

SAFETY DATA SHEETS

This SDS packet was issued with item:

078037082

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

078037090 078037108

SAFETY DATA SHEET



1. Identification

Product identifier	Butorphanol Tartrate Injection
Other means of identification	
Synonyms	Torbugesic® * Torbugesic® SA * Torbugesic injectable * Torbugesic-SA
Recommended use	Veterinary product used as opioid analgesic
Recommended restrictions	Not for human use
Manufacturer/Importer/Supplier/Distributor information	
Company Name (US)	Zoetis Inc. 10 Sylvan Way Parsippany, New Jersey 07054 (USA)
Rocky Mountain Poison and Drug Center	1-866-531-8896
Product Support/Technical Services	1-888-963-8471
Emergency telephone numbers	CHEMTREC (24 hours): 1-800-424-9300 International CHEMTREC (24 hours): +1-703-527-3887
Company Name (EU)	Zoetis Belgium S.A. Rue Laid Burniat 1 1348 Louvain-la-Neuve Belgium
Telephone:	+32 10 808080
Emergency telephone number	International CHEMTREC (24 hours): +1-703-527-3887
Contact E-Mail	VMIPSrecords@zoetis.com

2. Hazard(s) identification

Physical hazards	Not classified.	
Health hazards	Serious eye damage/eye irritation	Category 2A
	Reproductive toxicity	Category 1B
	Reproductive toxicity	Effects on or via lactation
Environmental hazards	Hazardous to the aquatic environment, acute hazard	Category 3
	Hazardous to the aquatic environment, long-term hazard	Category 3
OSHA defined hazards	Not classified.	
Label elements		



Signal word	Danger
Hazard statement	Causes serious eye irritation. 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. Do not breathe mist or vapor. Avoid contact during pregnancy/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. Avoid release to the environment.

Response	If exposed or concerned: Get medical advice/attention. If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.
Storage	Store locked up.
Disposal	Dispose of contents/container in accordance with local/regional/national/international regulations.
Hazard(s) not otherwise classified (HNOC)	None known.
Supplemental information	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.

3. Composition/information on ingredients

Mixtures

Chemical name	Common name and synonyms	CAS number	%
Benzethonium chloride		121-54-0	<5*
Butorphaol tartrate		58786-99-5	2 mg/ml, 10 mg/ml
Citric acid		77-92-9	<5*
Sodium chloride		7647-14-5	<5*
Water for injection		7732-18-5	

Composition comments	In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.
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4. First-aid measures

Inhalation	Move to fresh air. For breathing difficulties, oxygen may be necessary. Call a physician or poison control center 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 CENTER 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 (CO2).
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	Move containers from fire area if you can do so without risk.
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. Ventilate the contaminated area. Do not breathe mist or vapor. Avoid contact with eyes, skin, and clothing. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. For personal protection, see section 8 of the SDS. Local authorities should be advised if significant spillages cannot be contained.
Methods and materials for containment and cleaning up	Ensure adequate ventilation. Avoid release to the environment. Prevent entry into waterways, sewer, basements or confined areas. Large Spills: Stop the flow of material, if this is without risk. Dike the spilled material, where this is possible. Cover with plastic sheet to prevent spreading. Absorb in vermiculite, dry sand or earth and place into containers. Clean surface thoroughly to remove residual contamination. Small Spills: Wipe up with absorbent material (e.g. cloth, fleece). Clean surface thoroughly to remove residual contamination. 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.
Environmental precautions	

7. Handling and storage

Precautions for safe handling	Wear appropriate personal protective equipment. Provide adequate ventilation. Avoid breathing mist or vapor. Avoid contact with eyes, skin, and clothing. Avoid accidental injection. Avoid prolonged exposure. Wash thoroughly after handling. When using, do not eat, drink or smoke. Avoid release to the environment. Observe good industrial hygiene practices.
Conditions for safe storage, including any incompatibilities	Store locked up. Store in a well-ventilated place. @ 15-30°C (59-86°F).. Protect from sunlight. Use care in handling/storage. Keep out of the reach of children.

