potential does not exist,

handle over lined trays or benchtops.

Personal protective equipment

Respiratory protection : If adequate local exhaust ventilation is not available or expo-

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sure assessment demonstrates exposures outside the rec-

ommended guidelines, use respiratory protection.

Filter type : Particulates 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 : colourless

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

100 °C

Flash point : No data available

Evaporation rate : No data available

Flammability (solid, gas) : Not applicable

Flammability (liquids) : No data available

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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)

No data available Water solubility

Partition coefficient: n-

octanol/water

Not applicable

Auto-ignition temperature No data available

Decomposition temperature No data available

Viscosity

No data available Viscosity, kinematic

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 reac- :

tions

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

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### **Acute toxicity**

Not classified based on available information.

**Product:** 

Acute oral toxicity : Acute toxicity estimate: > 5,000 mg/kg

Method: Calculation method

## **Components:**

## 17-(cyclobutylmethyl)morphinan-3,14-diyl [S-(R\*,R\*)]-2,3-dihydroxysuccinate:

Acute oral toxicity : LD50 (Mouse): 395 mg/kg

LD50 (Dog): > 50 mg/kg

LD50 (Monkey): > 50 mg/kg

Acute inhalation toxicity : Remarks: No data available

Acute dermal toxicity : Remarks: No data available

#### Skin corrosion/irritation

Not classified based on available information.

### Components:

## 17-(cyclobutylmethyl)morphinan-3,14-diyl [S-(R\*,R\*)]-2,3-dihydroxysuccinate:

Remarks : No data available

## Serious eye damage/eye irritation

Not classified based on available information.

## **Components:**

## 17-(cyclobutylmethyl)morphinan-3,14-diyl [S-(R\*,R\*)]-2,3-dihydroxysuccinate:

Species : Rat

Result : No eye irritation

# Respiratory or skin sensitisation

## Skin sensitisation

Not classified based on available information.

## Respiratory sensitisation

Not classified based on available information.

### **Components:**

### 17-(cyclobutylmethyl)morphinan-3,14-diyl [S-(R\*,R\*)]-2,3-dihydroxysuccinate:

Exposure routes : Dermal

Assessment : Does not cause skin sensitisation.

Result : negative

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### Germ cell mutagenicity

Not classified based on available information.

### **Components:**

## 17-(cyclobutylmethyl)morphinan-3,14-diyl [S-(R\*,R\*)]-2,3-dihydroxysuccinate:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)

Result: negative

Test Type: DNA damage and repair, unscheduled DNA syn-

thesis in mammalian cells (in vitro)

Result: negative

### Carcinogenicity

Not classified based on available information.

### **Components:**

# 17-(cyclobutylmethyl)morphinan-3,14-diyl [S-(R\*,R\*)]-2,3-dihydroxysuccinate:

Species : Rat
Application Route : Oral
Exposure time : 2 Years
Result : negative

Species : Mouse
Application Route : Oral
Exposure time : 2 Years
Result : negative

## Reproductive toxicity

Not classified based on available information.

### Components:

# 17-(cyclobutylmethyl)morphinan-3,14-diyl [S-(R\*,R\*)]-2,3-dihydroxysuccinate:

Effects on fertility : Test Type: Fertility/early embryonic development

Species: Rat

**Application Route: Oral** 

Fertility: LOAEL: 160 mg/kg body weight

Result: Effects on fertility

Effects on foetal develop-

ment

Test Type: Embryo-foetal development

Species: Rat

Application Route: Subcutaneous

Developmental Toxicity: LOAEL: 1 mg/kg body weight Result: No teratogenic effects, Increased stillbirths

Test Type: Embryo-foetal development

Species: Rabbit Application Route: Oral

Developmental Toxicity: LOAEL: 30 mg/kg body weight Result: No teratogenic effects, Maternal toxicity observed.,

Postimplantation loss.

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Test Type: Embryo-foetal development

Species: Rat

Application Route: Subcutaneous

Developmental Toxicity: LOAEL: 0.5 mg/kg body weight

Result: Maternal toxicity observed.

Reproductive toxicity - As-

sessment

Some evidence of adverse effects on sexual function and fertility, based on animal experiments., Some evidence of

adverse effects on development, based on animal experi-

ments.

### STOT - single exposure

May cause damage to organs (Central nervous system) if swallowed.

### **Components:**

### 17-(cyclobutylmethyl)morphinan-3,14-diyl [S-(R\*,R\*)]-2,3-dihydroxysuccinate:

Target Organs : Central nervous system
Assessment : Causes damage to organs.

### STOT - repeated exposure

May cause damage to organs (Blood, Central nervous system) through prolonged or repeated exposure if swallowed.

### Components:

## 17-(cyclobutylmethyl)morphinan-3,14-diyl [S-(R\*,R\*)]-2,3-dihydroxysuccinate:

Target Organs : Blood, Central nervous system

Assessment : Causes damage to organs through prolonged or repeated

exposure.

### Repeated dose toxicity

## **Components:**

### 17-(cyclobutylmethyl)morphinan-3,14-diyl [S-(R\*,R\*)]-2,3-dihydroxysuccinate:

Species : Rat

LOAEL : 0.4 mg/kg
Application Route : Subcutaneous
Exposure time : 6 Months

Target Organs : Blood, Central nervous system

Species : Monkey
LOAEL : 0.15 mg/kg
Application Route : Intramuscular
Exposure time : 6 Months

Target Organs : Central nervous system

Species: DogLOAEL: 0.1 mg/kgApplication Route: IntramuscularExposure time: 3 Months

Symptoms : reduced body weight gain

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### **Aspiration toxicity**

Not classified based on available information.

**Experience with human exposure** 

### **Components:**

### 17-(cyclobutylmethyl)morphinan-3,14-diyl [S-(R\*,R\*)]-2,3-dihydroxysuccinate:

Ingestion Symptoms: Drowsiness, Sweating, Nausea, Dizziness, Verti-

go, Palpitation, respiratory depression

#### 12. ECOLOGICAL INFORMATION

### **Ecotoxicity**

### **Components:**

## 17-(cyclobutylmethyl)morphinan-3,14-diyl [S-(R\*,R\*)]-2,3-dihydroxysuccinate:

Toxicity to daphnia and other : EC50 (Daphnia magna (Water flea)): 38.1 mg/l

aquatic invertebrates

Exposure time: 48 h

Method: OECD Test Guideline 202

## Persistence and degradability

No data available

### Bioaccumulative potential

No data available

## 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 han-

dling 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

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#### **IMDG-Code**

Not regulated as a dangerous good

Transport in bulk according to IMO instruments

Not applicable for product as supplied.

Special precautions for user

Not applicable

#### 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 Agen-

cy, 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

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

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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