

Butorphanol Formulation

/ersion 8.0	Revision Date: 06.07.2024		S Number: 3955-00018	Date of last issue: 23.04.2024 Date of first issue: 03.10.2016			
SECTION	1. IDENTIFICATION						
Produ	Product name		: Butorphanol Formulation				
Other	means of identification	:	Dolorex® (A006	877)			
Manu	ifacturer or supplier's o	deta	ils				
Comp	bany	:	: MSD				
Addre	ess	:), 6th floor, Ciudad Autonoma .rgentina C1013AAP			
Telep	hone	:	908-740-4000				
Emer	gency telephone	:	1-908-423-6000				
E-ma	il address	:	EHSDATASTEV	VARD@msd.com			
Reco	mmended use of the cl	hem	ical and restricti	ons on use			
	Recommended use Restrictions on use		Veterinary product Not applicable				
GHS Spec	2. HAZARDS IDENTIFIE Classification ific target organ toxicity - e exposure (Oral)			ntral nervous system)			
	ific target organ toxicity - ated exposure (Oral)	:	Category 2 (Blo	od, Central nervous system)			
GHS	label elements						
Haza	rd pictograms	:					
Signa	al Word	:	: Warning				
Haza	rd Statements	:	H371 May cause damage to organs (Central nervous syst swallowed. H373 May cause damage to organs (Blood, Central nervo system) through prolonged or repeated exposure if swallo				
Preca	Precautionary Statements :		Prevention:				

P260 Do not breathe mist or vapors. P264 Wash skin thoroughly after handling. P270 Do not eat, drink or smoke when using this product.



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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.

SECTION 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

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.
In some of slip contest	_	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.
In case of eye contact	:	Flush eyes with water as a precaution.
		Get medical attention if irritation develops and persists.
If swallowed	:	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	:	May cause damage to organs if swallowed.
and effects, both acute and delayed		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 when the potential for exposure exists (see section 8).
Notes to physician	:	Treat symptomatically and supportively.

SECTION 5. FIRE-FIGHTING MEASURES



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Suitable extinguishing media		:	Water spray Alcohol-resistant Carbon dioxide (C Dry chemical				
Unsuitable extinguishing media		:	None known.				
Speci fightir	Specific hazards during fire		: Exposure to combustion products may be a hazard to healt				
	rdous combustion prod-	:	Carbon oxides				
Speci ods	fic extinguishing meth-	:	cumstances and t Use water spray t	g measures that are appropriate to local cir- the surrounding environment. to cool unopened containers. ged containers from fire area if it is safe to de			
	Special protective equipment for fire-fighters		 In the event of fire, wear self-contained breathing apparatu Use personal protective equipment. 				
SECTION	6. ACCIDENTAL RELE	ASI	EMEASURES				
tive e	onal precautions, protec- quipment and emer- / procedures	:	Follow safe hand	tective equipment. ling advice (see section 7) and personal nent recommendations (see section 8).			
Enviro	onmental precautions	:	Prevent spreading oil barriers). Retain and dispos	akage or spillage if safe to do so. g over a wide area (e.g., by containment or se of contaminated wash water. should be advised if significant spillages			
	ods and materials for inment and cleaning up	:	For large spills, p containment to ke can be pumped, s container. Clean up remainin absorbent. Local or national disposal of this m employed in the c determine which Sections 13 and	t absorbent material. rovide diking or other appropriate eep material from spreading. If diked materia store recovered material in appropriate ng materials from spill with suitable regulations may apply to releases and aterial, as well as those materials and items cleanup of releases. You will need to regulations are applicable. 15 of this SDS provide information regarding ational requirements.			

SECTION 7. HANDLING AND STORAGE

Technical measures	:	See Engineering measures under EXPOSURE
		CONTROLS/PERSONAL PROTECTION section.
Local/Total ventilation	:	Use only with adequate ventilation.