8. Exposure controls/personal protection

Occupational exposure limits	This mixture has no ingredients that have PEL, TLV, or other recommended exposure limit.
Biological limit values	No biological exposure limits noted for the ingredient(s).

Exposure guidelines

US - California OELs: Skin designation

Sodium chloride (CAS 7647-14-5) Can be absorbed through the skin.

US - Minnesota Haz Subs: Skin designation applies

Sodium chloride (CAS 7647-14-5) Skin designation applies.

US ACGIH Threshold Limit Values: Skin designation

Sodium chloride (CAS 7647-14-5) Danger of cutaneous absorption

US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000)

Sodium chloride (CAS 7647-14-5) Can be absorbed through the skin.

Control banding approach	Butorphanol tartrate - Zoetis OEB 4 (control exposure to the range of 1ug/m3 to <10ug/m3)
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Appropriate engineering controls	Ensure adequate ventilation, especially in confined areas. Good general ventilation (typically 10 air changes per hour) should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level. 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.
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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 vapor 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	Solution
Physical state	Liquid.
Form	Liquid.
Color	Clear, colorless
Odor	Not available.
Odor 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 applicable.
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.
Vapor pressure	Not available.
Vapor 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.
Oxidizing properties	Not oxidizing.

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.
Incompatible materials	Strong oxidizing agents.
Hazardous decomposition products	No hazardous decomposition products are known. May include products of carbon. nitrogen. May include hydrogen chloride.

11. Toxicological information**Information on likely routes of exposure**

Inhalation	Under normal conditions of intended use, this material is not expected to be an inhalation hazard.
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Skin contact	Causes mild skin irritation.	
Benzethonium chloride		Severity: Mild - Severe
Citric acid		Species: Rabbit Severity: Mild
Sodium chloride		Species: Rabbit Severity: Mild

Eye contact	Causes serious eye irritation.	
Sodium chloride		Species: Rabbit Severity: Moderate
Benzethonium chloride		Species: Rabbit Severity: Severe
Citric acid		Species: Rabbit Severity: Severe

Ingestion May cause discomfort if swallowed.

Symptoms related to the physical, chemical and toxicological characteristics 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.

Information on toxicological effects

Acute toxicity Not acutely toxic

Product	Species	Test Results
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Butorphanol Tartrate Injection

Acute

Oral

LD50	Rat	> 5000 mg/kg (Calculated ATE)
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Components	Species	Test Results
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Benzethonium chloride (CAS 121-54-0)

Acute

Intravenous

LD50	Rat	19 mg/kg
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Oral

LD50	Rat	368 mg/kg 295 mg/kg
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Subcutaneous

LD50	Rat	119 mg/kg
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Chronic

Dermal

Mouse	2 years Not carcinogenic
Rat	2 years Not carcinogenic

Butorphaol tartrate (CAS 58786-99-5)

Acute

Oral

LD50	Rat	315 mg/kg
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Chronic

Oral

NOAEL	Mouse	60 mg/kg/day, 2 years Not carcinogenic
	Rat	60 mg/kg/day, 2 years Not carcinogenic

Components	Species	Test Results
Citric acid (CAS 77-92-9)		
<u>Acute</u>		
Oral		
LD50	Rat	3000 mg/kg
Sodium chloride (CAS 7647-14-5)		
<u>Acute</u>		
Oral		
LD50	Mouse	4000 mg/kg
	Rat	3000 mg/kg
Skin corrosion/irritation	Prolonged skin contact may cause temporary irritation.	
<u>Corrosivity</u>		
Benzethonium chloride	Severity: Mild - Severe	
Serious eye damage/eye irritation	Causes serious eye irritation.	
<u>Eye Contact</u>		
Sodium chloride	Species: Rabbit Severity: Moderate	
Benzethonium chloride	Species: Rabbit Severity: Severe	
Citric acid	Species: Rabbit Severity: Severe	
Respiratory or skin sensitization		
Respiratory sensitization	Not a respiratory sensitizer.	
Skin sensitization	This product is not expected to cause skin sensitization.	
Germ cell mutagenicity	No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.	
<u>Mutagenicity</u>		
Benzethonium chloride	Ames (Salmonella) Result: Negative	
Butorphaol tartrate	Bacterial Mutagenicity (Ames) Result: Negative Species: Salmonella , E. coli	
Benzethonium chloride	In vitro chromosomal aberration Result: Negative	
	Sister Chromatid Exchange (SCE) Result: Negative	
Butorphaol tartrate	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.	
IARC Monographs. Overall Evaluation of Carcinogenicity		
Not listed.		
OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053)		
Not listed.		
US. National Toxicology Program (NTP) Report on Carcinogens		
Not listed.		
Reproductive toxicity	May cause harm to breastfed babies. May damage fertility or the unborn child.	

