

SAFETY DATA SHEETS

This SDS packet was issued with item:

078946662

The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).

078946661

Section 1. Identification

GHS product identifier : Zorbium
Product code : Not available.
Other means of identification : Buprenorphine Transdermal Solution; CA5552010AM; CA555210DAM

Relevant identified uses of the substance or mixture and uses advised against

Identified uses : Veterinary pharmaceutical.
Uses advised against : Human Health

Company Name : Elanco US Inc.
 2500 Innovation Way
 Greenfield IN, US 46140
Telephone number : 1-877 Elanco1 (1-877-352-6261)
Emergency telephone number : Elanco Product Technical Support / Human or Animal Exposure Reporting:
 1-888-545-5973
Email : elanco_sds@elancoah.com
Transportation Emergency telephone number : CHEMTREC: 1-800-424-9300
 (Outside U.S. CHEMTREC International: 00 1-703-527-3887)

Section 2. Hazards identification

OSHA/HCS status : This material is considered hazardous by the OSHA Hazard Communication Standard (29 CFR 1910.1200).
Classification of the substance or mixture : FLAMMABLE LIQUIDS - Category 2
 ACUTE TOXICITY (dermal) - Category 4
 EYE IRRITATION - Category 2A
 TOXIC TO REPRODUCTION - Category 2
 TOXIC TO REPRODUCTION - Effects on or via lactation
 SPECIFIC TARGET ORGAN TOXICITY (SINGLE EXPOSURE) (Narcotic effects) - Category 3

GHS label elements

Hazard pictograms :   

Signal word : Danger
Hazard statements : H225 - Highly flammable liquid and vapor.
 H312 - Harmful in contact with skin.
 H319 - Causes serious eye irritation.
 H336 - May cause drowsiness or dizziness.
 H361 - Suspected of damaging fertility or the unborn child.
 H362 - May cause harm to breast-fed children.


Precautionary statements

Section 2. Hazards identification

- Prevention** : P201 - Obtain special instructions before use.
P202 - Do not handle until all safety precautions have been read and understood.
P280 - Wear protective gloves, protective clothing and eye or face protection.
P210 - Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
P241 - Use explosion-proof electrical, ventilating or lighting equipment.
P242 - Use non-sparking tools.
P243 - Take action to prevent static discharges.
P271 - Use only outdoors or in a well-ventilated area.
P261 - Avoid breathing vapor.
P263 - Avoid contact during pregnancy or while nursing.
P270 - Do not eat, drink or smoke when using this product.
P264 - Wash thoroughly after handling.
- Response** : P308 + P313 - IF exposed or concerned: Get medical advice or attention.
P304 + P340, P312 - IF INHALED: Remove person to fresh air and keep comfortable for breathing. Call a POISON CENTER or doctor if you feel unwell.
P303 + P361 + P353 - IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water.
P302 + P312, P352 - IF ON SKIN: Call a POISON CENTER or doctor if you feel unwell. Wash with plenty of water.
P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P337 + P313 - If eye irritation persists: Get medical advice or attention.
- Storage** : P405 - Store locked up.
P403 + P233 - Store in a well-ventilated place. Keep container tightly closed.
P403 + P235 - Keep cool.
- Disposal** : P501 - Dispose of contents and container in accordance with all local, regional, national and international regulations.
- Supplemental label elements** : None known.
- Hazards not otherwise classified** : None known.

Section 3. Composition/information on ingredients

Substance/mixture : Mixture

Ingredient name	%	CAS number
 ethanol [5α,7α(S)]-α-tert-butyl-17-(cyclopropylmethyl)-4,5-epoxy-18,19-dihydro-3-hydroxy-6-methoxy-α-methyl-6,14-ethenomorphinan-7-methanol hydrochloride	≥90 ≤3	64-17-5 53152-21-9

Any concentration shown as a range is to protect confidentiality or is due to batch variation.

There are no ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified and hence require reporting in this section.

Occupational exposure limits, if available, are listed in Section 8.

