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

Product Identifier

Material Name: Neumega

Trade Name: NEUMEGA
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 product

Details of the Supplier of the Safety Data Sheet

Pfizer Inc
Pfizer Pharmaceuticals Group
235 East 42nd Street
New York, New York 10017
1-800-879-3477

Pfizer Ltd
Ramsgate Road
Sandwich, Kent
CT13 9NJ
United Kingdom
+00 44 (0)1304 616161

Emergency telephone number:
CHEMTREC (24 hours): 1-800-424-9300
Contact E-Mail: pfizer-MSDS@pfizer.com

Emergency telephone number: Emergency telephone number:
International CHEMTREC (24 hours): +1-703-527-3887

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

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

Other Hazards


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.
3. COMPOSITION / INFORMATION ON INGREDIENTS

### Hazardous

<table>
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<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
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<th>GHS Classification</th>
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**Addition Information:**

* Proprietary
** to adjust pH

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:**
For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.

**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: 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.

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 spilled material by a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of dry solids. 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. Use appropriate engineering controls to maintain exposures below the B-OEB taking all applicable routes of exposure into consideration. Minimize dust generation and accumulation. 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 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.

Hydrochloric Acid

ACGIH Ceiling Threshold Limit: 2 ppm
Australia PEAK 5 ppm
Austria OEL - MAKs 7.5 mg/m³

WB00005
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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<tr>
<th>Country</th>
<th>Standard</th>
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<th>Value 2</th>
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<tr>
<td>Vietnam OEL - TWAs</td>
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</tbody>
</table>

Glycine
- Latvia OEL - TWA: 5 mg/m³

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)
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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:

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.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State: Lyophilized powder

Color: 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: No data available.

Melting/Freezing Point (°C): No data available

Boiling Point (°C): No data available

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

Sodium phosphate, dibasic

No data available

Sodium phosphate, monobasic

No data available

Hydrochloric Acid

No data available

Oprelvekin

No data available

Glycine

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

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

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

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

Oprelvekin
  Rat Intravenous Minimum Lethal Dose > 10 mg/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.

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

Hydrochloric Acid
  Skin Irritation Severe
  Eye Irritation Severe

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

Oprelvekin
  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))

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

Genetic Toxicity: (Study Type, Cell Type/Organism, Result)
11. TOXICOLOGICAL INFORMATION

**Oprelvekin**
*In Vitro* Bone Marrow Metaphase Analysis  Human Lymphocytes  Negative  
*In Vitro* Mammalian Cell Mutagenicity  Mouse Lymphoma  Negative  
*In Vivo* Micronucleus  Mouse Bone Marrow  Negative

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

**Hydrochloric Acid**  
IARC:  Group 3 (Not Classifiable)

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.

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
15. REGULATORY INFORMATION

**Canada - WHMIS: Classifications**

*WHMIS hazard class:*

None required

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<th>CERCLA/SARA 313 Emission reporting</th>
<th>California Proposition 65</th>
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16. OTHER INFORMATION

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

Acute toxicity, oral-Cat.3; H331 - Toxic if inhaled
Specific target organ toxicity, single exposure; Narcotic effects-Cat.3; H335 - May cause respiratory irritation
Skin corrosion/irritation-Cat.1A; H314 - Causes severe skin burns and eye damage

T - Toxic
C - Corrosive

R23 - Toxic by inhalation.
R35 - Causes severe burns.

Data Sources:
Pfizer proprietary drug development information. Publicly available toxicity 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 11 - Toxicology Information.

Revision date: 30-Oct-2014
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