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Advice on safe handling		 Do not breathe mist or vapors. 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 practice, based on the results of the workplace exposu assessment Do not eat, drink or smoke when using this product. Take care to prevent spills, waste and minimize release environment. 				
Conditions for safe storage		Store locked	: Keep in properly labeled containers. Store locked up.			
Materials to avoid		: Do not store Strong oxidiz	substances and mixtures			

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components	CAS-No.	Value type (Form of exposure)	Control parame- ters / 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 ²	Internal
		STEL	25 µg/m3	Internal

Ingredients with workplace control parameters

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 exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.
Filter type : Hand protection	Particulates type

: Chemical-resistant gloves



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	emarks protection	 Consider double gloving. Wear safety glasses with side shields or goggles. If the work environment or activity involves dusty condition mists or aerosols, wear the appropriate goggles. Wear a faceshield or other full face protection if there is potential for direct contact to the face with dusts, mists, or aerosols. 			
Skin a	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 potent contaminated clothing. 			
Hygie	Hygiene measures		to chemical is likely during typical use, provide systems and safety showers close to the ce. do not eat, drink or smoke. minated clothing before re-use. e operation of a facility should include review of controls, proper personal protective equipment, degowning and decontamination procedures, giene monitoring, medical surveillance and the nistrative controls.		

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	:	liquid
Color	:	colorless
Odor	:	No data available
Odor Threshold	:	No data available
рН	:	No data available
Melting point/freezing point	:	No data available
Initial boiling point and boiling range	:	100 °C
Flash point	:	No data available
Flash point Evaporation rate	:	No data available No data available
·	:	
Evaporation rate	::	No data available
Evaporation rate Flammability (solid, gas)		No data available Not applicable No data available



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Vapor pressure		:	No data available	e
Relative vapor density		:	No data available	9
Relativ	e density	:	No data available	e
Densit	y	:	No data available	9
	ity(ies) ter solubility	:	No data available	e
	Partition coefficient: n-		Not applicable	
	octanol/water Autoignition temperature		No data available	e
Decom	position temperature	:	No data available	e
Viscos Vis	ity cosity, kinematic	:	No data available	e
Explos	ive properties	:	Not explosive	
Oxidizi	ng properties	:	The substance o	r mixture is not classified as oxidizing.
Particle Particle	e characteristics e size	:	Not applicable	

SECTION 10. STABILITY AND REACTIVITY

Reactivity Chemical stability Possibility of hazardous reac- tions	:	Not classified as a reactivity hazard. Stable under normal conditions. Can react with strong oxidizing agents.
Conditions to avoid Incompatible materials Hazardous decomposition products	:	None known. Oxidizing agents 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: > 5.000 mg/kg
		Method: Calculation method