Section 4. First aid measures

Description of necessary first aid measures

- Eye contact** : Immediately flush eyes with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses. Continue to rinse for at least 10 minutes. Get medical attention.
- Inhalation** : Remove victim to fresh air and keep at rest in a position comfortable for breathing. If it is suspected that fumes are still present, the rescuer should wear an appropriate mask or self-contained breathing apparatus. If not breathing, if breathing is irregular or if respiratory arrest occurs, provide artificial respiration or oxygen by trained personnel. It may be dangerous to the person providing aid to give mouth-to-mouth resuscitation. Get medical attention. If necessary, call a poison center or physician. If unconscious, place in recovery position and get medical attention immediately. Maintain an open airway. Loosen tight clothing such as a collar, tie, belt or waistband. In case of

Section 4. First aid measures

inhalation of decomposition products in a fire, symptoms may be delayed. The exposed person may need to be kept under medical surveillance for 48 hours.

- Skin contact** : Wash with plenty of soap and water. Remove contaminated clothing and shoes. Wash contaminated clothing thoroughly with water before removing it, or wear gloves. Continue to rinse for at least 10 minutes. Get medical attention. If necessary, call a poison center or physician. Wash clothing before reuse. Clean shoes thoroughly before reuse.
- Ingestion** : Wash out mouth with water. Remove dentures if any. If material has been swallowed and the exposed person is conscious, give small quantities of water to drink. Stop if the exposed person feels sick as vomiting may be dangerous. Do not induce vomiting unless directed to do so by medical personnel. If vomiting occurs, the head should be kept low so that vomit does not enter the lungs. Get medical attention. If necessary, call a poison center or physician. Never give anything by mouth to an unconscious person. If unconscious, place in recovery position and get medical attention immediately. Maintain an open airway. Loosen tight clothing such as a collar, tie, belt or waistband.

Most important symptoms/effects, acute and delayed

Potential acute health effects

- Eye contact** : Causes serious eye irritation.
- Inhalation** : Can cause central nervous system (CNS) depression. May cause drowsiness or dizziness.
- Skin contact** : Harmful in contact with skin.
- Ingestion** : Can cause central nervous system (CNS) depression.

Over-exposure signs/symptoms

- Eye contact** : Adverse symptoms may include the following:
pain or irritation
watering
redness
- Inhalation** : Adverse symptoms may include the following:
nausea or vomiting
headache
drowsiness/fatigue
dizziness/vertigo
unconsciousness
reduced fetal weight
increase in fetal deaths
skeletal malformations
- Skin contact** : Adverse symptoms may include the following:
reduced fetal weight
increase in fetal deaths
skeletal malformations
- Ingestion** : Adverse symptoms may include the following:
reduced fetal weight
increase in fetal deaths
skeletal malformations

Indication of immediate medical attention and special treatment needed, if necessary

- Notes to physician** : In case of inhalation of decomposition products in a fire, symptoms may be delayed. The exposed person may need to be kept under medical surveillance for 48 hours.
- Specific treatments** : Contains a mu opioid partial agonist (20 mg buprenorphine/mL). In the case of an emergency provide the physician with package insert. Naloxone may not be effective in reversing respiratory depression produced by buprenorphine. The onset of Naloxone effect may be delayed by 30 minutes or more. Doxapram hydrochloride has also been used as a respiratory stimulant.

Section 4. First aid measures

- Protection of first-aiders** : No action shall be taken involving any personal risk or without suitable training. If it is suspected that fumes are still present, the rescuer should wear an appropriate mask or self-contained breathing apparatus. It may be dangerous to the person providing aid to give mouth-to-mouth resuscitation. Wash contaminated clothing thoroughly with water before removing it, or wear gloves.

See toxicological information (Section 11)

Section 5. Fire-fighting measures

Extinguishing media

- Suitable extinguishing media** : Use dry chemical, CO₂, water spray (fog) or foam.

- Unsuitable extinguishing media** : Do not use water jet.

