



# SAFETY DATA SHEET

Revision date 16-Jun-2025

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## Section 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

### 1.1. Product identifier

**Product Name** Diazepam Injection (Hospira, Inc.)  
**Product Code(s)** PZ03411  
**Trade Name:** Diazepam Injection, USP  
**Chemical Family:** Mixture

### 1.2. Relevant identified uses of the substance or mixture and uses advised against

**Recommended Use** Pharmaceutical product used as antianxiety agent

### 1.3. Details of the supplier of the safety data sheet

Hospira, A Pfizer Company  
275 North Field Drive  
Lake Forest, Illinois 60045  
1-800-879-3477

Pfizer Ireland Pharmaceuticals  
OSG Building  
Ringaskiddy, Co. Cork.  
Ireland  
+353 21 4378701

**E-mail address** pfizer-MSDS@pfizer.com

### 1.4. Emergency telephone number

**Emergency Telephone** Chemtrec 1-800-424-9300 International Chemtrec (24 hours):+1-703-527-3887

## Section 2: HAZARDS IDENTIFICATION

### 2.1. Classification of the substance or mixture

GHS - Classification: Regulated according to Regulation (EC) 1272/2008 and/or other applicable regulations.

**Reproductive toxicity**

Category 2

**Physical Hazards**

Flammable liquids Category 3 - (H226)

### OSHA Classification

**Hazards not otherwise classified (HNOC)**

Not applicable

**Hazards classified under paragraph (d)(1)(ii) of 1910.1200**

Not applicable

### 2.2. Label elements

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## Signal word

## Hazard statements

## Warning

H226 - Flammable liquid and vapor

H361 - Suspected of damaging fertility or the unborn child

## Precautionary Statements - EU (§28, 1272/2008)

P201 - Obtain special instructions before use

P202 - Do not handle until all safety precautions have been read and understood

P210 - Keep away from heat, hot surfaces, sparks, open flames and other ignition sources.

No smoking

P280 - Wear protective gloves/protective clothing/eye protection/face protection

P303 + P361 + P353 - IF ON SKIN (or hair): Take off immediately all contaminated clothing.

Rinse skin with water/ shower

P308 + P313 - IF exposed or concerned: Get medical advice/attention

P370 + P378 - In case of fire: Use dry sand, dry chemical or alcohol-resistant foam to extinguish

P403 + P235 - Store in a well-ventilated place. Keep cool

P405 - Store locked up

P501 - Dispose of contents/container in accordance with local, regional, national, and international regulations as applicable

## 2.3. Other hazards

## Other hazards

An Occupational Exposure Value has been established for one or more of the ingredients (see Section 8).

## PBT & vPvB

The product does not contain any substance(s) classified as PBT or vPvB.

## Endocrine Disruptor Information

This product does not contain any known or suspected endocrine disruptors.

## 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.

## Section 3: COMPOSITION/INFORMATION ON INGREDIENTS

### 3.1 Substances

#### Substances

Not applicable

### 3.2 Mixtures

#### Hazardous

Chemical name	Weight-%	REACH registration number	EC No (EU Index No)	Classification according to Regulation (EC) No. 1272/2008	Specific concentration limit (SCL)	M-Factor	M-Factor (long-term)

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				[CLP]			
Ethyl alcohol (ethanol) (CAS #: 64-17-5)	8.98	-	200-578-6 (603-002-00-5)	Flam. Liq. 2 (H225)	Not classified	No data available	No data available
Diazepam (CAS #: 439-14-5)	0.5		207-122-5	Acute Tox. 4 (H302)2 (H361)Acute 1 (H401)Chronic 2 (H411)	Not classified	No data available	No data available
Benzoic acid (CAS #: 65-85-0)	< 1		200-618-2 (607-705-00-8)	Skin Irrit. 2 (H315) Eye Dam. 1 (H318) STOT RE 1 (H372)	Not classified	No data available	No data available
BENZYL ALCOHOL (CAS #: 100-51-6)	< 1		202-859-9 (603-057-00-5)	Acute Tox. 4 (H302) Skin Sens. 1B (H317) Eye Irrit. 2 (H319)	Not classified	No data available	No data available

