

Butorphanol Formulation

Version **Revision Date:** SDS Number: Date of last issue: 2024/07/06 918665-00020 7.1 2024/09/28 Date of first issue: 2016/10/03

1. PRODUCT AND COMPANY IDENTIFICATION

Chemical product name **Butorphanol Formulation**

Other means of identification Dolorex® (A006877)

Supplier's company name, address and phone number

Company name of supplier MSD

Address Kumagaya, Saitama Prefecture, Xicheng 810 MSD Co., Ltd.

Menuma factory

Telephone 048-588-8411

E-mail address EHSDATASTEWARD@msd.com

Emergency telephone number: +1-908-423-6000

Recommended use of the chemical and restrictions on use

Veterinary product Recommended use Restrictions on use Not applicable

2. HAZARDS IDENTIFICATION

GHS classification of chemical product

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 Warning

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.

Precautionary statements Prevention:

P260 Do not breathe mist or vapours.



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P264 Wash skin thoroughly after handling.

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

Response:

P308 + P311 IF exposed or concerned: Call a POISON

CENTER/ doctor.

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)	ENCS No.
17-(cyclobutylmethyl)morphinan-	58786-99-5	>= 1 - < 2.5	-
3,14-diyl [S-(R*,R*)]-2,3-			
dihydroxysuccinate			

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, remove to fresh air. If inhaled

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. In case of eye contact

Get medical attention if irritation develops and persists.

If swallowed, DO NOT induce vomiting. If swallowed

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

delaved

May cause damage to organs if swallowed.

May cause 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

MSD Public

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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, protec: :

tive 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



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employed in the cleanup of releases. You will need to deter-

mine which regulations are applicable.

Sections 13 and 15 of this SDS provide information regarding

certain local or national requirements.

7. HANDLING AND STORAGE

Handling

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.

Avoidance of contact : Oxidizing agents

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.

Storage

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

Packaging material : Unsuitable material: None known.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Threshold limit value and permissible exposure limits for each component in the work environment

Components	CAS-No.	Value type	Control parame-	Basis
		(Form of	ters / Concentra-	
		exposure)	tion standard /	



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			Permissible con- centration	
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 ²	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-

sure assessment demonstrates exposures outside the rec-

ommended guidelines, use respiratory protection.

Filter type Hand protection Particulates type

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, dis-

posable suits) to avoid exposed skin surfaces.

Use appropriate degowning techniques to remove potentially

contaminated clothing.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state : liquid

Colour : colourless

Odour : No data available

Odour Threshold : No data available



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Melting point/freezing point No data available

Boiling point, initial boiling

point and boiling range

100 °C

Flammability (solid, gas) Not applicable

Flammability (liquids) No data available

Lower explosion limit and upper explosion limit / flammability limit

Upper explosion limit / Up- :

per flammability limit

No data available

Lower explosion limit /

Lower flammability limit

No data available

Flash point No data available

Decomposition temperature No data available

pН No data available

Evaporation rate No data available

No data available Auto-ignition temperature

Viscosity

Viscosity, kinematic No data available

Solubility(ies)

Water solubility No data available

Partition coefficient: n-

octanol/water

Not applicable

No data available Vapour pressure

Density and / or relative density

Relative density No data available

No data available Density

Relative vapour density No data available

Explosive properties Not explosive

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

Particle characteristics

Particle size Not applicable



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10. STABILITY AND REACTIVITY

Reactivity Not classified as a reactivity hazard. Chemical stability Stable under normal conditions. : Can react with strong oxidizing agents. Possibility of hazardous reac-

Conditions to avoid : None known. Incompatible materials Oxidizing agents

Hazardous decomposition : No hazardous decomposition products are known.

products

11. TOXICOLOGICAL INFORMATION

Information on likely routes of: Inhalation

exposure Skin contact Ingestion

Eye contact

Acute toxicity

Not classified based on available information.

