

## **SAFETY DATA SHEETS**

**This SDS packet was issued with item:**

078037090

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

078037082 078037108

# SAFETY DATA SHEET



## 1. Identification

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

## 2. Hazard(s) identification

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



<b>Signal word</b>	Danger
<b>Hazard statement</b>	Causes serious eye irritation. May damage fertility or the unborn child. May cause harm to breast-fed children.
<b>Precautionary statement</b>	
<b>Prevention</b>	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.

<b>Response</b>	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.
<b>Storage</b>	Store locked up.
<b>Disposal</b>	Dispose of contents/container in accordance with local/regional/national/international regulations.
<b>Hazard(s) not otherwise classified (HNOC)</b>	None known.
<b>Supplemental information</b>	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.

### 4. First-aid measures

<b>Inhalation</b>	Move to fresh air. For breathing difficulties, oxygen may be necessary. Call a physician or poison control center immediately.
<b>Skin contact</b>	Wash off with soap and water. Get medical attention if irritation develops and persists. Wash contaminated clothing before reuse.
<b>Eye contact</b>	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.
<b>Ingestion</b>	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.
<b>Most important symptoms/effects, acute and delayed</b>	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.
<b>Indication of immediate medical attention and special treatment needed</b>	opioid analgesic. Provide general supportive measures and treat symptomatically. Monitor respiratory, cardiac and central nervous system.
<b>General information</b>	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

<b>Suitable extinguishing media</b>	Water fog. Foam. Dry chemical powder. Carbon dioxide (CO <sub>2</sub> ).
<b>Unsuitable extinguishing media</b>	Do not use water jet as an extinguisher, as this will spread the fire.
<b>Specific hazards arising from the chemical</b>	During fire, gases hazardous to health may be formed.
<b>Special protective equipment and precautions for firefighters</b>	Self-contained breathing apparatus and full protective clothing must be worn in case of fire.
<b>Fire fighting equipment/instructions</b>	Move containers from fire area if you can do so without risk.
<b>Specific methods</b>	Use standard firefighting procedures and consider the hazards of other involved materials.
<b>General fire hazards</b>	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)

**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.

**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**

<b>Appearance</b>	Solution
<b>Physical state</b>	Liquid.
<b>Form</b>	Liquid.
<b>Color</b>	Clear, colorless
<b>Odor</b>	Not available.
<b>Odor threshold</b>	Not available.
<b>pH</b>	Not available.
<b>Melting point/freezing point</b>	Not available.
<b>Initial boiling point and boiling range</b>	Not available.
<b>Flash point</b>	Not available.
<b>Evaporation rate</b>	Not available.
<b>Flammability (solid, gas)</b>	Not applicable.
<b>Upper/lower flammability or explosive limits</b>	
<b>Flammability limit - lower (%)</b>	Not available.
<b>Flammability limit - upper (%)</b>	Not available.
<b>Explosive limit - lower (%)</b>	Not available.
<b>Explosive limit - upper (%)</b>	Not available.
<b>Vapor pressure</b>	Not available.
<b>Vapor density</b>	Not available.
<b>Relative density</b>	Not available.
<b>Solubility(ies)</b>	
<b>Solubility (water)</b>	Not available.
<b>Partition coefficient (n-octanol/water)</b>	Not available.
<b>Auto-ignition temperature</b>	Not available.
<b>Decomposition temperature</b>	Not available.
<b>Viscosity</b>	Not available.
<b>Other information</b>	
<b>Explosive properties</b>	Not explosive.
<b>Oxidizing properties</b>	Not oxidizing.

**10. Stability and reactivity**

<b>Reactivity</b>	The product is stable and non-reactive under normal conditions of use, storage and transport.
<b>Chemical stability</b>	Material is stable under normal conditions.
<b>Possibility of hazardous reactions</b>	No dangerous reaction known under conditions of normal use.
<b>Conditions to avoid</b>	Contact with incompatible materials.
<b>Incompatible materials</b>	Strong oxidizing agents.
<b>Hazardous decomposition products</b>	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**

<b>Inhalation</b>	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)		
<b>Acute</b>		
<b>Oral</b>		
LD50	Rat	3000 mg/kg
Sodium chloride (CAS 7647-14-5)		
<b>Acute</b>		
<b>Oral</b>		
LD50	Mouse	4000 mg/kg
	Rat	3000 mg/kg
<b>Skin corrosion/irritation</b>	Prolonged skin contact may cause temporary irritation.	
<b>Corrosivity</b>		
Benzethonium chloride	Severity: Mild - Severe	
<b>Serious eye damage/eye irritation</b>	Causes serious eye irritation.	
<b>Eye Contact</b>		
Sodium chloride	Species: Rabbit Severity: Moderate	
Benzethonium chloride	Species: Rabbit Severity: Severe	
Citric acid	Species: Rabbit Severity: Severe	
<b>Respiratory or skin sensitization</b>		
<b>Respiratory sensitization</b>	Not a respiratory sensitizer.	
<b>Skin sensitization</b>	This product is not expected to cause skin sensitization.	
<b>Germ cell mutagenicity</b>	No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.	
<b>Mutagenicity</b>		
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	
<b>Carcinogenicity</b>	This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA.	
<b>IARC Monographs. Overall Evaluation of Carcinogenicity</b>		
Not listed.		
<b>OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053)</b>		
Not listed.		
<b>US. National Toxicology Program (NTP) Report on Carcinogens</b>		
Not listed.		
<b>Reproductive toxicity</b>	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 &amp; Fertility, Fetal mortality

Result: LOAEL

Species: Rat

Organ: Subcutaneous

2.5 mg/kg/day Reproductive &amp; 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)			
<b>Aquatic</b>			
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)			
<b>Aquatic</b>			
<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

<b>Disposal instructions</b>	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.
<b>Local disposal regulations</b>	Dispose in accordance with all applicable regulations.
<b>Hazardous waste code</b>	None known.
<b>Waste from residues / unused products</b>	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.
<b>Contaminated packaging</b>	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