SAFETY DATA SHEET

1. Identification

Product identifier: Butorphanol Tartrate Injection

Other means of identification:
- TORBUGESIC®
- TORBUGESIC® SA
- Torbugesic injectable
- Torbugesic-SA

Synonyms: Veterinary product used as opioid analgesic

Recommended use: Not for human use

Recommended restrictions: Not for human use

Manufacturer/Importer/Supplier/Distributor information

Manufacturer:
- 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: 1-800-366-5288
- Emergency telephone numbers: CHEMTREC (24 hours): 1-800-424-9300
- Contact E-Mail: VMIPSrecords@zoetis.com

Company Name (EU):
- Zoetis Belgium S.A.
  Mercuriusstraat 20
  1930 Zaventem
  Belgium

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:
- Acute toxicity, dermal: Category 3
- Serious eye damage/eye irritation: Category 2A
- Reproductive toxicity: Category 1B
- Reproductive toxicity: Effects on or via lactation

Environmental hazards: Not classified.

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.
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

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Common name and synonyms</th>
<th>CAS number</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Benzethonium chloride</td>
<td></td>
<td>121-54-0</td>
<td>&lt;5*</td>
</tr>
<tr>
<td>Butorphanol Tartrate</td>
<td></td>
<td>58786-99-5</td>
<td>2 mg/ml, 10 mg/ml</td>
</tr>
<tr>
<td>Citric acid</td>
<td></td>
<td>77-92-9</td>
<td>&lt;5*</td>
</tr>
<tr>
<td>Sodium chloride</td>
<td></td>
<td>7647-14-5</td>
<td>&lt;5*</td>
</tr>
<tr>
<td>Water for injection</td>
<td></td>
<td>7732-18-5</td>
<td></td>
</tr>
</tbody>
</table>

Composition comments
*Designates that a specific chemical identity and/or percentage of composition has been withheld as a trade secret. 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

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. 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.

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. @ 20 - 25C / 68 - 77F. Protect from sunlight. Use care in handling/storage. Store away from incompatible materials (see Section 10 of the SDS).

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. 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

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.
Skin contact: Causes mild skin irritation.
- Benzethonium chloride Species: Rabbit Severity: Mild
- Citric acid Species: Rabbit Severity: Mild
- Sodium chloride Species: Rabbit Severity: Mild
Eye contact: Causes serious eye irritation.
Eye contact
Sodium chloride Species: Rabbit
Severity: Moderate
Benzethonium chloride Species: Rabbit
Severity: Severe
Citric acid Species: Rabbit
Severity: Severe

Ingestion
Health injuries are not known or expected under normal use.

Symptoms related to the physical, chemical and toxicological characteristics
Mild skin irritation. Severe eye irritation. Symptoms may include stinging, tearing, redness, swelling, and blurred vision. 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

<table>
<thead>
<tr>
<th>Product</th>
<th>Species</th>
<th>Test Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Butorphanol Tartrate Injection</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Acute</td>
<td>Oral</td>
<td>LD50</td>
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</table>

Components

<table>
<thead>
<tr>
<th>Product</th>
<th>Species</th>
<th>Test Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Benzethonium chloride (CAS 121-54-0)</td>
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<td></td>
</tr>
<tr>
<td>Acute</td>
<td>Intravenous</td>
<td>LD50</td>
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<tr>
<td>Oral</td>
<td>LD50</td>
<td>Rat</td>
</tr>
<tr>
<td>Subcutaneous</td>
<td>LD50</td>
<td>Rat</td>
</tr>
<tr>
<td>Butorphanol Tartrate (CAS 58786-99-5)</td>
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<td></td>
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<tr>
<td>Acute</td>
<td>Oral</td>
<td>LD50</td>
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<tr>
<td>Chronic</td>
<td>Oral</td>
<td>NOAEL</td>
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<td></td>
<td></td>
<td>Rat</td>
</tr>
<tr>
<td>Citric acid (CAS 77-92-9)</td>
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<td></td>
</tr>
<tr>
<td>Acute</td>
<td>Oral</td>
<td>LD50</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Rat</td>
</tr>
<tr>
<td>Sodium chloride (CAS 7647-14-5)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Acute</td>
<td>Oral</td>
<td>LD50</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Rat</td>
</tr>
</tbody>
</table>

Skin corrosion/irritation
Prolonged skin contact may cause temporary irritation.

Serious eye damage/eye 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 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.

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.

IARC Monographs. Overall Evaluation of Carcinogenicity
Not available.
OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)
Not listed.
US. National Toxicology Program (NTP) Report on Carcinogens
Not available.

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
Prolonged inhalation may be harmful.

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.
Components Test Results Species

Benzethonium chloride (CAS 121-54-0)

Aquatic

Fish LC50 Bluegill (Lepomis macrochirus) 1.4 mg/l, 96 hours

Sodium chloride (CAS 7647-14-5)

Aquatic

Crustacea EC50 Water flea (Daphnia magna) 340.7 - 469.2 mg/l, 48 hours

Fish LC50 Fathead minnow (Pimephales promelas) 6020 - 7070 mg/l, 96 hours

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. Empty containers should be taken to an approved waste handling site for recycling or disposal.

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

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.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories
- Immediate Hazard - Yes
- Delayed Hazard - Yes
- Fire Hazard - No
- Pressure Hazard - No
- Reactivity Hazard - No

SARA 302 Extremely hazardous substance
Not listed.

SARA 311/312 Hazardous chemical
No

SARA 313 (TRI reporting)
Not regulated.

Other federal regulations
- Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List
  Not regulated.
- 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
- US. California Controlled Substances. CA Department of Justice (California Health and Safety Code Section 11100)
  Not listed.
- US. Massachusetts RTK - Substance List
  Not regulated.
- US. New Jersey Worker and Community Right-to-Know Act
  Not listed.
- US. Pennsylvania Worker and Community Right-to-Know Law
  Not listed.
- US. Rhode Island RTK
  Not regulated.
- US. California Proposition 65
  California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins.

International Inventories

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

*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 10-30-2016
Version # 03
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
This document has undergone significant changes and should be reviewed in its entirety.