Product:

Acute toxicity estimate: > 2,000 mg/kg Acute oral toxicity

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.



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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

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



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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.

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.



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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 : Dog LOAEL : 0.1 mg/kg Application Route : Intramuscular Exposure time : 3 Months

Symptoms : reduced body weight gain

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



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Persistence and degradability

No data available

Bioaccumulative potential

No data available

Mobility in soil

No data available

Hazardous to the ozone layer

Not applicable

Other adverse effects

No data available

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 han-

dling site for recycling or disposal.

If not otherwise specified: Dispose of as unused product.

14. TRANSPORT INFORMATION

International Regulations

UNRTDG

UN number Not applicable Proper shipping name Not applicable Class Not applicable Subsidiary risk Not applicable Not applicable Packing group Labels Not applicable

Environmentally hazardous no

IATA-DGR

UN/ID No. Not applicable Not applicable Proper shipping name Not applicable Class Not applicable Subsidiary risk Packing group Not applicable Not applicable Labels Packing instruction (cargo Not applicable

aircraft)

Packing instruction (passen-

ger aircraft)

Not applicable

IMDG-Code

UN number Not applicable Proper shipping name Not applicable



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Class : Not applicable
Subsidiary risk : Not applicable
Packing group : Not applicable
Labels : Not applicable
EmS Code : Not applicable
Marine pollutant : Not applicable

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

National Regulations

Refer to section 15 for specific national regulation.

Special precautions for user

Not applicable

15. REGULATORY INFORMATION

Related Regulations

Fire Service Law

Not applicable to dangerous materials / designated flammables.

Chemical Substance Control Law

Not applicable for Specified Chemical Substance, Monitoring Chemical Substance and Priority Assessment Chemical Substance.

Industrial Safety and Health Law

Harmful Substances Prohibited from Manufacture

Not applicable

Harmful Substances Required Permission for Manufacture

Not applicable

Substances Prevented From Impairment of Health

Not applicable

Circular concerning Information on Chemicals having Mutagenicity - Annex 2: Information on Existing Chemicals having Mutagenicity

Not applicable

Circular concerning Information on Chemicals having Mutagenicity - Annex 1: Information on Notified Substances having Mutagenicity

Not applicable

Substances Subject to be Notified Names

Not applicable

Substances Subject to be Indicated Names

Not applicable

Skin and Eye Damage Substances for PPE Requirements (ISHL MO Art. 594-2)

Not applicable



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Carcinogenic Substances (Article 577-2 of the Occupational Health and Safety Regulations)

Not applicable

Ordinance on Prevention of Hazards Due to Specified Chemical Substances

Not applicable

Ordinance on Prevention of Lead Poisoning

Not applicable

Ordinance on Prevention of Tetraalkyl Lead Poisoning

Not applicable

Ordinance on Prevention of Organic Solvent Poisoning

Not applicable

Enforcement Order of the Industrial Safety and Health Law - Attached table 1 (Dangerous Substances)

Not applicable

Poisonous and Deleterious Substances Control Law

Not applicable

Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof

Not applicable

High Pressure Gas Safety Act

Not applicable

Explosive Control Law

Not applicable

Vessel Safety Law

Not regulated as a dangerous good

Aviation Law

Not regulated as a dangerous good

Marine Pollution and Sea Disaster Prevention etc Law

Bulk transportation : Not classified as noxious liquid substance

Pack transportation : Not classified as marine pollutant

Narcotics and Psychotropics Control Act

Narcotic or Psychotropic Raw Material (Export / Import Permission)

Not applicable

Specific Narcotic or Psychotropic Raw Material (Export / Import permission)

Not applicable

Waste Disposal and Public Cleansing Law

Industrial waste

The components of this product are reported in the following inventories:

AICS : not determined



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DSL : not determined

IECSC : not determined

16. OTHER INFORMATION

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/

Date format : yyyy/mm/dd

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 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



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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.

JP / EN