## NonHazardous

Chemical name	Weight-%	REACH registration number	EC No (EU Index No)	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Specific concentration limit (SCL)	M-Factor	M-Factor (long-term)
Water (CAS #: 7732-18-5)	*	-	231-791-2	Not classified	Not classified	No data available	No data available
Propylene glycol (CAS #: 57-55-6)	*		200-338-0	Not classified	Not classified	No data available	No data available
Sodium benzoate (CAS #: 532-32-1)	*		208-534-8	Not classified	Not classified	No data available	No data available

## Full text of H- and EUH-phrases: see section 16

## Acute Toxicity Estimate

Chemical name	Oral LD50 mg/kg	Dermal LD50 mg/kg	Inhalation LC50 - 4 hour - dust/mist - mg/L	Inhalation LC50 - 4 hour - vapor - mg/L	Inhalation LC50 - 4 hour - gas - ppm
Water 7732-18-5	89838.9	No data available	No data available	No data available	No data available
Propylene glycol 57-55-6	20000	20800	No data available	No data available	No data available
Ethyl alcohol (ethanol) 64-17-5	7060	No data available	116.9 133.8	No data available	No data available
Sodium benzoate 532-32-1	4070	No data available	No data available	No data available	No data available
Diazepam 439-14-5	249	No data available	No data available	No data available	No data available
Benzoic acid 65-85-0	1700	10000	12.2	No data available	No data available
BENZYL ALCOHOL 100-51-6	1200+ 1230	2000	4.178	No data available	No data available

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This product does not contain candidate substances of very high concern at a concentration  $\geq 0.1\%$  (Regulation (EC) No. 1907/2006 (REACH), Article 59).

## Additional information

\* Proprietary

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. Non-hazardous ingredients provided for completeness.

## Section 4: FIRST AID MEASURES

### 4.1. Description of first aid measures

Inhalation	Remove to fresh air. Seek immediate medical attention/advice.
Eye contact	Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids. Consult a physician.
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.

### 4.2. Most important symptoms and effects, both acute and delayed

Most important symptoms and effects	For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.
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### 4.3. Indication of any immediate medical attention and special treatment needed

Note to physicians	None.
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## Section 5: FIRE-FIGHTING MEASURES

### 5.1. Extinguishing media

Suitable Extinguishing Media	Dry chemical, CO <sub>2</sub> , alcohol-resistant foam or water spray.
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### 5.2. Special hazards arising from the substance or mixture

Specific hazards arising from the chemical	Flammable liquid and vapor. Vapors will form flammable or explosive mixtures with air at room temperature.
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Hazardous combustion products	Formation of toxic gases is possible during heating or fire. May include oxides of carbon.
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#### Explosion data

Sensitivity to mechanical impact	No information available.
Sensitivity to static discharge	No information available.

### 5.3. Advice for firefighters

Special protective equipment and precautions for fire-fighters	Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Use personal protection equipment.
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## Section 6: ACCIDENTAL RELEASE MEASURES

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## 6.1. Personal precautions, protective equipment and emergency procedures

**Personal precautions** Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure. Eliminate all sources of ignition and ventilate area using explosion-proof equipment.

**For emergency responders** Use personal protection recommended in Section 8.

## 6.2. Environmental precautions

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

## 6.3. Methods and material for containment and cleaning up

**Methods for containment** Prevent further leakage or spillage if safe to do so.

**Methods for cleaning up** Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly.

**Prevention of secondary hazards** Clean contaminated objects and areas thoroughly observing environmental regulations.

## 6.4. Reference to other sections

**Reference to other sections** See section 8 for more information. See section 13 for more information.

## **Section 7: HANDLING AND STORAGE**

### 7.1. Precautions for safe handling

**Advice on safe handling** Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Avoid breathing dust/fume/gas/mist/vapors/spray. Avoid contact with skin, eyes or clothing. When handling, use appropriate personal protective equipment (see Section 8). Use only with adequate ventilation. Wash thoroughly after handling. 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.

**General hygiene considerations** Handle in accordance with good industrial hygiene and safety practice.

### 7.2. Conditions for safe storage, including any incompatibilities

**Storage Conditions** Store as directed by product packaging. Keep away from open flames, hot surfaces and sources of ignition.