- Specific hazards arising from the chemical** : Highly flammable liquid and vapor. Runoff to sewer may create fire or explosion hazard. In a fire or if heated, a pressure increase will occur and the container may burst, with the risk of a subsequent explosion.

- Hazardous thermal decomposition products** : Decomposition products may include the following materials:
carbon dioxide
carbon monoxide
nitrogen oxides
halogenated compounds

- Special protective actions for fire-fighters** : Promptly isolate the scene by removing all persons from the vicinity of the incident if there is a fire. No action shall be taken involving any personal risk or without suitable training. Move containers from fire area if this can be done without risk. Use water spray to keep fire-exposed containers cool.

- Special protective equipment for fire-fighters** : Fire-fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full face-piece operated in positive pressure mode.

Section 6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

- For non-emergency personnel** : No action shall be taken involving any personal risk or without suitable training. Evacuate surrounding areas. Keep unnecessary and unprotected personnel from entering. Do not touch or walk through spilled material. Shut off all ignition sources. No flares, smoking or flames in hazard area. Avoid breathing vapor or mist. Provide adequate ventilation. Wear appropriate respirator when ventilation is inadequate. Put on appropriate personal protective equipment.

- For emergency responders** : If specialized clothing is required to deal with the spillage, take note of any information in Section 8 on suitable and unsuitable materials. See also the information in "For non-emergency personnel".

- Environmental precautions** : Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers. Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air).

Methods and materials for containment and cleaning up

- Small spill** : Stop leak if without risk. Move containers from spill area. Use spark-proof tools and explosion-proof equipment. Dilute with water and mop up if water-soluble. Alternatively, or if water-insoluble, absorb with an inert dry material and place in an appropriate waste disposal container. Dispose of via a licensed waste disposal contractor.


Section 6. Accidental release measures

- Large spill** : Stop leak if without risk. Move containers from spill area. Use spark-proof tools and explosion-proof equipment. Approach release from upwind. Prevent entry into sewers, water courses, basements or confined areas. Wash spillages into an effluent treatment plant or proceed as follows. Contain and collect spillage with non-combustible, absorbent material e.g. sand, earth, vermiculite or diatomaceous earth and place in container for disposal according to local regulations (see Section 13). Dispose of via a licensed waste disposal contractor. Contaminated absorbent material may pose the same hazard as the spilled product. Note: see Section 1 for emergency contact information and Section 13 for waste disposal.

Section 7. Handling and storage

Precautions for safe handling


- Protective measures** : Put on appropriate personal protective equipment (see Section 8). Avoid exposure - obtain special instructions before use. Avoid contact during pregnancy or while nursing. Do not handle until all safety precautions have been read and understood. Do not get in eyes or on skin or clothing. Do not ingest. Avoid breathing vapor or mist. Use only with adequate ventilation. Wear appropriate respirator when ventilation is inadequate. Do not enter storage areas and confined spaces unless adequately ventilated. Keep in the original container or an approved alternative made from a compatible material, kept tightly closed when not in use. Store and use away from heat, sparks, open flame or any other ignition source. Use explosion-proof electrical (ventilating, lighting and material handling) equipment. Use only non-sparking tools. Take precautionary measures against electrostatic discharges. Empty containers retain product residue and can be hazardous. Do not reuse container. Because this is a controlled substance, special handling and storage requirements must be observed to assure compliance with Drug Enforcement Administration regulations.
- Advice on general occupational hygiene** : Eating, drinking and smoking should be prohibited in areas where this material is handled, stored and processed. Workers should wash hands and face before eating, drinking and smoking. Remove contaminated clothing and protective equipment before entering eating areas. See also Section 8 for additional information on hygiene measures.

- Conditions for safe storage, including any incompatibilities** :  Do not store above the following temperature: 25°C (77°F). Store in accordance with local regulations. Store in a segregated and approved area. Store in original container protected from direct sunlight in a dry, cool and well-ventilated area, away from incompatible materials (see Section 10) and food and drink. Store locked up. Eliminate all ignition sources. Separate from oxidizing materials. Keep container tightly closed and sealed until ready for use. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Do not store in unlabeled containers. Use appropriate containment to avoid environmental contamination. See Section 10 for incompatible materials before handling or use.

