

Butorphanol Formulation

Vers 6.0		Revision Date: 06.07.2024		5 Number: 669-00018		sue: 23.04.2024 sue: 03.10.2016
Sec	tion 1: lo	dentification				
	Product	name	:	Butorphanol Form	nulation	
	Other m	eans of identification	:	Dolorex® (A0068	377)	
	Manufa	cturer or supplier's d	letai	ls		
	Compar	ıy	:	MSD		
	Address	3	:	33 Whakatiki Stre Upper Hutt - New		g 908
	Telepho	one	:	0800 800 543		
	Emerge	ncy telephone number	· :	0800 764 766 (08 CHEMCALL)	300 POISON)	0800 243 622 (0800
	E-mail a	address	:	EHSDATASTEW	ARD@msd.con	n
	Recom	mended use of the cl	nemi	ical and restrictic	ons on use	
		nended use ions on use	:	Veterinary produce Not applicable	ct	

Section 2: Hazard identification

GHS Classification Reproductive toxicity	:	Category 2
Specific target organ toxicity - single exposure (Oral)	:	Category 2 (Central nervous system)
Specific target organ toxicity - repeated exposure (Oral)	:	Category 2 (Blood, Central nervous system)
GHS label elements Hazard pictograms	:	
Signal word	:	Warning
Hazard statements	:	H361fd Suspected of damaging fertility. Suspected of damag- ing the unborn child. H371 May cause damage to organs (Central nervous system) if swallowed. H373 May cause damage to organs (Blood, Central nervous
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Preca	autionary statements	system) throug	gh prolonged or repeated exposure if swallowed.
		P201 Obtain s P202 Do not h and understoo P260 Do not b P264 Wash sh P270 Do not e	oreathe mist or vapours. kin thoroughly after handling. eat, drink or smoke when using this product. otective gloves/ protective clothing/ eye protec-
		Response: P308 + P311 CENTER/ doc	IF exposed or concerned: Call a POISON tor.
		Storage: P405 Store lo	cked up.
		Disposal: P501 Dispose disposal plant	of contents/ container to an approved waste
	r hazards which do ı known.	not result in classifica	ation
Section 3	: Composition/inforr	nation on ingredients	3
Subst	tance / Mixture	: Mixture	

Components

Chemical name	CAS-No.	Concentration (% w/w)
17-(cyclobutylmethyl)morphinan-3,14-diyl [S-	58786-99-5	>= 1 -< 2.5
(R*,R*)]-2,3-dihydroxysuccinate		

Section 4: First-aid measures

General advice	 In the case of accident or if you feel unwell, seek medica vice immediately. When symptoms persist or in all cases of doubt seek me 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 of water.	plenty
	Remove contaminated clothing and shoes.	
	Get medical attention.	
	Wash clothing before reuse.	
	Thoroughly clean shoes before reuse.	
In some of our contract		
In case of eye contact	: Flush eyes with water as a precaution.	
	Get medical attention if irritation develops and persists.	

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lf swa	llowed	Get medical att	O NOT induce vomiting. ention. oroughly with water.
	important symptoms ffects, both acute and ed	: Suspected of d unborn child. May cause dar May cause dar	thing by mouth to an unconscious person. amaging fertility. Suspected of damaging the nage to organs if swallowed. nage to organs through prolonged or repeated
Prote	ction of first-aiders	and use the red	allowed. Inders should pay attention to self-protection, commended personal protective equipment Itial for exposure exists (see section 8).
Notes	to physician		atically and supportively.
ction 5	Fire-fighting measure	S	
Suital	ble extinguishing media	: Water spray Alcohol-resista Carbon dioxide Dry chemical	
Unsui media	table extinguishing	: None known.	
Speci fightir	fic hazards during fire-	: Exposure to co	mbustion products may be a hazard to health
Hazaı ucts	dous combustion prod-	: Carbon oxides	
Speci ods	fic extinguishing meth-	cumstances an Use water spra	ing measures that are appropriate to local cir- d the surrounding environment. y to cool unopened containers. naged containers from fire area if it is safe to o
Creat		Evacuate area	
	al protective equipment		fire, wear self-contained breathing apparatus. rotective equipment.
ction 6	Accidental release me	easures	
tive e	nal precautions, protec- quipment and emer- procedures	Follow safe ha	rotective equipment. ndling advice (see section 7) and personal pro ent recommendations (see section 8).
Enviro	onmental precautions	Prevent further Prevent spread barriers). Retain and disp	o the environment. leakage or spillage if safe to do so. ling over a wide area (e.g. by containment or pose of contaminated wash water. is should be advised if significant spillages ained.
	ods and materials for inment and cleaning up		ert absorbent material. provide dyking or other appropriate contain-