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Com	ponents:		
	yclobutylmethyl)mo e oral toxicity	rphinan-3,14-diyl [S-(: LD50 (Mouse):	(R*,R*)]-2,3-dihydroxysuccinate: : 395 mg/kg
		LD50 (Dog): >	50 mg/kg
		LD50 (Monkey	r): > 50 mg/kg
Acute	e inhalation toxicity	: Remarks: No c	data available
Acute	e dermal toxicity	: Remarks: No c	data available
-	corrosion/irritation lassified based on ava	ailable information.	
	ponents:		
17-(c Rema		rphinan-3,14-diyl [S-(: No data availa	(R*,R*)]-2,3-dihydroxysuccinate:
Sorio		irritation	
	ous eye damage/eye		
Not c	lassified based on ava		
Not c			
Not c <u>Com</u> 17-(c	lassified based on ava ponents: yclobutylmethyl)mo	ailable information.	(R*,R*)]-2,3-dihydroxysuccinate:
Not c <u>Com</u>	lassified based on ava ponents: yclobutylmethyl)mo ies	ailable information. rphinan-3,14-diyl [S-(: Rat	
Not c <u>Com</u> 17-(c	lassified based on ava ponents: yclobutylmethyl)mo ies	ailable information. rphinan-3,14-diyl [S-(
Not c <u>Com</u> 17-(c Speci Resu	lassified based on ava ponents: yclobutylmethyl)mo ies	ailable information. rphinan-3,14-diyl [S-(: Rat : No eye irritatio	
Not c Com 17-(c Spec Resu Resp Skin	lassified based on ava ponents: yclobutylmethyl)mo ies It iratory or skin sensi sensitization	ailable information. rphinan-3,14-diyl [S-(ː Rat ː No eye irritatio itization	
Not c Com 17-(c Spec Resu Resp Skin	lassified based on ava ponents: yclobutylmethyl)mo ies It iratory or skin sensi	ailable information. rphinan-3,14-diyl [S-(ː Rat ː No eye irritatio itization	
Not c Com 17-(c Spec Resu Resp Skin Not c Resp	lassified based on ava ponents: yclobutyImethyI)mo ies It iratory or skin sensi sensitization lassified based on ava iratory sensitization	ailable information. rphinan-3,14-diyl [S-(: Rat : No eye irritatio itization ailable information.	
Not c Com 17-(c Speci Resu Resp Skin Not c Resp Not c	lassified based on ava ponents: yclobutylmethyl)mo ies lt iratory or skin sensi sensitization lassified based on ava iratory sensitization lassified based on ava	ailable information. rphinan-3,14-diyl [S-(: Rat : No eye irritatio itization ailable information.	
Not c Com 17-(c Speci Resu Resp Skin Not c Resp Not c	lassified based on ava ponents: yclobutyImethyI)mo ies It iratory or skin sensi sensitization lassified based on ava iratory sensitization	ailable information. rphinan-3,14-diyl [S-(: Rat : No eye irritatio itization ailable information.	
Not c Com 17-(c Speci Resu Resp Skin Not c Resp Not c Com	lassified based on ava ponents: yclobutylmethyl)mo ies lt iratory or skin sensi sensitization lassified based on ava iratory sensitization lassified based on ava ponents: yclobutylmethyl)mo	ailable information. rphinan-3,14-diyl [S-(: Rat : No eye irritatio itization ailable information.	
Not c Com 17-(c Speci Resu Resp Skin Not c Resp Not c Com 17-(c	lassified based on ava ponents: yclobutylmethyl)mo ies lt iratory or skin sensi sensitization lassified based on ava iratory sensitization lassified based on ava ponents: yclobutylmethyl)mo es of exposure ssment	ailable information. rphinan-3,14-diyl [S-(: Rat : No eye irritatio itization ailable information. ailable information. rphinan-3,14-diyl [S-(: Dermal	n
Not c Com 17-(c Speci Resu Resp Skin Not c Resp Not c Com 17-(c Route Asses Resu	lassified based on ava ponents: yclobutylmethyl)mo ies lt iratory or skin sensi sensitization lassified based on ava iratory sensitization lassified based on ava ponents: yclobutylmethyl)mo es of exposure ssment	ailable information. rphinan-3,14-diyl [S-(: Rat : No eye irritation itization ailable information. rphinan-3,14-diyl [S-(: Dermal : Does not caus : negative	n (R*,R*)]-2,3-dihydroxysuccinate:
Not c Com 17-(c Speci Resu Resp Skin Not c Com 17-(c Route Asses Resu Germ Not c	lassified based on ava ponents: yclobutylmethyl)mo ies lt iratory or skin sensi sensitization lassified based on ava iratory sensitization lassified based on ava ponents: yclobutylmethyl)mo es of exposure ssment lt	ailable information. rphinan-3,14-diyl [S-(: Rat : No eye irritation itization ailable information. rphinan-3,14-diyl [S-(: Dermal : Does not caus : negative	n (R*,R*)]-2,3-dihydroxysuccinate:
Not c Com 17-(c Speci Resu Resp Skin Not c Com 17-(c Route Asses Resu Germ Not c Com	lassified based on ava ponents: yclobutylmethyl)mo ies lt iratory or skin sensi sensitization lassified based on ava ponents: yclobutylmethyl)mo es of exposure ssment lt n cell mutagenicity lassified based on ava ponents:	ailable information.	n (R*,R*)]-2,3-dihydroxysuccinate:

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		Test Type: DNA damage and repair, unscheduled DNA syn- thesis in mammalian cells (in vitro) Result: negative
Carcinogenicity Not classified based on availal	ble	information.
Components:		
	ina	n-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 Result	÷	2 Years
Result	•	negative
Reproductive toxicity Not classified based on availal	ble	information.
Components:		
17-(cvclobutvlmethvl)morph	ina	n-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
Effects on fetal development	:	Result: Effects on fertility. Test Type: Embryo-fetal development
		Species: Rat Application Route: Subcutaneous Developmental Toxicity: LOAEL: 1 mg/kg body weight Result: No teratogenic effects., Increased stillbirths
		Test Type: Embryo-fetal 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-fetal 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



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П		experiments.	
May c	-single exposure cause damage to orga conents:	ans (Central nervous	system) if swallowed.
		rphinan-3,14-diyl [S	-(R*,R*)]-2,3-dihydroxysuccinate:
Targe	et Organs ssment	: Central nervo	
May c	-repeated exposure cause damage to orga sure if swallowed.	ns (Blood, Central n	ervous system) through prolonged or repeated
Comp	oonents:		
			-(R*,R*)]-2,3-dihydroxysuccinate:
	et Organs ssment		al nervous system age to organs through prolonged or repeated
Repe	ated dose toxicity		
Com	oonents:		
		rphinan-3,14-diyl [S	-(R*,R*)]-2,3-dihydroxysuccinate:
Expos		: Rat : 0,4 mg/kg : Subcutaneou : 6 Months : Blood, Centra	is al nervous system
Expos	es EL cation Route sure time tt Organs	: Monkey : 0,15 mg/kg : Intramuscula : 6 Months : Central nervo	
Speci LOAE Applic Expos Symp	L cation Route sure time	: Dog : 0,1 mg/kg : Intramuscula : 3 Months : reduced body	
Not cl	ation toxicity assified based on ava rience with human e		
-	oonents:		

17-(cyclobutylmethyl)morphinan-3,14-diyl [S-(R*,R*)]-2,3-dihydroxysuccinate: Ingestion : Symptoms: Drowsiness, Sweating, Nausea, Dizziness, Verti-



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II		go, Palpitation,	respiratory depression
SECTION	12. ECOLOGICAL IN	NFORMATION	
Ecot	oxicity		
Com	ponents:		
17-(c	yclobutylmethyl)mo	rphinan-3,14-diyl [S-(R*,R*)]-2,3-dihydroxysuccinate:
	tity to daphnia and oth tic invertebrates	Exposure time:	a magna (Water flea)): 38,1 mg/l : 48 h) Test Guideline 202
Persi	istence and degrada	bility	
No da	ata available		
Bioa	ccumulative potentia	al	
No da	ata available		
Mobi	ility in soil		
No da	ata available		
Othe	r adverse effects		
No da	ata available		
	13. DISPOSAL CON	SIDERATIONS	

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.

SECTION 14. TRANSPORT INFORMATION

International Regulations

UNRTDG Not regulated as a dangerous good

IATA-DGR Not regulated as a dangerous good

IMDG-Code Not regulated as a dangerous good

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code Not applicable for product as supplied.

Special precautions for user

Not applicable





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SECTION	15. REGULATORY I	NFORMATION			
mixtu	u re ntina. Carcinogenic Su	-	legislation specific for the substance : Not applicable	∍ or	
	Control of precursors and essential chemicals for the : Not applicable preparation of drugs.				
The i AICS DSL	• ·	oduct are reported in : not determined : not determined	-		
DSL		. not determined			
IECS	C	: not determined	t de la constante de la consta		
SECTION	16. OTHER INFORM	ATION			

Revision Date	:	06.07.2024
Date format	:	dd.mm.yyyy

Further information

Sources of key data used to	:	Internal technical data, data from raw material SDSs, OECD
compile the Material Safety		eChem Portal search results and European Chemicals Agen-
Data Sheet		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.

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



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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.

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