Section 8. Exposure controls/personal protection

Control parameters

Occupational exposure limits

Ingredient name	Exposure limits
 ethanol	ACGIH TLV (United States, 1/2021). STEL: 1000 ppm 15 minutes. OSHA PEL 1989 (United States, 3/1989). TWA: 1000 ppm 8 hours. TWA: 1900 mg/m ³ 8 hours. NIOSH REL (United States, 10/2020). TWA: 1000 ppm 10 hours. TWA: 1900 mg/m ³ 10 hours. OSHA PEL (United States, 5/2018). TWA: 1000 ppm 8 hours. TWA: 1900 mg/m ³ 8 hours.
[5α,7α(S)]-α-tert-butyl-17-(cyclopropylmethyl)-4,5-epoxy-18,19-dihydro-3-hydroxy-6-methoxy-α-methyl-6,14-ethenomorphinan-7-methanol hydrochloride	None.

Section 8. Exposure controls/personal protection

Appropriate engineering controls	: Use only with adequate ventilation. Use process enclosures, local exhaust ventilation or other engineering controls to keep worker exposure to airborne contaminants below any recommended or statutory limits. The engineering controls also need to keep gas, vapor or dust concentrations below any lower explosive limits. Use explosion-proof ventilation equipment.
Environmental exposure controls	: Emissions from ventilation or work process equipment should be checked to ensure they comply with the requirements of environmental protection legislation. In some cases, fume scrubbers, filters or engineering modifications to the process equipment will be necessary to reduce emissions to acceptable levels.
<u>Individual protection measures</u>	
Hygiene measures	: Wash hands, forearms and face thoroughly after handling chemical products, before eating, smoking and using the lavatory and at the end of the working period. Appropriate techniques should be used to remove potentially contaminated clothing. Wash contaminated clothing before reusing. Ensure that eyewash stations and safety showers are close to the workstation location.
Eye/face protection	: Safety eyewear complying with an approved standard should be used when a risk assessment indicates this is necessary to avoid exposure to liquid splashes, mists, gases or dusts. If contact is possible, the following protection should be worn, unless the assessment indicates a higher degree of protection: chemical splash goggles.
<u>Skin protection</u>	
Hand protection	: Chemical-resistant, impervious gloves complying with an approved standard should be worn at all times when handling chemical products if a risk assessment indicates this is necessary. Considering the parameters specified by the glove manufacturer, check during use that the gloves are still retaining their protective properties. It should be noted that the time to breakthrough for any glove material may be different for different glove manufacturers. In the case of mixtures, consisting of several substances, the protection time of the gloves cannot be accurately estimated.
Body protection	: Personal protective equipment for the body should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product. When there is a risk of ignition from static electricity, wear anti-static protective clothing. For the greatest protection from static discharges, clothing should include anti-static overalls, boots and gloves.
Other skin protection	: Appropriate footwear and any additional skin protection measures should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.
Respiratory protection	: Based on the hazard and potential for exposure, select a respirator that meets the appropriate standard or certification. Respirators must be used according to a respiratory protection program to ensure proper fitting, training, and other important aspects of use.

Section 9. Physical and chemical properties and safety characteristics

The conditions of measurement of all properties are at standard temperature and pressure unless otherwise indicated.

Appearance

Physical state	: Liquid.
Color	: Clear. Colorless.
Odor	: Alcohol-like.
Odor threshold	: Not available.
pH	: Not available.
Melting point/freezing point	: Not available.

Section 9. Physical and chemical properties and safety characteristics

Boiling point, initial boiling point, and boiling range : Not available.

Flash point : Open cup: 16°C (60.8°F)

Evaporation rate : Not available.

Flammability : Not available.

Lower and upper explosion limit/flammability limit : Not available.

