

SAFETY DATA SHEETS

This SDS packet was issued with item:

078056551

N/A

Dolorex

Page 1 of 4

Section 1: Identification of the Substance and Supplier

Product name	Dolorex Liquid containing 1-1.5% butorphanol tartrate
Recommended use	Centrally acting narcotic agonist-antagonist analgesic.
Company details	Intervet Limited 12 Shakespeare Ave, Upper Hutt Phone: 0800 447 838, Fax 0800 424 838 Website: www.intervet.co.nz Hours 8am – 5 pm, Mon – Fri
Emergency telephone	0800 764 766 (0800 POISON) 24 hours human health 0800 243 622 (0800 CHEMCALL) 24 hours
Date of preparation	October 2008

Section 2: Hazards Identification

Hazard classifications	6.9B
Priority identifiers	Warning
Secondary identifier	6.9B May cause target organ damage through prolonged or repeated oral exposure at high doses.
Risk & Safety Phrases	R48/22 Harmful: danger of serious damage to health by prolonged exposure if swallowed

Section 3: Composition/Information on Ingredients

Chemical name	CAS number	Concentration
Butorphanol tartrate	58786-99-5	0.019g/mL

Section 4: First Aid Measures

Necessary first aid measures	ACCIDENTIAL INJECTION: Wash and disinfect self injection injuries. Seek medical advice if irritancy or an allergic response occurs – show this SDS. SKIN CONTACT: In case of skin contact, while wearing protective gloves, carefully remove any contaminated clothing, including shoes, and wash skin thoroughly with soap and water. If irritation or symptoms occur or persist, consult a doctor. EYE CONTACT: In case of eye contact, immediately rinse eyes thoroughly with plenty of water. If wearing contact lenses, remove only after initial rinse, and continue rinsing eyes for at least 15 minutes. If irritation occurs or persists, consult a doctor. INGESTION: Rinse mouth and drink a glass of water. Do not induce vomiting unless under the direction of a qualified medical professional or National Poisons Centre. If symptoms persist, consult a doctor.
Required instructions	For advice contact the National Poisons Centre 0800 POISON (0800 764 766) or a

Dolorex

Page 2 of 4

doctor.

Notes for medical personnel

Butorphanol is a potent analgesic with appreciable narcotic antagonist activity. Butorphanol is absorbed orally or parentally. The human therapeutic dose is 1-4mg IM or 0.2-2mg IV. Peak plasma concentration occurs ½ - 1 hour after IM injection and 1-1½ hours after oral administration. Pharmacological effect lasts 3-4 hrs. For gross over dosage, Naloxone is the specific antagonist.

Section 5: Fire Fighting Measures

Type of hazard	Not classified as flammable
Fire hazard properties	Not applicable
Regulatory requirements	Not applicable
Extinguishing media and methods	Carbon dioxide (CO ₂), extinguishing powder or water spray
Hazchem code	None allocated
Recommended protective clothing	Wear self-contained breathing apparatus (SCBA) plus protective gloves.

Section 6: Accidental Release Measures

Emergency procedures	Wear chemical resistant gloves and overalls, facemask or goggles. Prevent further spillage. Adsorb spilled product and place in sealable container for disposal. Wash down affected area with water plus detergent. Absorb and collect washings and place in the same sealable container for disposal. Seek advice from the local authority regarding disposal.
-----------------------------	---

Section 7: Handling and Storage

Precautions for safe handling	Avoid contact with skin, eyes, and mucosa. Keep containers adequately sealed during material transfer, transport, or when not in use. See Section 8 (Exposure Controls) for additional guidance.
Regulatory requirements	Not required
Handling practices	Avoid contact with skin. Keep containers adequately sealed during material transfer, transport, or when not in use.
Approved handlers	Not required.
Conditions for safe storage	See below.
Store site requirements	Store in original container and below 25°C. Keep out of reach of children
Packaging	Schedule 4

Dolorex

Section 8: Exposure Control/Personal Protection

Workplace exposure standards	No WES is set for this substance at this time.
Application in the workplace	Ensure adequate ventilation. Keep container sealed when not in use.
Exposure standards outside the workplace	No TEL are required for this substance at this time No EEL is set for this substance at this time
Personal protection	Wear chemical resistant gloves, facemask or goggles.

