

SAFETY DATA SHEET



1. Identification

Product identifier	Butorphanol Tartrate Tablets
Other means of identification	
Synonyms	Torbutrol® * Torbutrol Tablets
Recommended use	Veterinary product used as opioid analgesic
Recommended restrictions	Not for human use
Manufacturer/Importer/Supplier/Distributor information	
Company Name (USA)	Zoetis Inc. 10 Sylvan Way Parsippany, New Jersey 07054 (USA)
Rocky Mountain Poison and Drug Center	1-866-531-8896
Product Support/Technical Services	1-800-366-5288
Emergency telephone numbers	CHEMTREC (24 hours): 1-800-424-9300 International CHEMTREC (24 hours): +1-703-527-3887
Company Name (CA)	Zoetis Canada Inc. 16740 Trans-Canada Highway Kirkland, Quebec, H9H 4M7
Emergency telephone number	International CHEMTREC (24 hours): +1-703-527-3887
Contact E-Mail	productsupport@zoetis.com
Product Support	1-800-461-0917

All Safety Data Sheets are available via our Zoetis Canada website at <https://www.zoetis.ca/sds/sds.aspx>

Supplier Not available.

2. Hazard(s) identification

Physical hazards	Not classified.	
Health hazards	Reproductive toxicity	Category 1B
	Reproductive toxicity	Effects on or via lactation
Environmental hazards	Not classified.	

Label elements



Signal word	Danger
Hazard statement	May damage fertility or the unborn child. May cause harm to breast-fed children.
Precautionary statement	
Prevention	Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Avoid contact during pregnancy and while nursing. Wash thoroughly after handling. Do not eat, drink or smoke when using this product. Wear protective gloves/protective clothing/eye protection/face protection.
Response	IF exposed or concerned: Get medical advice/attention.
Storage	Store locked up.

Disposal	Dispose of contents/container in accordance with local/regional/national/international regulations.
Other hazards	None known.
Supplemental information	Opioid analgesic.

3. Composition/information on ingredients

Mixtures

Chemical name	Common name and synonyms	CAS number	%
Butorphanol Tartrate		58786-99-5	1, 5 or 10 mg***
Inert ingredients*		Mixture	

All concentrations are in percent by weight unless ingredient is a gas. Gas concentrations are in percent by volume.

Composition comments *** per tablet/capsule/lozenge/suppository
* Non-hazardous Ingredients

4. First-aid measures

Inhalation	Move to fresh air. For breathing difficulties, oxygen may be necessary. Call a physician or poison control centre immediately.
Skin contact	Wash off with soap and water. Get medical attention if irritation develops and persists. Wash contaminated clothing before reuse.
Eye contact	Do not rub eyes. Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Continue rinsing. Get medical attention immediately.
Ingestion	IF SWALLOWED: Immediately call a POISON CENTRE or doctor/physician. Rinse mouth. Do not induce vomiting without advice from poison control center. Never give anything by mouth to a victim who is unconscious or is having convulsions.
Most important symptoms/effects, acute and delayed	opioid analgesic: Ingestion of this material may cause effects similar to those seen in clinical use including dry mouth, drowsiness, headache, dizziness, nausea, vomiting, weakness, anxiety, and dilated pupils. Cases of severe overdose may lead to respiratory depression, hypotension, coma, convulsions, cardiac arrhythmia, and tachycardia.
Indication of immediate medical attention and special treatment needed	opioid analgesic. Provide general supportive measures and treat symptomatically. Monitor respiratory, cardiac and central nervous system.
General information	IF exposed or concerned: Get medical advice/attention. Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves. Show this safety data sheet to the doctor in attendance.

5. Fire-fighting measures

Suitable extinguishing media	Water fog. Foam. Dry chemical powder. Carbon dioxide (CO ₂).
Unsuitable extinguishing media	Do not use water jet as an extinguisher, as this will spread the fire.
Specific hazards arising from the chemical	During fire, gases hazardous to health may be formed.
Special protective equipment and precautions for firefighters	Self-contained breathing apparatus and full protective clothing must be worn in case of fire.
Fire fighting equipment/instructions	Use water spray to cool unopened containers.
Specific methods	Use standard firefighting procedures and consider the hazards of other involved materials.
General fire hazards	No unusual fire or explosion hazards noted.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures	Keep unnecessary personnel away. Ensure adequate ventilation. Wear appropriate protective equipment and clothing during clean-up. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Avoid the generation of dusts during clean-up. Avoid inhalation of dust. Avoid contact with eyes, skin, and clothing. Local authorities should be advised if significant spillages cannot be contained. For personal protection, see section 8 of the SDS.
--	--

Methods and materials for containment and cleaning up Ensure adequate ventilation. Remove sources of ignition.
Large Spills: Stop the flow of material, if this is without risk. Absorb in vermiculite, dry sand or earth and place into containers. Following product recovery, flush area with water.
Small Spills: Wipe up with absorbent material (e.g. cloth, fleece). Clean surface thoroughly to remove residual contamination.

