MATERIAL SAFETY DATA SHEET

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

Pfizer Inc
Pfizer Pharmaceuticals Group
235 East 42nd Street
New York, New York 10017
1-212-573-2222

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:
ChemSafe (24 hours): +44 (0)208 762 8322

Material Name: EXUBERA (insulin human [rDNA origin]) Inhalation Powder

Trade Name:	EXUBERA
Chemical Family:	Polypeptide hormone
Intended Use:	Antidiabetic agent

2. HAZARDS IDENTIFICATION

Appearance: White, fine, odorless powder filled into unit-dose foil blisters

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

Additional Hazard Information:

Short Term: Antidiabetic drug: has blood-sugar lowering properties. May cause respiratory tract irritation. May be absorbed through mucous membranes and cause systemic effects.

Known Clinical Effects: The primary adverse effects of insulin overdose is hypoglycemia. Signs and symptoms may occur suddenly and can include sweating, palpitation, tremor, hunger, restlessness, tingling in the hands, feet, lips, or tongue, lightheadedness, inability to concentrate, headache, drowsiness, anxiety, blurred vision, slurred speech, depressive mood, irritability, abnormal behavior, unsteady movement, and personality changes. Signs of severe hypoglycemia can include disorientation, unconsciousness, and seizures. Clinical use has caused effects on the respiratory system, including cough, difficulty breathing, sore throat, and nose bleed. Additionally, dry mouth chest pain may occur.

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 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

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Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	Classification	%
Insulin (human)	11061-68-0	234-279-7	Not Listed	60 or 85%
Sodium hydroxide	1310-73-2	215-185-5	C;R35	**

Ingredient	CAS Number	EU EINECS/ELINCS List	Classification	%
Mannitol	69-65-8	200-711-8	Not Listed	*
Glycine	56-40-6	200-272-2	Not Listed	*
Sodium citrate, dihydrate	6132-04-3	Not listed	Not Listed	*

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

For the full text of the R phrases mentioned in this Section, see Section 16

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.

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.

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 the spill or leak. Spills should be handled by vacuuming or wet mopping. Avoid brush sweeping and cleaning with compressed air. Avoid generating airborne dust. 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.

7. HANDLING AND STORAGE

General Handling:	Minimize dust generation and accumulation. Avoid inhalation and contact with skin, eye, and clothing. Releases to the environment should be avoided.
Storage Conditions:	Store at room temperature in properly labeled containers. Keep away from heat, sparks and flames.
Storage Temperature:	Store as directed by product packaging.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

Insulin (human)

Pfizer OEL TWA-8 Hr:	300 µg/m^3

Glycine

Latvia OEL - TWA	= 5 mg/m^3 TWA

Sodium hydroxide

ACGIH Ceiling Threshold Limit:	= 2 mg/m^3 Ceiling
Australia PEAK	= 2 mg/m^3 Peak
Austria OEL - MAKs	= 2 mg/m^3 MAK
Belgium OEL - TWA	= 2 mg/m^3 TWA
Bulgaria OEL - TWA	= 2.0 mg/m^3 TWA
Czech Republic OEL - TWA	= 1 mg/m^3 TWA
Finland OEL - TWA	= 2 mg/m^3 TWA
France OEL - TWA	= 2 mg/m^3 VME
Greece OEL - TWA	= 2 mg/m^3 TWA
Hungary OEL - TWA	= 2 mg/m^3 TWA
Latvia OEL - TWA	= 0.5 mg/m^3 TWA
OSHA - Final PELS - TWAs:	2 mg/m^3
Poland OEL - TWA	= 0.5 mg/m^3 NDS
Slovakia OEL - TWA	= 2 mg/m^3 TWA
Slovenia OEL - TWA	= 2 mg/m^3 TWA
Sweden OEL - TWAs	= 1 mg/m^3 LLV

Analytical Method:	Analytical method available for Insulin. Contact Pfizer Inc for further information.
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:	
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:	Fine powder filled into unit-dose foil blisters	**Color:**	White
Odor:	Odorless	**Molecular Formula:**	Mixture
Molecular Weight:	Mixture		