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			be pumped, stor Clean up remain bent. Local or nationa posal of this ma employed in the mine which regu Sections 13 and	aterial from spreading. If dyked material can re recovered material in appropriate container. hing materials from spill with suitable absor- I regulations may apply to releases and dis- terial, as well as those materials and items cleanup of releases. You will need to deter- ulations are applicable. I 15 of this SDS provide information regarding hational requirements.
Section 7	: Handling and storage	е		
Tech	nical measures			g measures under EXPOSURE RSONAL PROTECTION section.
	I/Total ventilation be on safe handling	:	Do not breathen Do not swallow. Avoid contact w Avoid prolonged Wash skin thoro Handle in accor practice, based sessment Do not eat, drinl	dequate ventilation. mist or vapours. I or repeated contact with skin. bughly after handling. dance with good industrial hygiene and safety on the results of the workplace exposure as- k or smoke when using this product. event spills, waste and minimize release to the
Hygie	ene measures		flushing systems place. When using do Wash contamins The effective op engineering con appropriate deg	nemical is likely during typical use, provide eye s and safety showers close to the working not eat, drink or smoke. ated clothing before re-use. eration of a facility should include review of trols, proper personal protective equipment, owning and decontamination procedures, he monitoring, medical surveillance and the ative controls
Cond	litions for safe storage	:	Keep in properly Store locked up	/ labelled containers.
Mate	rials to avoid	:		ance with the particular national regulations. h the following product types:

Section 8: Exposure controls/personal protection

Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parame- ters / Permissible concentration	Basis
17-	58786-99-5	TWA	3 µg/m3 (OEB 4)	Internal

Strong oxidizing agents



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(cyclobutylmeth) 3,14-diyl [S-(R*,						
o, o.y. [O (,		-				
dihydroxysuccin						
				Wipe limit	30 µg/100 cm ²	Internal
				STEL	25 µg/m3	Internal
Engineering m	easures	:	design and op protect produ Essentially no Use closed p If handled in a cabinet, fume tial exists for	perated in acco cts, workers, ar o open handling rocessing syste a laboratory, us hood, or other	ms or containment te e a properly designed containment device if If this potential does r	ciples to chnologies biosafety the poten-
Personal prote	ctive equipm	nent	:			
Respiratory prot	ection	:	sure assessm ommended g	nent demonstra uidelines, use r	ntilation is not availab tes exposures outside espiratory protection.	
Filter type Hand protection		:	Particulates t	уре		
Material		:	Chemical-res	istant gloves		
Remarks Eye protection		:	If the work en mists or aeros Wear a faces	plasses with sid vironment or ac sols, wear the a hield or other fu	e shields or goggles. ctivity involves dusty c ppropriate goggles. Ill face protection if the the face with dusts, n	ere is a
Skin and body p	rotection	:	Work uniform Additional boo task being pe posable suits	rformed (e.g., s) to avoid expos ate degowning t	oat. ould be used based u leevelets, apron, gau sed skin surfaces. rechniques to remove	ntlets, dis-

Appearance	: liquid
Colour	: colourless
Odour	: No data available
Odour Threshold	: No data available
рН	: No data available
Melting point/freezing point	: No data available



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	tial boiling point and boiling nge	:	100 °C	
Fla	Flash point		No data available	9
Ev	Evaporation rate		No data available	9
Fla	ammability (solid, gas)	:	Not applicable	
Fla	ammability (liquids)	:	No data available	9
	pper explosion limit / Upper mmability limit	:	No data available	9
	wer explosion limit / Lower mmability limit	:	No data available	
Va	pour pressure	:	No data available)
Re	lative vapour density	:	No data available	9
Re	lative density	:	No data available	9
De	ensity	:	No data available	9
So	lubility(ies) Water solubility	:	No data available	9
	rtition coefficient: n-	:	Not applicable	
	tanol/water to-ignition temperature	:	No data available	9
De	composition temperature	:	No data available	9
Vis	scosity Viscosity, kinematic	:	No data available	9
Ex	plosive properties	:	Not explosive	
Ox	idizing properties	:	The substance o	r mixture is not classified as oxidizing.
	rticle characteristics rticle size	:	Not applicable	