Environmental precautions

Never return spills to original containers for re-use. For waste disposal, see section 13 of the SDS. Avoid discharge into drains, water courses or onto the ground.

7. Handling and storage

Precautions for safe handling

Avoid contact with eyes, skin, and clothing. If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes. Avoid prolonged exposure. Minimise dust generation and accumulation. When using, do not eat, drink or smoke. Wash thoroughly after handling. Wear appropriate personal protective equipment. Avoid release to the environment.

Conditions for safe storage, including any incompatibilities

Store locked up. Keep tightly closed in a dry, cool and well-ventilated place. @ 15-30°C (59-86°F). Keep away from heat and sources of ignition. Store away from incompatible materials (see Section 10 of the SDS). Keep out of the reach of children.

8. Exposure controls/personal protection

Occupational exposure limits

No exposure limits noted for ingredient(s).

Biological limit values

No biological exposure limits noted for the ingredient(s).

Control banding approach

Butorphanol tartrate - Zoetis OEB 4 (control exposure to the range of 1ug/m3 to <10ug/m3)

Appropriate engineering controls

Ensure adequate ventilation, especially in confined areas. Keep air contamination levels below the exposure limits or within the OEB range listed above in this section. General ventilation normally adequate. Provide eyewash station.

Individual protection measures, such as personal protective equipment

Eye/face protection

If contact is likely, safety glasses with side shields are recommended.

Skin protection

Hand protection

Wear appropriate chemical resistant gloves. Impervious gloves.

Other

Wear appropriate chemical resistant clothing. Use protective clothing (uniforms, lab coats, disposable coveralls, etc.) in both production and laboratory areas.

Respiratory protection

No personal respiratory protective equipment normally required. In case of insufficient ventilation, wear suitable respiratory equipment. If airborne exposures are within or exceed the Occupational Exposure Band (OEB) range, wear an appropriate respirator with a protection factor sufficient to control exposures to the bottom of the OEB range. Chemical respirator with organic vapour cartridge, full facepiece, dust and mist filter.

Thermal hazards

Not applicable.

General hygiene considerations

Observe any medical surveillance requirements. When using, do not eat, drink or smoke. Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants.

9. Physical and chemical properties

Appearance

tablet

Physical state

Solid.

Form

Solid.

Colour

Not available.

Odour

Not available.

Odour threshold

Not available.

pH

Not available.

Melting point/freezing point

Not available.

Initial boiling point and boiling range

Not available.

Flash point

Not available.

Evaporation rate

Not available.

Flammability (solid, gas)

Not available.

Upper/lower flammability or explosive limits

Flammability limit - lower (%)	Not available.
Flammability limit - upper (%)	Not available.
Explosive limit - lower (%)	Not available.
Explosive limit – upper (%)	Not available.

Vapour pressure Not available.

Vapour density Not available.

Relative density Not available.

Solubility(ies)

Solubility (water) Not available.

Partition coefficient (n-octanol/water) Not available.

Auto-ignition temperature Not available.

Decomposition temperature Not available.

Viscosity Not available.

Other information

Explosive properties Not explosive.

Oxidising properties Not oxidising.

10. Stability and reactivity

Reactivity The product is stable and non-reactive under normal conditions of use, storage and transport.

Chemical stability Material is stable under normal conditions.

Possibility of hazardous reactions No dangerous reaction known under conditions of normal use.

Conditions to avoid Contact with incompatible materials. Sunlight. Keep away from heat, sparks and open flame.

Incompatible materials Strong oxidising agents.

Hazardous decomposition products No hazardous decomposition products are known. May include products of carbon, nitrogen.

11. Toxicological information

Information on likely routes of exposure

Inhalation No adverse effects due to inhalation are expected.

Skin contact No adverse effects due to skin contact are expected.

Eye contact Direct contact with eyes may cause temporary irritation.

Ingestion May be harmful if swallowed. However, ingestion is not likely to be a primary route of occupational exposure.

Symptoms related to the physical, chemical and toxicological characteristics Direct contact with eyes may cause temporary irritation. Exposure may cause temporary irritation, redness, or discomfort. Ingestion of this material may cause effects similar to those seen in clinical use including dry mouth, drowsiness, headache, dizziness, nausea, vomiting, weakness, anxiety, and dilated pupils. Cases of severe overdose may lead to respiratory depression, hypotension, coma, convulsions, cardiac arrhythmia, and tachycardia.

