

SAFETY DATA SHEET



1. Identification

Product identifier	Torbugesic Butorphanol Tartrate
Other means of identification	
Synonyms	Torbugesic® * Torbugesic® SA * Torbugesic injectable * Torbugesic-SA
Recommended use of the chemical and restrictions on use	
Recommended use	Veterinary product used as opioid analgesic
Restrictions on use	Not for human use
Details of manufacturer or importer	
Company Name (AU)	Zoetis Australia Pty Ltd ABN 94 156 476 425 Level 6, 5 Rider Boulevard Rhodes NSW 2138 AUSTRALIA
Tel	1800 814 883
Fax	(02) 8876 0444
Email	productsupport.au@zoetis.com
Emergency Phone	1800 814 883 (all hours)
Police and Fire Brigade	Dial 000
If ineffective	Dial Poisons Information Centre (13 1126 from anywhere in Australia)

2. Hazard(s) identification

Classification of the hazardous chemical

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

Label elements, including precautionary statements

Hazard symbol(s)



Health hazard

Exclamation mark

Signal word

Danger

Hazard statement(s)

Causes serious eye irritation. May damage fertility or the unborn child. May cause harm to breast-fed children. Harmful to aquatic life with long lasting effects.

Precautionary statement(s)

Prevention

Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Do not breathe mist or vapour. Avoid contact during pregnancy/while nursing. Wash thoroughly after handling. Do not eat, drink or smoke when using this product. Wear eye protection/face protection. Use personal protective equipment as required. 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.
Other hazards which do not result in classification	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

Mixture

Identity of chemical ingredients	CAS number and other unique identifiers	Concentration of ingredients (%)
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	*Designates that a specific chemical identity and/or percentage of composition has been withheld as a trade secret.
-----------------------------	---

4. First-aid measures

Description of necessary 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.

Personal protection for first-aid responders	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.
---	--

Symptoms caused by exposure	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.
------------------------------------	---

Medical attention and special treatment	opioid analgesic. Provide general supportive measures and treat symptomatically. Monitor respiratory, cardiac and central nervous system.
--	---

5. Fire-fighting measures

Extinguishing media

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 fire fighters	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.
---	---

Hazchem code	None.
---------------------	-------

General fire hazards	No unusual fire or explosion hazards noted.
-----------------------------	---

Specific methods Use standard firefighting procedures and consider the hazards of other involved materials.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

For non-emergency personnel Keep unnecessary personnel away.

For emergency responders Ensure adequate ventilation. Ventilate the contaminated area. Do not breathe mist or vapour. Avoid contact with eyes, skin, and clothing. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Use personal protection recommended in Section 8 of the SDS.

Environmental precautions Avoid discharge into drains, water courses or onto the ground.

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.

7. Handling and storage

Precautions for safe handling Wear appropriate personal protective equipment. Provide adequate ventilation. Avoid breathing mist or vapour. 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 and personal protection

Control parameters Follow standard monitoring procedures.

Occupational exposure limits

UK. EH40 Workplace Exposure Limits (WELs)

Components	Type	Value
Sodium chloride (CAS 7647-14-5)	TWA	5 mg/m ³

Germany. DFG MAK List (advisory OELs). Commission for the Investigation of Health Hazards of Chemical Compounds in the Work Area (DFG)

Components	Type	Value	Form
Citric acid (CAS 77-92-9)	TWA	2 mg/m ³	Inhalable fraction.

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

Exposure guidelines No exposure standards allocated.

US ACGIH Threshold Limit Values: Skin designation

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

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, for example personal protective equipment (PPE)

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.
Hygiene measures	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.
Colour	Clear, colorless
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 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.
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 physical and chemical parameters	
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.
Incompatible materials	Strong oxidising 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 possible routes of exposure

Inhalation Under normal conditions of intended use, this material is not expected to be an inhalation hazard.

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 exposure 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.

Acute toxicity Not acutely toxic

Product	Species	Test Results
Torbugesic Butorphanol Tartrate		
Acute		
Oral		
LD50	Rat	> 5000 mg/kg (Calculated ATE)
Components		
Benzethonium chloride (CAS 121-54-0)		
Acute		
Intravenous		
LD50	Rat	19 mg/kg
Oral		
LD50	Rat	368 mg/kg 295 mg/kg
Subcutaneous		
LD50	Rat	119 mg/kg
Chronic		
Dermal		
	Mouse	2 years Not carcinogenic
	Rat	2 years Not carcinogenic

Components	Species	Test Results
Butorphaol tartrate (CAS 58786-99-5)		
Acute		
Oral		
LD50	Rat	315 mg/kg
Chronic		
Oral		
NOAEL	Mouse	60 mg/kg/day, 2 years Not carcinogenic
	Rat	60 mg/kg/day, 2 years Not carcinogenic
Citric acid (CAS 77-92-9)		
Acute		
Oral		
LD50	Rat	3000 mg/kg
Sodium chloride (CAS 7647-14-5)		
Acute		
Oral		
LD50	Mouse	4000 mg/kg
	Rat	3000 mg/kg
Skin corrosion/irritation	Prolonged skin contact may cause temporary irritation.	
Corrosivity		
Benzethonium chloride	Severity: Mild - Severe	
Serious eye damage/irritation	Causes serious eye irritation.	
Eye contact		
Sodium chloride	Species: Rabbit Severity: Moderate	
Benzethonium chloride	Species: Rabbit Severity: Severe	
Citric acid	Species: Rabbit Severity: Severe	
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		
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	Due to partial or complete lack of data the classification is not possible.	
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.**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*Acute*

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 for this product.**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 methods**

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.

Residual waste 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

ADG

Not regulated as dangerous goods.

RID

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

Safety, health and environmental regulations

National regulations This Safety Data Sheet was prepared in accordance with Australia Model Code of Practice for the preparation of Safety Data Sheets for Hazardous Chemicals (23/12/2011).

APVMA No. 50128

Poison Schedule (Product) – Schedule 8

Australia Medicines & Poisons Appendix A

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix B

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix D

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix E

Sodium chloride (CAS 7647-14-5)

Australia Medicines & Poisons Appendix F

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix G

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix H

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix I

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix J

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix K

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 10

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 2

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 3

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 4

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 5

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 6

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 7

Sodium chloride (CAS 7647-14-5)

Australia Medicines & Poisons Schedule 8

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 9

Poisons schedule number not allocated.

High Volume Industrial Chemicals (HVIC)

Citric acid (CAS 77-92-9)

1000 - 9999 TONNES See the regulation for additional information.

Sodium chloride (CAS 7647-14-5)

100000 - 999999 TONNES See the regulation for additional information.

Water for injection (CAS 7732-18-5)

1000 - 9999 TONNES See the regulation for additional information.

Importation of Ozone Depleting Substances (Customs(Prohibited imports) Regulations 1956, Schedule 10)

Not listed.

National Pollutant Inventory (NPI) substance reporting list

Not listed.

Prohibited Carcinogenic Substances

Not regulated.

Prohibited Substances (National Model Regulation for the control of Workplace Hazardous Substances, Schedule 2 NOHSC:1005 (1994) as amended)

Not listed.

Restricted Importation of Organochlorine Chemicals (Customs(Prohibited Imports) Regulations 1956, Schedule 9)

Not listed.

Restricted Carcinogenic Substances

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 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

Issue date	30-October-2016
Revision date	23-November-2021
Key abbreviations or acronyms used	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	This document has undergone significant changes and should be reviewed in its entirety.