Vapor pressure	Ingredient name	Vapor Pressure at 20°C			Vapor pressure at 50°C		
		mm Hg	kPa	Method	mm Hg	kPa	Method
	ethanol	42.95	5.7				
	2,6-di-tert-butyl-p-cresol	0.01	0.0013				

Relative vapor density : Not available.

Relative density : 0.808

Solubility : Easily soluble in the following materials: cold water and hot water.

Solubility in water : Not available.

Partition coefficient: n-octanol/water : Not applicable.

Auto-ignition temperature	Ingredient name	°C	°F	Method
	ethanol	455	851	DIN 51794

Decomposition temperature : Not available.

Viscosity : Not available.

Flow time (ISO 2431) : Not available.

Particle characteristics

Median particle size : Not applicable.

Section 10. Stability and reactivity

Reactivity : No specific test data related to reactivity available for this product or its ingredients.

Chemical stability : The product is stable.

Possibility of hazardous reactions : Under normal conditions of storage and use, hazardous reactions will not occur.

Conditions to avoid : Avoid all possible sources of ignition (spark or flame). Do not pressurize, cut, weld, braze, solder, drill, grind or expose containers to heat or sources of ignition.

Incompatible materials : Reactive or incompatible with the following materials:
oxidizing materials

Hazardous decomposition products : Under normal conditions of storage and use, hazardous decomposition products should not be produced.

Section 11. Toxicological information

Information on toxicological effects

Acute toxicity

Product/ingredient name	Result	Species	Dose	Exposure
ethanol	LC50 Inhalation Vapor LD50 Dermal LD50 Oral	Rat Rabbit Rat	124700 mg/m ³ >5000 mg/kg 7 g/kg	4 hours - -

Irritation/Corrosion

Product/ingredient name	Result	Species	Score	Exposure	Observation
ethanol	Eyes - Mild irritant	Rabbit	-	24 hours 500 mg	-
	Eyes - Moderate irritant	Rabbit	-	0.066666667 minutes 100 mg	-
	Eyes - Moderate irritant	Rabbit	-	100 uL	-
	Eyes - Severe irritant	Rabbit	-	500 mg	-
	Skin - Mild irritant	Rabbit	-	400 mg	-
	Skin - Moderate irritant	Rabbit	-	24 hours 20 mg	-

Sensitization

Not available.

Mutagenicity

Not available.

Carcinogenicity

Not available.

Classification

Product/ingredient name	OSHA	IARC	NTP
ethanol	-	1	-

Reproductive toxicity

Not available.

Teratogenicity

Not available.

Specific target organ toxicity (single exposure)

Name	Category	Route of exposure	Target organs
Zorbium	Category 3	-	Narcotic effects

Specific target organ toxicity (repeated exposure)

Not available.

Aspiration hazard

Not available.

Information on the likely routes of exposure : Not available.

Potential acute health effects

Eye contact : Causes serious eye irritation.

Inhalation : Can cause central nervous system (CNS) depression. May cause drowsiness or dizziness.

Skin contact : Harmful in contact with skin.

Section 11. Toxicological information

Ingestion : Can cause central nervous system (CNS) depression.

Symptoms related to the physical, chemical and toxicological characteristics

Eye contact : Adverse symptoms may include the following:
pain or irritation
watering
redness

Inhalation : Adverse symptoms may include the following:
nausea or vomiting
headache
drowsiness/fatigue
dizziness/vertigo
unconsciousness
reduced fetal weight
increase in fetal deaths
skeletal malformations

Skin contact : Adverse symptoms may include the following:
reduced fetal weight
increase in fetal deaths
skeletal malformations

Ingestion : Adverse symptoms may include the following:
reduced fetal weight
increase in fetal deaths
skeletal malformations

Delayed and immediate effects and also chronic effects from short and long term exposure

Short term exposure

Potential immediate effects : Not available.

Potential delayed effects : Not available.

Long term exposure

Potential immediate effects : Not available.

Potential delayed effects : Not available.

Potential chronic health effects

Not available.

