

SAFETY DATA SHEET



1. Identification

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| Product identifier | Butorphanol Tartrate Tablets |
| Other means of identification | |
| Synonyms | Torbutrol® * Torbutrol Tablets |
| Recommended use | Veterinary product used as opioid analgesic |
| Recommended restrictions | Not for human use |
| Manufacturer/Importer/Supplier/Distributor information | |
| Company Name (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 International CHEMTREC (24 hours): +1-703-527-3887 |
| 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

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|------------------------------|-----------------------|-----------------------------|
| Physical hazards | Not classified. | |
| Health hazards | Reproductive toxicity | Category 1B |
| | Reproductive toxicity | Effects on or via lactation |
| Environmental hazards | Not classified. | |
| OSHA defined hazards | Not classified. | |
| Label elements | | |



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| Signal word | Danger |
| Hazard statement | May damage fertility or the unborn child. May cause harm to breast-fed children. |
| Precautionary statement | |
| Prevention | Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Avoid contact during pregnancy/while nursing. Wash thoroughly after handling. Do not eat, drink or smoke when using this product. Wear protective gloves/protective clothing/eye protection/face protection. |
| Response | If exposed or concerned: Get medical advice/attention. |
| Storage | Store locked up. |
| Disposal | Dispose of contents/container in accordance with local/regional/national/international regulations. |
| Hazard(s) not otherwise classified (HNOC) | None known. |
| Supplemental information | Opioid analgesic. |

3. Composition/information on ingredients

Mixtures

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

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

4. First-aid measures

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| 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

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

6. Accidental release measures

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| Personal precautions, protective equipment and emergency procedures | Keep unnecessary personnel away. Ensure adequate ventilation. Wear appropriate protective equipment and clothing during clean-up. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Avoid the generation of dusts during clean-up. Avoid inhalation of dust. Avoid contact with eyes, skin, and clothing. Local authorities should be advised if significant spillages cannot be contained. For personal protection, see section 8 of the SDS. |
| Methods and materials for containment and cleaning up | Ensure adequate ventilation. Remove sources of ignition. Large Spills: Stop the flow of material, if this is without risk. Absorb in vermiculite, dry sand or earth and place into containers. Following product recovery, flush area with water. Small Spills: Wipe up with absorbent material (e.g. cloth, fleece). Clean surface thoroughly to remove residual contamination. Never return spills to original containers for re-use. For waste disposal, see section 13 of the SDS. |
| Environmental precautions | Avoid discharge into drains, water courses or onto the ground. |

7. Handling and storage

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| Precautions for safe handling | Avoid contact with eyes, skin, and clothing. If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes. Avoid prolonged exposure. Minimize dust generation and accumulation. When using, do not eat, drink or smoke. Wash thoroughly after handling. Wear appropriate personal protective equipment. Avoid release to the environment. |
| Conditions for safe storage, including any incompatibilities | Store locked up. Keep tightly closed in a dry, cool and well-ventilated place. @ 15-30°C (59-86°F). Keep away from heat and sources of ignition. Store away from incompatible materials (see Section 10 of the SDS). Keep out of the reach of children. |

8. Exposure controls/personal protection

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| 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). |
| Control banding approach | Butorphanol tartrate - Zoetis OEB 4 (control exposure to the range of 1ug/m3 to <10ug/m3) |
| Appropriate engineering controls | Ensure adequate ventilation, especially in confined areas. Keep air contamination levels below the exposure limits or within the OEB range listed above in this section. General ventilation normally adequate. Provide eyewash station. |
| Individual protection measures, such as personal protective equipment | |
| Eye/face protection | If contact is likely, safety glasses with side shields are recommended. |
| Skin protection | |
| Hand protection | Wear appropriate chemical resistant gloves. Impervious gloves. |
| Other | Wear appropriate chemical resistant clothing. Use protective clothing (uniforms, lab coats, disposable coveralls, etc.) in both production and laboratory areas. |
| Respiratory protection | No personal respiratory protective equipment normally required. In case of insufficient ventilation, wear suitable respiratory equipment. If airborne exposures are within or exceed the Occupational Exposure Band (OEB) range, wear an appropriate respirator with a protection factor sufficient to control exposures to the bottom of the OEB range. Chemical respirator with organic 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

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| Appearance | Tablet |
| Physical state | Solid. |
| Form | Solid. |
| Color | Not available. |
| 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 available. |
| Upper/lower flammability or explosive limits | |
| Flammability limit - lower (%) | Not available. |
| Flammability limit - upper (%) | Not available. |
| Explosive limit - lower (%) | Not available. |
| Explosive limit - upper (%) | Not available. |
| Vapor pressure | Not available. |

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| 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

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| Reactivity | The product is stable and non-reactive under normal conditions of use, storage and transport. |
| Chemical stability | Material is stable under normal conditions. |
| Possibility of hazardous reactions | No dangerous reaction known under conditions of normal use. |
| Conditions to avoid | Contact with incompatible materials. Sunlight. Keep away from heat, sparks and open flame. |
| Incompatible materials | Strong oxidizing agents. |
| Hazardous decomposition products | No hazardous decomposition products are known. May include products of carbon, nitrogen. |

11. Toxicological information

Information on likely routes of exposure

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| Inhalation | No adverse effects due to inhalation are expected. |
| Skin contact | No adverse effects due to skin contact are expected. |
| Eye contact | Direct contact with eyes may cause temporary irritation. |
| Ingestion | May be harmful if swallowed. However, ingestion is not likely to be a primary route of occupational exposure. |

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

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| Acute toxicity | Expected to be a low hazard for usual industrial or commercial handling by trained personnel. May be harmful if swallowed. |
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| Product | Species | Test Results |
|---------------------------------------|--|--|
| Butorphanol Tartrate Tablets | | |
| Acute | | |
| Oral | | |
| LD50 | Rat | > 3000 mg/kg (ATE) |
| Components | | |
| Species | | |
| Test Results | | |
| Butorphanol 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 |
| Skin corrosion/irritation | Prolonged skin contact may cause temporary irritation. | |

Serious eye damage/eye irritation Direct contact with eyes may cause temporary irritation.

Respiratory or skin 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 listed.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not regulated.

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
Butorphanol Tartrate

Embryo / Fetal Development, Not Teratogenic (dose not specified)
Result: NOAEL
Species: Rat
Organ: Oral

Reproductivity
Butorphanol Tartrate

1 mg/kg/day Reproductive & Fertility, Fetal mortality
Result: LOAEL
Species: Rat
Organ: Subcutaneous

2.5 mg/kg/day Reproductive & Fertility, Fertility
Result: NOAEL
Species: Rat
Organ: Oral

Specific target organ toxicity - single exposure Not classified.

Specific target organ toxicity - repeated exposure Not classified.

Aspiration hazard Not an aspiration hazard.

Chronic effects None expected under normal and foreseeable conditions of use

Further information Caution - Pharmaceutical agent. opioid analgesic.

12. Ecological information

Ecotoxicity The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment. Avoid release to the environment.

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

Bioaccumulative potential No data available.

Mobility in soil No data available.

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

13. Disposal considerations

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

14. Transport information

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| 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 applicable. |

15. Regulatory information

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| 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. |
| OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050) | Not regulated. |
| Superfund Amendments and Reauthorization Act of 1986 (SARA) | |
| Hazard categories | Immediate Hazard - No 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 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

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

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

16. Other information, including date of preparation or last revision

Issue date 12-17-2013

Revision date 04-28-2017

Version # 03

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

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Revision information This document has undergone significant changes and should be reviewed in its entirety.