



MATERIAL SAFETY DATA SHEET

Revision date: 31-May-2013

Version: 1.0

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

Product Identifier

Material Name: Oprelvekin

Trade Name: Not applicable

Synonyms: Recombinant Interleukin-11, Neumega, Recombinant IL-11

Chemical Family: Not determined

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

Intended Use: Pharmaceutical active

Details of the Supplier of the Safety Data Sheet

Pfizer Global Manufacturing

Pfizer Inc

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Pfizer Ltd

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2. HAZARDS IDENTIFICATION

Appearance: Clear, colorless, solution

Classification of the Substance or Mixture

GHS - Classification Not classified as hazardous

EU Classification:

Label Elements

Signal Word: Not Classified

Hazard Statements: Not classified in accordance with international standards for workplace safety.

Other Hazards

Known Clinical Effects:

Serious allergic reactions, including anaphylaxis, have been reported. Common adverse effects include effects on cardiovascular system, fluid retention, swelling of the face, changes in blood pressure, irregular heartbeat (cardiac arrhythmia), visual disturbances, decreased red blood cell count (anemia), stroke.

Australian Hazard Classification (NOHSC):

Non-Hazardous Substance. Non-Dangerous Goods.

Note:

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

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3. COMPOSITION / INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	GHS Classification	%
Oprelvekin	145941-26-0	Not Listed	Not Listed	Not Listed	100

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

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:** For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.
- Medical Conditions:** None known
- Aggravated by Exposure:**

Indication of the Immediate Medical Attention and Special Treatment Needed

- Notes to Physician:** None

5. FIRE FIGHTING MEASURES

Extinguishing Media: Extinguish fires with CO2, extinguishing powder, foam, or water.

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

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

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.

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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

Restrict access to work area. Avoid open handling. Ground and bond all bulk transfer equipment. Minimize generating airborne mists and vapors. Use appropriate engineering controls to maintain exposures below the B-OEB taking all applicable routes of exposure into consideration. Avoid inhalation and contact with skin, eye, and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash hands and any exposed skin after removal of PPE. A change area to facilitate 'good laboratory/manufacturing' decontamination practices is recommended. 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 at room temperature in properly labeled containers. Keep away from heat, sparks and flames.

Specific end use(s): No data available

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Control Parameters

The Biotherapeutic Occupational Exposure Band (B-OEB) is an acceptable daily intake (ADI) range, based on available hazard data with appropriate safety factors applied. Engineering control measures should be utilized to bring exposures into the relevant B-OEB; supplementary administrative controls and personal protective equipment are to be used to achieve exposure control to the bottom of the band.

Oprelvekin

Pfizer Occupational Exposure Band (OEB): B-OEB 4 (control exposure to the range of 10 µg/day to <100 µg/day)

Exposure Controls

Engineering Controls: Engineering controls should be used as the primary means to control exposures. Use process containment, local exhaust ventilation, biosafety cabinet, or other engineering controls to maintain airborne levels within the B-OEB range. It is recommended that all operations be fully enclosed and no air recirculated.

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

Hands: Wear impervious, disposable gloves as minimum protection (double recommended).

Eyes: Wear safety glasses as minimum protection.

Skin: Wear impervious protective clothing when handling this compound. Full body protection recommended (scale dependent).

Respiratory protection: If airborne exposures are within or exceed the Biotherapeutic Occupational Exposure Band (B-OEB) range, wear an appropriate respirator with a protection factor sufficient to control exposures to the bottom of the B-OEB range.

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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:	6.8-7.2
Melting/Freezing Point (°C):	No data available
Boiling Point (°C):	No data available.

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

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No data available

Decomposition Temperature (°C):	No data available.
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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
Lower Explosive Limits (Liquid) (% by Vol.):	No data available

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:	No data available

11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects

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

Oprelvekin

Rat	Intravenous	Minimum Lethal Dose	> 10 mg/kg
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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)

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11. TOXICOLOGICAL INFORMATION

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4 Week(s)	Monkey	Subcutaneous	10 µg/kg/day	LOAEL	Liver
28 Day(s)	Rat	Subcutaneous	1000 µg/kg/day	NOAEL	No effects at maximum dose
13 Week(s)	Monkey	Subcutaneous	1 µg/kg/day	NOAEL	Liver
13 Week(s)	Dog	Oral	30 mg/kg/day	NOAEL	No effects at maximum dose
26 Week(s)	Rat	Subcutaneous	2000 µg/kg/day	NOAEL	No effects at maximum dose

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

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Fertility and Embryonic Development	Rat	Subcutaneous	10 µg/kg/day	NOAEL	Developmental toxicity, Fetotoxicity, Maternal toxicity
Fertility and Embryonic Development	Rabbit	Subcutaneous	1 µg/kg/day	NOAEL	Fetotoxicity, Fetal mortality, Maternal Toxicity

Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

Oprelvekin

<i>In Vitro</i> Bone Marrow Metaphase Analysis	Human Lymphocytes	Negative
<i>In Vitro</i> Mammalian Cell Mutagenicity	Mouse Lymphoma	Negative
<i>In Vivo</i> Micronucleus	Mouse Bone Marrow	Negative

Carcinogen Status: Not listed as a carcinogen by IARC, NTP or US OSHA.

12. ECOLOGICAL INFORMATION

Environmental Overview:	Environmental properties have not been investigated. Releases to the environment should be avoided.
Toxicity:	No data available
Persistence and Degradability:	No data available
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.

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14. TRANSPORT INFORMATION

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

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

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CERCLA/SARA 313 Emission reporting

Not Listed

California Proposition 65

Not Listed

EU EINECS/ELINCS List

Not Listed

16. OTHER INFORMATION

Data Sources:

Pfizer proprietary drug development information.

Prepared by:

Product Stewardship 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