General : No known significant effects or critical hazards.


Carcinogenicity : Animal testing did not show any carcinogenic effects. (active ingredient)
The ethanol carcinogenicity information reported only applies when it is consumed in alcoholic beverages.
Based on available data, the classification criteria are not met.

Mutagenicity : No known significant effects or critical hazards.

Reproductive toxicity : Suspected of damaging fertility or the unborn child.
May cause harm to breast-fed children.

Numerical measures of toxicity

Acute toxicity estimates

Product/ingredient name	Oral (mg/kg)	Dermal (mg/kg)	Inhalation (gases) (ppm)	Inhalation (vapors) (mg/l)	Inhalation (dusts and mists) (mg/l)
 Zorbium ethanol	N/A 7000	1100 N/A	N/A N/A	N/A 124.7	N/A N/A

Section 12. Ecological information

Toxicity

Product/ingredient name	Result	Species	Exposure
Ethanol	Acute EC50 17.921 mg/l Marine water	Algae - Ulva pertusa	96 hours
	Acute EC50 2000 µg/l Fresh water	Daphnia - Daphnia magna	48 hours
	Acute LC50 25500 µg/l Marine water	Crustaceans - Artemia franciscana - Larvae	48 hours
	Acute LC50 42000 µg/l Fresh water	Fish - Oncorhynchus mykiss	4 days
	Chronic NOEC 4.995 mg/l Marine water	Algae - Ulva pertusa	96 hours
	Chronic NOEC 100 µl/L Fresh water	Daphnia - Daphnia magna - Neonate	21 days
	Chronic NOEC 0.375 µl/L Fresh water	Fish - Gambusia holbrooki - Larvae	12 weeks

Persistence and degradability

Bioaccumulative potential

Product/ingredient name	LogP _{ow}	BCF	Potential
Ethanol	-0.35	-	low

Mobility in soil






Soil/water partition coefficient (K_{oc}) : Not available.

Other adverse effects : No known significant effects or critical hazards.

Section 13. Disposal considerations

Disposal methods : The generation of waste should be avoided or minimized wherever possible. Disposal of this product, solutions and any by-products should at all times comply with the requirements of environmental protection and waste disposal legislation and any regional local authority requirements. Dispose of surplus and non-recyclable products via a licensed waste disposal contractor. Waste should not be disposed of untreated to the sewer unless fully compliant with the requirements of all authorities with jurisdiction. Waste packaging should be recycled. Incineration or landfill should only be considered when recycling is not feasible. This material and its container must be disposed of in a safe way. Care should be taken when handling emptied containers that have not been cleaned or rinsed out. Empty containers or liners may retain some product residues. Vapor from product residues may create a highly flammable or explosive atmosphere inside the container. Do not cut, weld or grind used containers unless they have been cleaned thoroughly internally. Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers. Class III opioid. Any unused or expired product must be destroyed by a DEA registered reverse distributor. For further information contact local DEA field office or Elanco (1-888-545-5973)

Section 14. Transport information

	DOT Classification	TDG Classification	Mexico Classification	IMDG	IATA
UN number	UN1170	UN1170	UN1170	UN1170	UN1170
UN proper shipping name	Ethyl alcohol solution	Ethyl alcohol solution	Ethyl alcohol solution	Ethyl alcohol solution	Ethyl alcohol solution
Transport hazard class(es)	3 	3 	3 	3 	3 
Packing group	II	II	II	II	II
Environmental hazards	No.	No.	No.	No.	No.

Section 14. Transport information

Additional information

- DOT Classification** : **Packaging instruction** Exceptions: 4b, 150. Non-bulk: 202. Bulk: 242.
Special provisions 24, IB2, T4, TP1
- TDG Classification** : Product classified as per the following sections of the Transportation of Dangerous Goods Regulations: 2.18-2.19 (Class 3).
- IMDG** : **Emergency schedules** F-E, S-D

Special precautions for user : READ INSTRUCTIONS BEFORE USING
Do not handle until all safety precautions have been read and understood.