Section 9: Physical and Chemical Properties

Appearance	Clear, colourless liquid with characteristic odour.
Boiling Point	Approximately 100°C
Melting Point	Approximately 0°C
Vapour Pressure	2.37 kPa at 20°C
Specific Gravity	1.114
Solubility (H ₂ O)	Completely soluble in water.
Percent Volatiles	Not determined
Evaporation Rate	Not determined

Section 10: Stability and Reactivity

Stability of the substance	Stable under normal conditions.
Conditions to avoid	Avoid high temperatures
Material to avoid	Avoid food products
Hazardous decomposition products	No dangerous decomposition is expected if used according to manufacturer's specifications.

Section 11: Toxicological Information

Acute effects for individual ingredients only

ORAL	Butorphanol: Orally 10mg/kg gives slight cardiovascular and respiratory depression. NOAEL 0.3mg.kg bw/day Rat oral LD50 = 315mg/kg
TEL	No TELs are required for this substance at this time.

Chronic/long term effects for individual ingredients only

Section 12: Environmental Information

Effects for individual ingredients only.

Dolorex

Page 4 of 4

EEL No EEL is set for this substance at this time.

Section 13: Disposal Considerations

Disposal information	Disposal Dispose of this product only by using according to the label, or at an approved landfill, or other approved facility.
	Container Disposal Bury in an approved landfill or other approved facility.
Reference	Current version of NZS 8409 Management of Agrichemicals

Section 14: Transport Information

Relevant information	Not classified as a dangerous good for transport
-----------------------------	--

Section 15: Regulatory Information

Regulatory status	HSNO Approval Code: HSR001963. For a full listing of controls see www.ermanz.govt.nz ACVM registration number: A06877 For conditions of registration see www.nzfsa.govt.nz/acvm Prescription Animal Remedy (P.A.R) Class II For use only by, in the presence of, or under the control of a veterinarian.
HSNO and ACVM controls	-

Section 16: Other Information

Additional information	Dolorex is a trademark of Intervet Limited
-------------------------------	--

Intervet Limited urges each user or recipient of this SDS to read the entire data sheet to become aware of the potential hazards associated with this material. This SDS summarises, at the date of issue, our best knowledge of the health and safety hazard information. Although reasonable care has been taken in the preparation of this document, Intervet Limited extend no warranties and make no representations as to the accuracy or completeness of the information contained therein, and assume no responsibility regarding the suitability of this information for the user's intended purposes or for the consequence of its use. Each individual should make a determination as to the suitability of the information for their particular purpose(s).

Butorphanol Formulation

Version 2.0 Revision Date: 10/16/2017 SDS Number: 918671-00004 Date of last issue: 05/02/2017
 Date of first issue: 10/03/2016

SECTION 1. IDENTIFICATION

Product name : Butorphanol Formulation

Manufacturer or supplier's details

Company name of supplier : Merck & Co., Inc
 Address : 2000 Galloping Hill Road
 Kenilworth - New Jersey - USA 1685
 Telephone : 908-740-4000
 Telefax : 908-735-1496
 Emergency telephone : 1-908-423-6000
 E-mail address : EHSDATASTEWARD@merck.com

Recommended use of the chemical and restrictions on use


Recommended use : Veterinary product

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with 29 CFR 1910.1200

Reproductive toxicity : Category 2
 Specific target organ systemic toxicity - single exposure (Oral) : Category 1 (Central nervous system)
 Specific target organ systemic toxicity - repeated exposure (Oral) : Category 1 (Blood, Central nervous system)

GHS label elements

Hazard pictograms : 

Signal Word : Danger

Hazard Statements : H361fd Suspected of damaging fertility. Suspected of damaging the unborn child.
 H370 Causes damage to organs (Central nervous system) if swallowed.
 H372 Causes damage to organs (Blood, Central nervous system) through prolonged or repeated exposure if swallowed.

Precautionary Statements : **Prevention:**
 P201 Obtain special instructions before use.