Section 10: Stability and reactivity

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



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Incom	itions to avoid patible materials rdous decomposition	:	None known. Oxidizing age No hazardous	nts decomposition products are known.		
produ						
	1: Toxicological info					
Exposure routes		:	Inhalation Skin contact Ingestion Eye contact			
	e toxicity assified based on ava	ilable i	nformation.			
Produ	uct:					
Acute oral toxicity		:	: Acute toxicity estimate: > 2,000 mg/kg Method: Calculation method			
<u>Com</u> p	oonents:					
	yclobutylmethyl)mor	-	n -3,14-diyl [S-(LD50 (Mouse):	R*,R*)]-2,3-dihydroxysuccinate: 395 ma/ka		
	,		LD50 (Dog): >			
			LD50 (Monkey			
Acuto	inhalation toxicity		Remarks: No c			
	dermal toxicity		Remarks: No c			
	corrosion/irritation					
-	assified based on ava	ilable i	nformation.			
Comp	oonents:					
17-(cy	yclobutylmethyl)mor	phina	n-3,14-diyl [S-(R*,R*)]-2,3-dihydroxysuccinate:		
Rema			No data availa			
	us eye damage/eye i assified based on ava					
	oonents:					
		phina	1-3.14-divl [S-(R*,R*)]-2,3-dihydroxysuccinate:		
Speci		-	Rat	,, <u>,,,,,,,,,,,,,,,,,,,,,,,,,,,,,</u>		



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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	
Assessment	
Result	

Dermal Does not cause skin sensitisation. : negative

Chronic toxicity

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

Reproductive toxicity

Suspected of damaging fertility. Suspected of damaging the unborn child.

Components:

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



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Effects on fertility		Species: Rat Application Ro	L: 160 mg/kg body weight		
Effects on foetal develop- ment		Species: Rat Application Ro Developmenta	ubryo-foetal development oute: Subcutaneous Il Toxicity: LOAEL: 1 mg/kg body weight atogenic effects, Increased stillbirths		
		Species: Rabb Application Ro Developmenta	oute: Oral Il Toxicity: LOAEL: 30 mg/kg body weight atogenic effects, Maternal toxicity observed.,		
		Species: Rat Application Ro Developmenta	ubryo-foetal development oute: Subcutaneous Il Toxicity: LOAEL: 0.5 mg/kg body weight nal toxicity observed.		
Reproductive toxicity - As- : sessment		fertility, based	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.



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Repeated dose toxicity

Components:

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

Species LOAEL Application Route Exposure time Target Organs	: : : : : : : : : : : : : : : : : : : :	Rat 0.4 mg/kg Subcutaneous 6 Months Blood, Central nervous system
Species LOAEL Application Route Exposure time Target Organs	: : : : : : : : : : : : : : : : : : : :	Monkey 0.15 mg/kg Intramuscular 6 Months Central nervous system
Species LOAEL Application Route Exposure time Symptoms	: : :	Dog 0.1 mg/kg Intramuscular 3 Months 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			

Section 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



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Mobil	ity in soil			
No data available				
Other adverse effects				

No data available

Section 13: Disposal considerations

Disposal	methods
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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.

Section 14: Transport information

International Regulations

UNRTDG UN number Proper shipping name Class Subsidiary risk Packing group Labels Environmentally hazardous	Not applicable Not applicable Not applicable Not applicable Not applicable Not applicable no
IATA-DGR UN/ID No. Proper shipping name Class Subsidiary risk Packing group Labels Packing instruction (cargo aircraft) Packing instruction (passen- ger aircraft)	Not applicable Not applicable Not applicable Not applicable Not applicable Not applicable Not applicable
IMDG-Code UN number Proper shipping name Class Subsidiary risk Packing group Labels EmS Code Marine pollutant	Not applicable Not applicable Not applicable Not applicable Not applicable Not applicable Not applicable Not applicable

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

Not applicable for product as supplied.



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Natior	nal Regulations		

NZS 5433 UN number Proper shipping name Class Subsidiary risk Packing group Labels	 Not applicable
Hazchem Code	: Not applicable

Special precautions for user

Not applicable

Section 15: Regulatory information

Safety, health and environmental regulations/legislation specific for the substance or mixture

HSNO Approval Number

HSR100759 Veterinary Medicines Non dispersive Open System Application Group Standard

Tolerable Exposure Limits (TEL)

Not applicable

Environmental Exposure Limits (EEL)

Not applicable

HSW Controls

Certified handler certificate not required.

Tracking hazardous substance not required.

Refer to the Health and Safety at Work (Hazardous Substances) Regulations 2017, for further information.

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

AICS	: not determined
DSL	: not determined
IECSC	: not determined

Section 16: Other information

Revision Date	:	06.07.2024
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.



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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 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.

NZ / EN