Information on toxicological effects

Acute toxicity Expected to be a low hazard for usual industrial or commercial handling by trained personnel. May be harmful if swallowed.

Product	Species	Test results
Butorphanol Tartrate Tablets		
<u>Acute</u>		
Oral		
LD50	Rat	> 3000 mg/kg (ATE)

Components	Species	Test results
Butorphanol Tartrate (CAS 58786-99-5)		
<u>Acute</u>		
Oral		
LD50	Rat	315 mg/kg
<u>Chronic</u>		
Oral		
NOAEL	Mouse	60 mg/kg/day, 2 years Not carcinogenic
	Rat	60 mg/kg/day, 2 years Not carcinogenic
Skin corrosion/irritation	Prolonged skin contact may cause temporary irritation.	
Serious eye damage/eye irritation	Direct contact with eyes may cause temporary irritation.	
Respiratory or skin sensitisation		
Respiratory sensitisation	Not a respiratory sensitizer.	
Skin sensitisation	This product is not expected to cause skin sensitisation.	
Germ cell mutagenicity	No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.	
Mutagenicity		
Butorphanol Tartrate		Bacterial Mutagenicity (Ames) Result: negative Species: Salmonella , E. coli
		Unscheduled DNA Synthesis, (human fibroblast cells) Result: negative Species: Human
Carcinogenicity	This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA.	
Reproductive toxicity	May cause harm to breastfed babies. May damage fertility or the unborn child.	
Developmental effects		
Butorphanol Tartrate		Embryo / Fetal Development, Not Teratogenic (dose not specified) Result: NOAEL Species: Rat Organ: Oral
Reproductivity		
Butorphanol Tartrate		1 mg/kg/day Reproductive & Fertility, Fetal mortality Result: LOAEL Species: Rat Organ: Subcutaneous
		2.5 mg/kg/day Reproductive & Fertility, Fertility Result: NOAEL Species: Rat Organ: Oral
Specific target organ toxicity - single exposure	Not classified.	
Specific target organ toxicity - repeated exposure	Not classified.	
Aspiration hazard	Not an aspiration hazard.	
Chronic effects	None expected under normal and foreseeable conditions of use	
Further information	Caution - Pharmaceutical agent. opioid analgesic.	
12. Ecological information		
Ecotoxicity	The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment. Avoid release to the environment.	
Persistence and degradability	No data is available on the degradability of this product.	

Bioaccumulative potential	No data available.
Mobility in soil	No data available.
Other adverse effects	No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component.

13. Disposal considerations

Disposal instructions	Avoid release to the environment. Do not discharge into drains, water courses or onto the ground. Do not allow this material to drain into sewers/water supplies. Do not contaminate ponds, waterways or ditches with chemical or used container. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater. Dispose of contents/container in accordance with local/regional/national/international regulations.
Local disposal regulations	Dispose in accordance with all applicable regulations.
Hazardous waste code	None known.
Waste from residues / unused products	Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).
Contaminated packaging	Since emptied containers may retain product residue, follow label warnings even after container is emptied.

14. Transport information

TDG	Not regulated as dangerous goods.
IATA	Not regulated as dangerous goods.
IMDG	Not regulated as dangerous goods.
Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code	Not applicable.

15. Regulatory information

Canadian regulations	This product has been classified in accordance with the hazard criteria of the HPR and the SDS contains all the information required by the HPR.
-----------------------------	--

Controlled Drugs and Substances Act

Butorphanol Tartrate (CAS 58786-99-5) 9

Export Control List (CEPA 1999, Schedule 3)

Not listed.

Greenhouse Gases

Not listed.

Narcotic Control Regulations (C.R.C., c. 1041) Controlled Drugs and Substances Act, as amended

Butorphanol Tartrate (CAS 58786-99-5)

Precursor Control Regulations

Not regulated.

International regulations

Stockholm Convention

Not applicable.

Rotterdam Convention

Not applicable.

Kyoto protocol

Not applicable.

Montreal Protocol

Not applicable.

Basel Convention

Not applicable.

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	No
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	No
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	No
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)

A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

16. Other information

Issue date 28-April-2017

Version No. 01

List of abbreviations ATE: Acute Toxicity Estimate according to REGULATION (EC) No 1272/2008 (CLP).

Disclaimer Zoetis Inc. believes that the information contained in this Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time. The information in the sheet was written based on the best knowledge and experience currently available.

Revision information Product and Company Identification: Synonyms
Composition / Information on Ingredients: Ingredients
Toxicological Information: Toxicological Data
GHS: Classification