### 7.3. Specific end use(s)

**Specific use(s)** Pharmaceutical drug product.

## **Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION**

### 8.1. Control parameters

#### **Exposure Limits**

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

#### **Diazepam**

Pfizer OEL TWA-8 Hr: 7 µg/m<sup>3</sup>

#### **BENZYL ALCOHOL**

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Pfizer OEL TWA-8 Hr: 10 ppm

## Propylene glycol

Ireland

TWA: 10 mg/m<sup>3</sup>; particulate  
TWA: 150 ppm; total vapour and particulates  
TWA: 470 mg/m<sup>3</sup>; total vapour and particulates  
STEL: 1410 mg/m<sup>3</sup> (calculated); particulates  
STEL: 30 mg/m<sup>3</sup> (calculated);  
STEL: 450 ppm (calculated); total vapor and particulates  
TWA: 7 mg/m<sup>3</sup>;  
TWA-NDS: 100 mg/m<sup>3</sup>; vapor and inhalable fraction  
MAC: 7 mg/m<sup>3</sup>  
TWA: 150 ppm; total vapour and particulate  
TWA: 474 mg/m<sup>3</sup>; total vapour and particulate  
TWA: 10 mg/m<sup>3</sup>; particulate  
STEL: 450 ppm; total vapour and particulate  
STEL: 1422 mg/m<sup>3</sup>; total vapour and particulate  
STEL: 30 mg/m<sup>3</sup>; particulate

Latvia

Poland

Russia

United Kingdom

## Ethyl alcohol (ethanol)

ACGIH TLV

Austria

STEL: 1000 ppm  
TWA-TMW: 1000 ppm;  
TWA-TMW: 1900 mg/m<sup>3</sup>;  
STEL-KZGW: 2000 ppm (3 X 60 min);  
STEL-KZGW: 3800 mg/m<sup>3</sup> (3 X 60 min);

Bulgaria

Czech Republic

TWA: 1000 mg/m<sup>3</sup>;  
1000 mg/m<sup>3</sup>  
Ceiling: 3000 mg/m<sup>3</sup>

Denmark

TWA: 1000 ppm;  
TWA: 1900 mg/m<sup>3</sup>;  
STEL: 2000 ppm;  
STEL: 3800 mg/m<sup>3</sup>;

Estonia

TWA: 500 ppm;  
TWA: 1000 mg/m<sup>3</sup>;  
STEL: 1000 ppm;  
STEL: 1900 mg/m<sup>3</sup>;

Finland

TWA: 1000 ppm;  
TWA: 1900 mg/m<sup>3</sup>;  
STEL: 1300 ppm;  
STEL: 2500 mg/m<sup>3</sup>;

France

Germany DFG

1900 mg/m<sup>3</sup>  
TWA-MAK: 200 ppm; II(4);  
TWA-MAK: 380 mg/m<sup>3</sup>; II(4);  
Peak: 800 ppm;  
Peak: 1520 mg/m<sup>3</sup>;

Germany TRGS

TWA-AGW; 200 ppm (exposure factor 4);  
TWA-AGW; 380 mg/m<sup>3</sup> (exposure factor 4);

Hungary

TWA-AK: 1000 ppm;  
TWA-AK: 1900 mg/m<sup>3</sup>;  
STEL-CK: 2000 ppm;  
STEL-CK: 3800 mg/m<sup>3</sup>;

Ireland

Latvia

Netherlands

STEL: 1000 ppm;  
TWA: 1000 mg/m<sup>3</sup>;  
TWA: 137 ppm;  
TWA: 260 mg/m<sup>3</sup>;  
STEL: 1000 ppm;  
STEL: 1900 mg/m<sup>3</sup>;

Sk

Poland

Romania

TWA-NDS: 1900 mg/m<sup>3</sup>;  
TWA: 1000 ppm;