Developmental effects

Butorphaol tartrate

Embryo / Fetal Development, Not Teratogenic (dose not specified)

Result: NOAEL

Species: Rat

Organ: Oral

Reproductivity

Butorphaol 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 Prolonged inhalation may be harmful.

Further information Symptoms may be delayed.

12. Ecological information

Ecotoxicity Harmful to aquatic life with long lasting effects. Avoid release to the environment.

Components		Species	Test Results
Benzethonium chloride (CAS 121-54-0)			
Aquatic			
Algae	ErC50	Algae	0.3 mg/l, 72 hours
Crustacea	EC50	Daphnia magna (Water Flea)	0.22 mg/l, 48 hours
<i>Acute</i>			
Fish	LC50	Bluegill (Lepomis macrochirus)	1.4 mg/l, 96 hours
Sodium chloride (CAS 7647-14-5)			
Aquatic			
<i>Acute</i>			
Crustacea	EC50	Water flea (Daphnia magna)	340.7 - 469.2 mg/l, 48 hours
Fish	LC50	Rainbow trout,donaldson trout (Oncorhynchus mykiss)	4747 - 7824 mg/l, 96 hours

Persistence and degradability No data is available on the degradability of this product.

Biodegradability**Percent degradation (Aerobic biodegradation)**

Benzethonium chloride

0 % OECD 301B

Test Duration: 29 days

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. 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.
Contaminated packaging	Since emptied containers may retain product residue, follow label warnings even after container is emptied.

14. Transport information

DOT

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 established.

15. Regulatory information

US federal regulations This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.

U.S. Drug Enforcement Agency Controlled Drug Substance, Schedule II

Toxic Substances Control Act (TSCA)

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

CERCLA Hazardous Substance List (40 CFR 302.4)

Not listed.

SARA 304 Emergency release notification

Not regulated.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053)

Not listed.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

SARA 302 Extremely hazardous substance

Not listed.

SARA 311/312 Hazardous chemical Yes

Classified hazard categories Serious eye damage or eye irritation
Reproductive toxicity

SARA 313 (TRI reporting)

Not regulated.

Other federal regulations

Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List

Sodium chloride (CAS 7647-14-5)

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)

Not regulated.

Safe Drinking Water Act (SDWA) Not regulated.

US state regulations

California Proposition 65

California Safe Drinking Water and Toxic Enforcement Act of 2016 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins.

California Proposition 65 - CRT: Listed date/Male reproductive toxin

Sodium chloride (CAS 7647-14-5)

Listed: July 5, 2013

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Industrial Chemicals (AICIS)	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)	Yes
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	Yes
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
Taiwan	Taiwan Chemical Substance Inventory (TCSI)	Yes
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, including date of preparation or last revision

Issue date 12-17-2013

Revision date 01-17-2022

Version # 05

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
Identification: Recommended restrictions
Hazard(s) identification: Prevention
Hazard(s) identification: Supplemental information
Composition / Information on Ingredients: Disclosure Overrides
Accidental release measures: Methods and materials for containment and cleaning up
Handling and storage: Conditions for safe storage, including any incompatibilities
Toxicological Information: Toxicological Data
Toxicological information: Acute toxicity
Toxicological information: Further information
Toxicological information: Ingestion
Toxicological information: Symptoms related to the physical, chemical and toxicological characteristics
Ecological information: Ecotoxicity
Disposal considerations: Disposal instructions