Butorphanol Formulation

Version 2.0 Revision Date: 10/16/2017 SDS Number: 918671-00004 Date of last issue: 05/02/2017
 Date of first issue: 10/03/2016

P202 Do not handle until all safety precautions have been read and understood.
 P260 Do not breathe mist or vapors.
 P264 Wash skin thoroughly after handling.
 P270 Do not eat, drink or smoke when using this product.
 P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response:

P307 + P311 IF exposed: Call a POISON CENTER or doctor/ physician.

Storage:

P405 Store locked up.

Disposal:

P501 Dispose of contents/ container to an approved waste disposal plant.

Other hazards

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Hazardous ingredients

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

Butorphanol Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 05/02/2017
2.0	10/16/2017	918671-00004	Date of first issue: 10/03/2016

		Rinse mouth thoroughly with water. Never give anything by mouth to an unconscious person.
Most important symptoms and effects, both acute and delayed	:	Suspected of damaging fertility. Suspected of damaging the unborn child. Causes damage to organs if swallowed. Causes 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.
Notes to physician	:	Treat symptomatically and supportively.

SECTION 5. FIRE-FIGHTING MEASURES

Suitable extinguishing media	:	Water spray Alcohol-resistant foam Carbon dioxide (CO ₂) 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
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 for fire-fighters	:	In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures	:	Use personal protective equipment. Follow safe handling advice and personal protective equipment recommendations.
Environmental precautions	:	Discharge into the environment must be avoided. 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

Butorphanol Formulation

Version 2.0 Revision Date: 10/16/2017 SDS Number: 918671-00004 Date of last issue: 05/02/2017
 Date of first issue: 10/03/2016

cannot be contained.

Methods and materials for containment and cleaning up : Soak up with inert absorbent material.
 For large spills, provide diking or other appropriate containment to keep material from spreading. If diked 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.

SECTION 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 : Avoid inhalation of vapor or mist.
 Do not swallow.
 Avoid contact with eyes.
 Avoid prolonged or repeated contact with skin.
 Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment
 Take care to prevent spills, waste and minimize release to the environment.

Conditions for safe storage : Keep in properly labeled 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
 Organic peroxides
 Explosives
 Gases

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

Ingredients	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
17-(Cyclobutylmethyl)morphinan-3,14-diol [S-(R*,R*)]-2,3-	58786-99-5	TWA	3 µg/m ³ (OEB 4)	Merck

Butorphanol Formulation

Version 2.0 Revision Date: 10/16/2017 SDS Number: 918671-00004 Date of last issue: 05/02/2017
 Date of first issue: 10/03/2016

dihydroxysuccinate				
		Wipe limit	30 µg/100 cm ²	Merck

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 : General and local exhaust ventilation is recommended to maintain vapor exposures below recommended limits. Where concentrations are above recommended limits or are unknown, appropriate respiratory protection should be worn. Follow OSHA respirator regulations (29 CFR 1910.134) and use NIOSH/MSHA approved respirators. Protection provided by air purifying respirators against exposure to any hazardous chemical is limited. Use a positive pressure air supplied respirator if there is any potential for uncontrolled release, exposure levels are unknown, or any other circumstance where air purifying respirators may not provide adequate protection.

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 : Ensure that eye flushing systems and safety showers are located 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,

Butorphanol Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 05/02/2017
2.0	10/16/2017	918671-00004	Date of first issue: 10/03/2016

appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	:	liquid
Color	:	colorless
Odor	:	No information available.
Odor 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
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Vapor pressure	:	No data available
Relative vapor density	:	No data available
Relative density	:	No data available
Density	:	No data available
Solubility(ies)	:	
Water solubility	:	No data available
Partition coefficient: n-octanol/water	:	Not applicable
Autoignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity	:	

Butorphanol Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 05/02/2017
2.0	10/16/2017	918671-00004	Date of first issue: 10/03/2016

Viscosity, kinematic	:	No data available
Explosive properties	:	Not explosive
Oxidizing properties	:	The substance or mixture is not classified as oxidizing.
Particle size	:	Not applicable

SECTION 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.

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
---------------------	---	--

Ingredients:

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

Butorphanol Formulation

Version 2.0 Revision Date: 10/16/2017 SDS Number: 918671-00004 Date of last issue: 05/02/2017
Date of first issue: 10/03/2016

Skin corrosion/irritation

Not classified based on available information.

Ingredients:**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.

