



SAFETY DATA SHEET

Revision date: 03-Nov-2014

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1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND THE COMPANY/UNDERTAKING

Product Identifier

Material Name: Trimebutine Maleate Injectable Solution

Trade Name: Debridat®

Chemical Family: Mixture

Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

Intended Use: Pharmaceutical product used as antispasmodic and/or gastric motility regulator.

Details of the Supplier of the Safety Data Sheet

Pfizer Inc
Pfizer Pharmaceuticals Group
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New York, New York 10017
1-800-879-3477

Pfizer Ltd
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Emergency telephone number:

CHEMTREC (24 hours): 1-800-424-9300

Contact E-Mail: pfizer-MSDS@pfizer.com

2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture

GHS - Classification Not classified as hazardous

EU Classification:

EU Indication of danger: Not classified

Label Elements

Other Hazards

No data available

Australian Hazard Classification (NOHSC):

Non-Hazardous Substance. Non-Dangerous Goods.

Note:

This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warnings included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

3. COMPOSITION / INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	GHS Classification	%
Trimebutine maleate	34140-59-5	251-845-9	Not Listed	Not Listed	50 mg/5 mL

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3. COMPOSITION / INFORMATION ON INGREDIENTS

Benzyl Alcohol	100-51-6	202-859-9	Xn; R20/22	Acute Tox.4 (H302) Acute Tox.4 (H332)	*
BENZYL ALCOHOL	100-51-6	202-859-9	Xn; R20/22	Acute Tox. 4 (H302) Acute Tox. 4 (H332)	*

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	GHS Classification	%
Sodium chloride	7647-14-5	231-598-3	Not Listed	Not Listed	*
Water for injection	7732-18-5	231-791-2	Not Listed	Not Listed	*

Additional Information:

* Proprietary
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.
In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

For the full text of the R phrases and CLP/GHS abbreviations mentioned in this Section, see Section 16

4. FIRST AID MEASURES

Description of First Aid Measures

Eye Contact: Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.

Skin Contact: Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.

Ingestion: Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

Inhalation: Remove to fresh air and keep patient at rest. Seek medical attention immediately.

Most Important Symptoms and Effects, Both Acute and Delayed

Symptoms and Effects of Exposure: No data available

Medical Conditions Aggravated by Exposure: None known

Indication of the Immediate Medical Attention and Special Treatment Needed

Notes to Physician: None

5. FIRE FIGHTING MEASURES

Extinguishing Media: Use carbon dioxide, dry chemical, or water spray.

Special Hazards Arising from the Substance or Mixture

Hazardous Combustion Products: Formation of toxic gases is possible during heating or fire.

Fire / Explosion Hazards: Fine particles (such as dust and mists) may fuel fires/explosions.

Advice for Fire-Fighters

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Wear approved positive pressure, self-contained breathing apparatus and full protective turn out gear.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment and Emergency Procedures

Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

Environmental Precautions

Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

Methods and Material for Containment and Cleaning Up

Measures for Cleaning / Collecting: Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly.

Additional Consideration for Large Spills: Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

7. HANDLING AND STORAGE

Precautions for Safe Handling

Minimize generating airborne mists and vapors. Avoid contact with eyes, skin and clothing. Avoid breathing vapor or mist. When handling, use appropriate personal protective equipment (see Section 8). Wash thoroughly after handling. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

Conditions for Safe Storage, Including any Incompatibilities

Storage Conditions: Store as directed by product packaging.

Specific end use(s): Pharmaceutical drug product

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Control Parameters

Refer to available public information for specific member state Occupational Exposure Limits.

Sodium chloride

Latvia OEL - TWA	5 mg/m ³
Lithuania OEL - TWA	5 mg/m ³

Trimebutine maleate

Pfizer OEL TWA-8 Hr:	1000µg/m ³
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Benzyl Alcohol

Bulgaria OEL - TWA	5.0 mg/m ³
Czech Republic OEL - TWA	40 mg/m ³
Finland OEL - TWA	10 ppm
	45 mg/m ³
Latvia OEL - TWA	5 mg/m ³
Lithuania OEL - TWA	5 mg/m ³
Poland OEL - TWA	240 mg/m ³

BENZYL ALCOHOL

Bulgaria OEL - TWA	5.0 mg/m ³
Czech Republic OEL - TWA	40 mg/m ³

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Finland OEL - TWA	10 ppm 45 mg/m ³
Latvia OEL - TWA	5 mg/m ³
Lithuania OEL - TWA	5 mg/m ³
Poland OEL - TWA	240 mg/m ³

Exposure Controls

Engineering Controls: Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section.

Personal Protective Equipment: Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).

Hands: Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.

Eyes: Wear safety glasses or goggles if eye contact is possible.

Skin: Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.

Respiratory protection: If the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State:	Solution	Color:	Clear, colorless
Odor:	No data available.	Odor Threshold:	No data available.
Molecular Formula:	Mixture	Molecular Weight:	Mixture

Solvent Solubility:	No data available
Water Solubility:	No data available
pH:	3.5 - 4.5
Melting/Freezing Point (°C):	No data available
Boiling Point (°C):	No data available.

Partition Coefficient: (Method, pH, Endpoint, Value)

Trimebutine maleate

No data available

Sodium chloride

No data available

Water for injection

No data available

Benzyl Alcohol

No data available

Decomposition Temperature (°C): No data available.

