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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

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

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

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

Material Name: Dehydrated Alcohol in Water for Injection

Trade Name: Not applicable
Chemical Family: Not determined
Intended Use: Diluent

2. HAZARDS IDENTIFICATION

Appearance:Clear liquidSignal Word:WARNING

Statement of Hazard: Flammable liquid and vapor.

Additional Hazard Information:

Short Term: May cause eye irritation. May cause respiratory tract irritation. (based on components).

Long Term: Chronic ingestion of ethanol has been associated with an increased incidence of cancer, liver cirrhosis, and, if ingested during pregnancy, congenital malformations.

EU Indication of danger: Flammable

EU Hazard Symbols:



EU Risk Phrases:

R11 - Highly flammable.

Australian Hazard Classification

(NOHSC):

Note:

Hazardous Substance. Dangerous Goods.

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.

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3. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	Classification	%
Ethyl alcohol (ethanol)	64-17-5	200-578-6	F;R11	20

Ingredient	CAS Number	EU EINECS/ELINCS List	Classification	%
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.

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.

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: Highly flammable. Vapors are heavier than air and may travel along surfaces to remote ignition

sources and flash back.

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 if it is safe to do so. Absorb spills with non-combustible

absorbent material and transfer into a labeled container for disposal.

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: Restrict access to work area. Avoid open handling. Minimize generating airborne mists and

vapors. Use process containment, local exhaust ventilation or perform work under fume hood/fume cupboard. 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. Releases to the environment should be avoided.

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Storage Conditions: Store at room temperature in properly labeled containers. Keep away from heat, sparks and

flames.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

Ethyl alcohol (ethanol)

ACGIH Threshold Limit Value (TWA) = 1000 ppm TWA Australia TWA = 1000 ppm TWA

= 1880 mg/m³ TWA **Austria OEL - MAKs** = 1000 ppm MAK

 $= 1900 \text{ mg/m}^3 \text{ MAK}$ Belgium OEL - TWA = 1000 ppm TWA

= 1907 mg/m³ TWA

Bulgaria OEL - TWA = 1000.0 mg/m³ TWA

Czech Republic OEL - TWA = 1000 mg/m³ TWA

Denmark OEL - TWA = 1000 ppm TWA

= 1900 mg/m³ TWA **Estonia OEL - TWA** = 1000 mg/m³ TWA = 500 ppm TWA

Finland OEL - TWA = 1000 ppm TWA = 1900 mg/m³ TWA France OEL - TWA = 1000 ppm VME

= 1900 mg/m³ VME Germany - TRGS 900 - TWAs = 500 ppm TWA

 $= 960 \text{ mg/m}^3 \text{ TWA}$ = 1000 ppm TWA

= 1900 mg/m³ TWA
Hungary OEL - TWA = 1900 mg/m³ TWA

 Ireland OEL - TWAs
 = 1000 ppm TWA

 = 1900 mg/m³ TWA

 Latvia OEL - TWA
 = 1000 mg/m³ TWA

 Lithuania OEL - TWA
 = 1000 mg/m³ TPPV

Lithuania OEL - TWA = 1000 mg/m³ IPRV = 500 ppm IPRV

Netherlands OEL - TWA = 1000 mg/m³ MAC = 500 ppm MAC

OSHA - Final PELS - TWAs: = 1000 ppm TWA = 1900 mg/m³ TWA

 Poland OEL - TWA
 = 1900 mg/m³ NDS

 Portugal OEL - TWA
 = 1000 ppm TWA

 Romania OEL - TWA
 = 1000 ppm TWA

 = 1900 mg/m³ TWA

Slovakia OEL - TWA = 500 ppm TWA = 960 mg/m³ TWA

Slovenia OEL - TWA = 1000 ppm TWA = 1900 mg/m³ TWA

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Spain OEL - TWA = 1000 ppm VLA-ED

= 1910 mg/m³ VLA-ED

Sweden OEL - TWAs = 1000 mg/m³ LLV
= 500 ppm LLV

Engineering Controls: Engineering controls should be used as the primary means to control exposures. Keep

airborne contamination levels below the exposure limits listed above in this section. General

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room ventilation is adequate unless the process generates dust, mist or fumes.

Personal Protective Equipment:

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: 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:LiquidColor:ClearMolecular Formula:MixtureMolecular Weight:Mixture

Boiling Point (°C): 79 Ethanol

Flash Point (Liquid) (°C): 13 (Ethanol)

10. STABILITY AND REACTIVITY

Stability: Stable under normal conditions of use.

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

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)

Ethyl alcohol (ethanol)

Mouse Oral LD50 3450 mg/kg
Rat Oral LD50 7060 mg/kg

Rat Inhalation LC50 10h 20,000 ppm

<u>Irritation / Sensitization: (Study Type, Species, Severity)</u>

Ethyl alcohol (ethanol)

Eye Irritation Rabbit Severe Skin Irritation Rabbit Mild

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

12. ECOLOGICAL INFORMATION

Environmental Overview: Environmental properties have not been investigated. Releases to the environment should be

avoided.

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

Ethyl alcohol (ethanol)

Rainbow Trout LC50/96h 12,900-15,300 mg/L

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. Aqueous products containing alcohol at 24 percent or less are not subject to the requirements of the EU ADR, IATA, or IMDG. They are similarly exempt from US DOT requirements provided that they contain no less than 50 percent water.

15. REGULATORY INFORMATION

EU Symbol:

EU Indication of danger: Flammable

EU Risk Phrases:

R11 - Highly flammable.

EU Safety Phrases:

S 2 - Keep out of the reach of children. S 7 - Keep container tightly closed.

S16 - Keep away from sources of ignition - No smoking.

OSHA Label:

WARNING

Flammable liquid and vapor.

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Canada - WHMIS: Classifications

WHMIS hazard class: B2 flammable liquids



Water for injection

Inventory - United States TSCA - Sect. 8(b)PresentAustralia (AICS):PresentREACH - Annex IV - Exemptions from thePresent

obligations of Register:

EU EINECS/ELINCS List 231-791-2

Ethyl alcohol (ethanol)

California Proposition 65 developmental toxicity, initial date 10/1/87 (when in alcoholic

beverages)

Inventory - United States TSCA - Sect. 8(b)PresentAustralia (AICS):PresentEU EINECS/ELINCS List200-578-6

16. OTHER INFORMATION

Text of R phrases mentioned in Section 3

R11 - Highly flammable.

Data Sources: Publicly available toxicity information.

Reasons for Revision: Updated Section 11 - Toxicology Information. Updated Section 14 - Transport Information.

Prepared by: Toxicology and Hazard Communication

Pfizer Global Environment, Health, and Safety

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