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

Species: Rat

Result: No eye irritation

Respiratory or skin sensitization**Skin sensitization**

Not classified based on available information.

Respiratory sensitization

Not classified based on available information.

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

Routes of exposure: Dermal

Assessment: Does not cause skin sensitization.

Result: negative

Germ cell mutagenicity

Not classified based on available information.

Ingredients:**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 synthesis in mammalian cells (in vitro)
Result: negative

Carcinogenicity

Not classified based on available information.

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

Species: Rat

Application Route: Oral

Exposure time: 2 Years

Butorphanol Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 05/02/2017
2.0	10/16/2017	918671-00004	Date of first issue: 10/03/2016

Result: negative

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

IARC

No ingredient of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

OSHA

No component of this product present at levels greater than or equal to 0.1% is on OSHA's list of regulated carcinogens.

NTP

No ingredient of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

Reproductive toxicity

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

Ingredients:

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 fetal development	:	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 - Assessment	:	Some evidence of adverse effects on sexual function and fertility, based on animal experiments., Some evidence of adverse effects on development, based on animal experiments.

Butorphanol Formulation

Version Revision Date: SDS Number: Date of last issue: 05/02/2017
2.0 10/16/2017 918671-00004 Date of first issue: 10/03/2016

STOT-single exposure

Causes damage to organs (Central nervous system) if swallowed.

Ingredients:**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

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

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

Ingestion : Symptoms: Drowsiness, Sweating, Nausea, Dizziness, Vertigo, Palpitation, respiratory depression

Butorphanol Formulation

Version Revision Date: SDS Number: Date of last issue: 05/02/2017
2.0 10/16/2017 918671-00004 Date of first issue: 10/03/2016

SECTION 12. ECOLOGICAL INFORMATION**Ecotoxicity****Ingredients:****17-(Cyclobutylmethyl)morphinan-3,14-diyl [S-(R*,R*)]-2,3-dihydroxysuccinate:**

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

SECTION 13. DISPOSAL CONSIDERATIONS**Disposal methods**

Waste from residues : 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.

Domestic regulation**49 CFR**

Not regulated as a dangerous good

Butorphanol Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 05/02/2017
2.0	10/16/2017	918671-00004	Date of first issue: 10/03/2016

SECTION 15. REGULATORY INFORMATION

EPCRA - Emergency Planning and Community Right-to-Know

CERCLA Reportable Quantity

This material does not contain any components with a CERCLA RQ.

SARA 304 Extremely Hazardous Substances Reportable Quantity

This material does not contain any components with a section 304 EHS RQ.

SARA 302 Extremely Hazardous Substances Threshold Planning Quantity

This material does not contain any components with a section 302 EHS TPQ.

SARA 311/312 Hazards : Reproductive toxicity
Specific target organ toxicity (single or repeated exposure)

SARA 313 : This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

US State Regulations

Pennsylvania Right To Know

Water

7732-18-5

California Prop. 65

This product does not contain any chemicals known to the State of California to cause cancer, birth, or any other reproductive defects.

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

AICS : not determined

DSL : not determined

IECSC : not determined

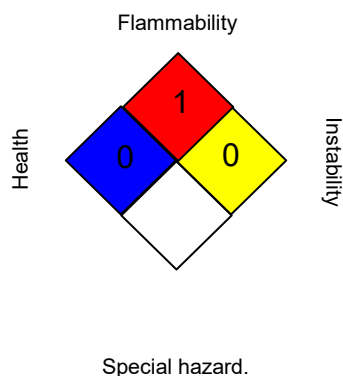
Butorphanol Formulation

Version 2.0 Revision Date: 10/16/2017 SDS Number: 918671-00004 Date of last issue: 05/02/2017
 Date of first issue: 10/03/2016

SECTION 16. OTHER INFORMATION

Further information

NFPA:



HMIS® IV:

HEALTH	*	4
FLAMMABILITY		1
PHYSICAL HAZARD		0

HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "*" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.

Full text of other abbreviations

AICS - Australian Inventory of Chemical Substances; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; 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; HMIS - Hazardous Materials Identification System; 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; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG -

Butorphanol Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 05/02/2017
2.0	10/16/2017	918671-00004	Date of first issue: 10/03/2016

United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

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

Revision Date : 10/16/2017

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

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.

US / Z8