



MATERIAL SAFETY DATA SHEET

Revision date: 19-Nov-2009

Version: 1.4

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

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Material Name: Tremelimumab (CP-675,206) IV Solution, 20mg/mL

Trade Name:	Not established
Compound Number:	CP-675,206
Chemical Family:	Mixture
Intended Use:	Pharmaceutical product used as Cancer immunotherapeutic agent

2. HAZARDS IDENTIFICATION

Appearance: Colorless to slightly yellow liquid

Statement of Hazard: Non-hazardous in accordance with international standards for workplace safety.

Additional Hazard Information:

Short Term:	Accidental ingestion may cause effects similar to those seen in clinical use. May cause hypersensitivity reactions in susceptible individuals.
Long Term:	Repeat-dose studies in animals have shown a potential to cause adverse effects on liver, gastrointestinal system and lymphatic system.

Known Clinical Effects: Adverse effects most commonly reported in clinical use include skin reaction, skin rash, itching sensation (pruritus), diarrhea, nausea, fatigue and immune-mediated disorders.

EU Indication of danger: Not classified

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 active substance or its intermediates 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	Classification	%
Tremelimumab	Proprietary	Not listed	Xn;R22	2.0%

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3. COMPOSITION/INFORMATION ON INGREDIENTS

L-Histidine	71-00-1	200-745-3	OEL	*
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Ingredient	CAS Number	EU EINECS/ELINCS List	Classification	%
Trehalose Dihydrate	6138-23-4	Not listed	Not Listed	*
L-Histidine HCl	1007-42-7	213-754-2	Not Listed	*
Polysorbate 80	9005-65-6	Not listed	Not Listed	*
Disodium EDTA (dihydrate)	6381-92-6	Not listed	Not Listed	*
Water for injection	7732-18-5	231-791-2	Not Listed	*

Additional Information: * Proprietary
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

4. 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.

5. FIRE FIGHTING MEASURES

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

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

Fire Fighting Procedures: During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

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

6. ACCIDENTAL RELEASE MEASURES

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

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.

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

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.

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7. HANDLING AND STORAGE

General Handling: Avoid open handling. Minimize generation of mists. Use local exhaust or perform work under hood/fume cupboard. Avoid inhalation and contact with skin, eyes, and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash hands and any exposed skin after removal of PPE. 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.

Storage Conditions: Store in a refrigerator. Do not freeze. Protect from light.

Storage Temperature: 2-8°C (36-46°F)

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

L-Histidine

Latvia OEL - TWA

Listed

Engineering Controls: Engineering controls should be used as the primary means to control exposures. Use process containment, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits.

Environmental Exposure Controls: Refer to specific Member State legislation for requirements under Community environmental legislation.

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

Hands: Wear impervious gloves if skin contact is possible.

Eyes: Safety glasses or goggles

Skin: Use protective clothing (uniforms, lab coats, disposable coveralls, etc.) in both production and laboratory areas.

Respiratory protection: Respiratory protection is recommended as a precaution to minimize exposure when handling this material in bulk.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State:	Liquid	Color:	Colorless to slightly yellow
Molecular Formula:	Mixture	Molecular Weight:	Mixture

10. STABILITY AND REACTIVITY

Stability: Stable under normal conditions of use.

Conditions to Avoid: None known

Incompatible Materials: As a precautionary measure, keep away from strong oxidizers

11. TOXICOLOGICAL INFORMATION

General Information: The information included in this section describes the potential hazards of the individual ingredients.

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11. TOXICOLOGICAL INFORMATION

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

Tremelimumab

Non-human Primate IV Maximally Tolerated Dose 100 mg/kg

Polysorbate 80

Rat Oral LD50 25 g/kg

L-Histidine

Rat Oral LD 50 > 15 g/kg

Rat Intravenous LD 50 > 2 g/kg

Mouse Oral LD 50 > 15 g/kg

Mouse Intravenous LD 50 > 2 g/kg

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.

Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)

Tremelimumab

6 Month(s) Monkey Intravenous 15 mg/kg/week Maximally Tolerated Dose Skin, Blood, Gastrointestinal System, Lymphatic system

1 Month(s) Monkey Intravenous 5 mg/kg/day NOEL Blood Gastrointestinal system Liver Lymphatic system

Trehalose Dihydrate

14 Day(s) Dog Oral 15 g/kg/day No effects at maximum dose

14 Day(s) Dog Intravenous 1 g/kg/day No effects at maximum dose

14 Day(s) Dog Subcutaneous 0.25 g/kg/day No effects at maximum dose

Reproduction & Development Toxicity: (Duration, Species, Route, Dose, End Point, Effect(s))

Tremelimumab

Embryo / Fetal Development Rat Intravenous 30 mg/kg/day NOEL 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 mixture have not been fully evaluated. Releases to the environment should be avoided.

13. DISPOSAL CONSIDERATIONS

Disposal Procedures:

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.

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14. TRANSPORT INFORMATION

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

15. REGULATORY INFORMATION

EU Symbol: Caution, substance not yet fully tested.
EU Indication of danger: Not classified

OSHA Label:
Non-hazardous in accordance with international standards for workplace safety.

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.

Trehalose Dihydrate

Australia (AICS): Listed

L-Histidine

Inventory - United States TSCA - Sect. 8(b) Listed

Australia (AICS): Listed

EU EINECS/ELINCS List 200-745-3

L-Histidine HCl

EU EINECS/ELINCS List 213-754-2

Polysorbate 80

Inventory - United States TSCA - Sect. 8(b) Listed

Australia (AICS): Listed

Disodium EDTA (dihydrate)

Australia (AICS): Listed

Water for injection

Inventory - United States TSCA - Sect. 8(b) Listed

Australia (AICS): Listed

REACH - Annex IV - Exemptions from the obligations of Register: Present

EU EINECS/ELINCS List 231-791-2

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16. OTHER INFORMATION

Data Sources: Pfizer proprietary drug development information. Safety data sheets for individual ingredients.

Reasons for Revision: Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking. Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 7 - Handling and Storage. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 9 - Physical and Chemical Properties.

Prepared by: Toxicology and Hazard Communication
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