Solvent Solubility:	Soluble: Most organic solvents
Solubility:	Soluble: Water, Dilute acids, Aqueous alkali
Polymerization:	Will not occur

9. PHYSICAL AND CHEMICAL PROPERTIES:

10. STABILITY AND REACTIVITY

Stability: Stable under normal conditions of use.
Conditions to Avoid: Heat, air and moisture
Incompatible Materials: Oxidizers

11. TOXICOLOGICAL INFORMATION

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

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

Mannitol
Rat Oral LD 50 13500 mg/kg
Mouse Oral LD 50 22 g/kg

Sodium hydroxide
Mouse IP LD50 40 mg/kg

Insulin (human)
Rat Oral LD50 > 2000 mg/kg
Rat Subcutaneous LD50 > 40 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)

Sodium hydroxide
Eye Irritation Rabbit Severe
Skin Irritation Rabbit Severe

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

Insulin (human)
30 Day(s) Rat Inhalation 6.0 mg/kg/day NOAEL No effects at maximum dose
6 Month(s) Rat Inhalation 5.8 mg/kg/day NOAEL No effects at maximum dose
30 Day(s) Monkey Inhalation 0.58 mg/kg/day NOAEL No effects at maximum dose
6 Month(s) Monkey Inhalation 0.64 mg/kg/day NOAEL No effects at maximum dose
4 Week(s) Rat Subcutaneous 1.8 mg/kg/day NOAEL No effects at maximum dose

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

Insulin (human)
In Vitro Bacterial Mutagenicity (Ames) *Salmonella* , *E. coli* Negative

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

12. ECOLOGICAL INFORMATION

Environmental Overview: In the environment, the active ingredient in this formulation is expected to sink or remain on the soil surface and not persist. Toxicity to aquatic organisms is not expected.

Mobility, Persistence and Degradability: The active ingredient in this formulation does not biodegrade rapidly due to its low water solubility, but is "inherently" biodegradable according to OECD guidelines. The active ingredient in this formulation has potential to partition with solids in wastewater treatment facilities.

Bioaccumulation and Toxicity: The active ingredient in this formulation is not expected to bioconcentrate or exhibit acute toxicity to aquatic organisms due to its high molecular weight. Long term toxicity is not expected. No toxicity to wastewater treatment microorganisms is expected.

Aquatic Toxicity: (Species, Method, End Point, Duration, Result)

Insulin (human)

Activated sludge	OECD	EC50	> 1000	mg/L
Brachydanio Rerio	OECD	LC50	96 Hours	> 100 mg/L
Daphnia magna	OECD	EC50	48 Hours	> 100 mg/L
Algae	OECD	EC50	72 Hours	18.52 mg/L
Algae	OECD	EC-50	72 Hours	32.67 mg/L

Aquatic Toxicity Comments: A greater than (>) symbol indicates that acute ecotoxicity was not observed at the maximum solubility. Since the substance is insoluble in aqueous solutions above this concentration, an acute ecotoxicity value (i.e. LC/EC50) is not achievable.

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.

14. TRANSPORT INFORMATION

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

15. REGULATORY INFORMATION

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.

Insulin (human)

EU EINECS/ELINCS List	234-279-7

Mannitol

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	200-711-8

Glycine

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	200-272-2

Sodium citrate, dihydrate

Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 5 Schedule 6

Sodium hydroxide

CERCLA/SARA Hazardous Substances and their Reportable Quantities:	= 1000 lb final RQ = 454 kg final RQ
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 5 Schedule 6
EU EINECS/ELINCS List	215-185-5

16. OTHER INFORMATION

Text of R phrases mentioned in Section 3

R35 - Causes severe burns.

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

Reasons for Revision: Updated Section 2 - Hazard Identification.

Prepared by: Toxicology and Hazard Communication
Pfizer Global Environment, Health, and Safety

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End of Safety Data Sheet