Transport in bulk according to IMO instruments : Not available.

Section 15. Regulatory information

U.S. Federal regulations : **TSCA 8(a) CDR Exempt/Partial exemption**: Not determined

Clean Air Act Section 112 (b) Hazardous Air Pollutants (HAPs) : Not listed

Clean Air Act Section 602 Class I Substances : Not listed

Clean Air Act Section 602 Class II Substances : Not listed

DEA List I Chemicals (Precursor Chemicals) : Not listed

DEA List II Chemicals (Essential Chemicals) : Not listed

SARA 302/304

Composition/information on ingredients

No products were found.

SARA 304 RQ : Not applicable.

SARA 311/312

Classification : FLAMMABLE LIQUIDS - Category 2
ACUTE TOXICITY (dermal) - Category 4
EYE IRRITATION - Category 2A
TOXIC TO REPRODUCTION - Category 2
TOXIC TO REPRODUCTION - Effects on or via lactation
SPECIFIC TARGET ORGAN TOXICITY (SINGLE EXPOSURE) (Narcotic effects) - Category 3

Composition/information on ingredients


Name	%	Classification
Ethanol	≥90	FLAMMABLE LIQUIDS - Category 2 EYE IRRITATION - Category 2A CARCINOGENICITY - Category 1A
[5α,7α(S)]-α-tert-butyl-11-(cyclopropylmethyl)-4,5-epoxy-18,19-dihydro-3-hydroxy-6-methoxy-α-methyl-6,14-ethenomorphinan-7-methanol hydrochloride	≤3	TOXIC TO REPRODUCTION - Category 2 TOXIC TO REPRODUCTION - Effects on or via lactation


State regulations

Massachusetts : The following components are listed: ETHYL ALCOHOL; ETHANOL; DENATURED ALCOHOL

New York : None of the components are listed.

Section 15. Regulatory information

- New Jersey** : The following components are listed: ETHYL ALCOHOL; METHYLCARBINOL; ETHANOL; ALCOHOL
- Pennsylvania** :  The following components are listed: ETHANOL; DENATURED ALCOHOL
- California Prop. 65**

 **WARNING:** This product can expose you to Butylated hydroxyanisole, which is known to the State of California to cause cancer. For more information go to www.P65Warnings.ca.gov.

Ingredient name	No significant risk level	Maximum acceptable dosage level
Butylated hydroxyanisole	Yes.	-

Inventory list

- United States** : Not determined.

Section 16. Other information

History

- Date of issue/Date of revision** : 4/6/2022
- Date of previous issue** : 4/23/2021
- Version** : 0.04
- Key to abbreviations** : ATE = Acute Toxicity Estimate
BCF = Bioconcentration Factor
GHS = Globally Harmonized System of Classification and Labelling of Chemicals
IATA = International Air Transport Association
IBC = Intermediate Bulk Container
IMDG = International Maritime Dangerous Goods
LogPow = logarithm of the octanol/water partition coefficient
MARPOL = International Convention for the Prevention of Pollution From Ships, 1973 as modified by the Protocol of 1978. ("Marpol" = marine pollution)
N/A = Not available
SGG = Segregation Group
UN = United Nations

- References** : Not available.

 Indicates information that has changed from previously issued version.

Notice to reader

As of the date of issuance, we are providing available information relevant to the handling of this material in the workplace. All information contained herein is offered with the good faith belief that it is accurate. THIS SAFETY DATA SHEET SHALL NOT BE DEEMED TO CREATE ANY WARRANTY OF ANY KIND (INCLUDING WARRANTY OF MERCHANT ABILITY OR FITNESS FOR A PARTICULAR PURPOSE). In the event of an adverse incident associated with this material, this safety data sheet is not intended to be a substitute for consultation with appropriately trained personnel. Nor is this safety data sheet intended to be a substitute for product literature which may accompany the finished product.

For additional information contact:

Elanco Animal Health
0011+1-877-352-6261
0011+1-800-428-4441