Evaporation Rate (Gram/s):	No data available
Vapor Pressure (kPa):	No data available
Vapor Density (g/ml):	No data available
Relative Density:	No data available
Viscosity:	No data available

Flammability:

Autoignition Temperature (Solid) (°C):	No data available
Flammability (Solids):	No data available
Flash Point (Liquid) (°C):	No data available
Upper Explosive Limits (Liquid) (% by Vol.):	No data available

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Lower Explosive Limits (Liquid) (% by Vol.): No data available
Polymerization: Will not occur

10. STABILITY AND REACTIVITY

Reactivity: No data available
Chemical Stability: Stable under normal conditions of use.
Possibility of Hazardous Reactions
Oxidizing Properties: No data available
Conditions to Avoid: Fine particles (such as dust and mists) may fuel fires/explosions.
Incompatible Materials: As a precautionary measure, keep away from strong oxidizers
Hazardous Decomposition Products: None known

11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects

General Information: The information included in this section describes the potential hazards of the individual ingredients.
Short Term: May cause eye and skin irritation (based on components) The active ingredient is not acutely toxic. Accidental ingestion may cause effects similar to those seen in clinical use. Based on its pharmacologic properties, exposure to this compound may cause effects on the gastrointestinal system.
Known Clinical Effects: Adverse effects associated with therapeutic use of trimebutine are infrequent include skin rash, sleepiness, headache, vomiting, and dizziness

Acute Toxicity: (Species, Route, End Point, Dose)

Trimebutine maleate

Rat Oral LD50 > 5000 mg/kg
Mouse Oral LD50 3230mg/kg
Rat IP LD50 365mg/kg

Sodium chloride

Rat Oral LD50 3000 mg/kg
Mouse Oral LD50 4000 mg/kg

Benzyl Alcohol

Rat Oral LD50 1230 mg/kg
Rat Para-periosteal LD50 53mg/kg
Rat Inhalation LC50 >4.178mg/L

Acute Toxicity Comments: A greater than symbol (>) indicates that the toxicity endpoint being tested was not achievable at the highest dose used in the test.

Irritation / Sensitization: (Study Type, Species, Severity)

Sodium chloride

Eye Irritation Rabbit Moderate
Skin Irritation Rabbit Mild

Benzyl Alcohol

Eye Irritation Rabbit Severe

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11. TOXICOLOGICAL INFORMATION

Skin Irritation Rabbit Minimal
Skin Irritation Guinea Pig Moderate

Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))

Trimebutine maleate

Reproductive & Fertility Rat Oral 1000 mg/kg/day NOAEL No effects at maximum dose
Reproductive & Fertility Rabbit Oral 1000 mg/kg/day NOAEL No effects at maximum dose

Carcinogen Status: None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

12. ECOLOGICAL INFORMATION

Environmental Overview: The environmental characteristics of this material have not been fully evaluated. Releases to the environment should be avoided.

Toxicity: No data available

Benzyl Alcohol

Pimephales promelas (Fathead Minnow) EPA LC50 96 Hours 460 mg/L
Daphnia magna (Water Flea) OECD EC50 48 Hours 230 mg/L
Pseudokirchneriella subcapitata (Green Alga) OECD EC50 72 Hours 500 mg/L

Benzyl Alcohol

Daphnia magna (Water Flea) OECD 21 Day(s) EC50 66 mg/L Reproduction

Persistence and Degradability: No data available

Benzyl Alcohol

OECD Activated sludge Ready 92% After 14 Day(s) Ready

Bio-accumulative Potential: No data available

Mobility in Soil: No data available

13. DISPOSAL CONSIDERATIONS

Waste Treatment Methods: Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. 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.

14. TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.

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Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

15. REGULATORY INFORMATION

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

Canada - WHMIS: Classifications

WHMIS hazard class:

None required

This product has been classified in accordance with the hazard criteria of the CPR and the MSDS contains all of the information required by the CPR.

Sodium chloride

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	231-598-3

Trimebutine maleate

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Australia (AICS):	Present
EU EINECS/ELINCS List	251-845-9

Water for injection

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
REACH - Annex IV - Exemptions from the obligations of Register:	Present
EU EINECS/ELINCS List	231-791-2

Benzyl Alcohol

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	202-859-9

BENZYL ALCOHOL

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed

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15. REGULATORY INFORMATION

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	202-859-9

16. OTHER INFORMATION

Text of R phrases and GHS Classification abbreviations mentioned in Section 3

Acute toxicity, oral-Cat.4; H302 - Harmful if swallowed
Acute toxicity, inhalation-Cat.4; H332 - Harmful if inhaled

Xn - Harmful

R20/22 - Harmful by inhalation and if swallowed.

Data Sources: Pfizer proprietary drug development information. Publicly available toxicity information.

Reasons for Revision: Updated Section 2 - Hazard Identification. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 10 - Stability and Reactivity. Updated Section 11 - Toxicology Information. Updated Section 13 - Disposal Considerations. Updated Section 15 - Regulatory Information. Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking. Updated Section 3 - Composition / Information on Ingredients. Updated Section 16 - Other Information. Updated Section 7 - Handling and Storage. Updated Section 4 - First Aid Measures.

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Product Stewardship Hazard Communication

Prepared by: Pfizer Global Environment, Health, and Safety Operations

Pfizer Inc believes that the information contained in this Material 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.

End of Safety Data Sheet