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Russia

Slovakia

Spain

Switzerland

OSHA PEL

United Kingdom

TWA: 1900 mg/m<sup>3</sup>;  
STEL: 5000 ppm;  
STEL: 9500 mg/m<sup>3</sup>;  
TWA: 1000 mg/m<sup>3</sup>  
MAC: 2000 mg/m<sup>3</sup>  
TWA: 500 ppm;  
TWA: 960 mg/m<sup>3</sup>;  
Ceiling: 1920 mg/m<sup>3</sup>;  
STEL (VLA-EC): 1000 ppm;  
STEL (VLA-EC): 1910 mg/m<sup>3</sup>;  
TWA-MAK: 500 ppm;  
TWA-MAK: 960 mg/m<sup>3</sup>;  
STEL-KZGW: 1000 ppm;  
STEL-KZGW: 1920 mg/m<sup>3</sup>;  
TWA: 1000 ppm  
TWA: 1900 mg/m<sup>3</sup>  
(vacated) TWA: 1000 ppm  
(vacated) TWA: 1900 mg/m<sup>3</sup>  
TWA: 1000 ppm;  
TWA: 1920 mg/m<sup>3</sup>;  
STEL: 3000 ppm;  
STEL: 5760 mg/m<sup>3</sup>;

## Sodium benzoate

ACGIH - Skin Absorbers

ACGIH TLV

Germany DFG

Germany TRGS

Russia

Switzerland

Skin - potential significant contribution to overall exposure by the cutaneous route  
TWA: 2.5 mg/m<sup>3</sup> Benzoate inhalable particulate matter  
pSk  
TWA-MAK: 10 mg/m<sup>3</sup>; II(2);inhalable fraction  
Peak: 20 mg/m<sup>3</sup>; inhalable fraction  
Sk  
TWA-AGW; 10 mg/m<sup>3</sup> (exposure factor 2); inhalable fraction  
Sk  
MAC: 5 mg/m<sup>3</sup>  
TWA-MAK: 0.2 ppm; respirable dust  
TWA-MAK: 1 mg/m<sup>3</sup>; respirable dust  
TWA-MAK: 10 mg/m<sup>3</sup>; inhalable dust  
STEL-KZGW: 0.8 ppm;  
STEL-KZGW: 4 mg/m<sup>3</sup>; respirable dust  
STEL-KZGW: 20 mg/m<sup>3</sup>; inhalable dust  
Sk

## Diazepam

Bulgaria

TWA: 0.1 mg/m<sup>3</sup>;  
STEL: 0.5 mg/m<sup>3</sup>;

## Benzoic acid

ACGIH - Skin Absorbers

ACGIH TLV

Germany DFG

Germany TRGS

Skin - potential significant contribution to overall exposure by the cutaneous route  
TWA: 0.5 mg/m<sup>3</sup> inhalable fraction and vapor  
pSk  
TWA-MAK: 0.1 ppm; II(4);respirable fraction  
TWA-MAK: 0.5 mg/m<sup>3</sup>; II(4);respirable fraction  
TWA-MAK: 0.39 ppm; I(2);inhalable fraction  
TWA-MAK: 2 mg/m<sup>3</sup>; I(2);inhalable fraction  
Peak: 2 mg/m<sup>3</sup>; respirable fraction  
Peak: 0.4 ppm;  
Peak: 0.78 ppm;  
Peak: 4 mg/m<sup>3</sup>; inhalable fraction  
Sk  
TWA-AGW; 0.1 ppm (exposure factor 4);

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Latvia  
Russia  
Switzerland

TWA-AGW; 0.5 mg/m<sup>3</sup> (exposure factor 4);  
Sk  
TWA: 5 mg/m<sup>3</sup>;  
MAC: 5 mg/m<sup>3</sup>  
TWA-MAK: 0.2 ppm; aerosol, vapour  
TWA-MAK: 1 mg/m<sup>3</sup>; aerosol, respirable dust, vapour  
TWA-MAK: 0.4 ppm; aerosol, vapour  
TWA-MAK: 2 mg/m<sup>3</sup>; aerosol, inhalable dust, vapour  
STEL-KZGW: 0.8 ppm; aerosol, vapour  
STEL-KZGW: 4 mg/m<sup>3</sup>; aerosol, respirable dust, vapour  
STEL-KZGW: 4 mg/m<sup>3</sup>; aerosol, inhalable dust, vapour  
Sk

## BENZYL ALCOHOL

Bulgaria  
Czech Republic

TWA: 5.0 mg/m<sup>3</sup>;  
40 mg/m<sup>3</sup>  
Ceiling: 80 mg/m<sup>3</sup>  
TWA: 10 ppm;  
TWA: 45 mg/m<sup>3</sup>;  
TWA-MAK: 22 mg/m<sup>3</sup>; I(2);  
TWA-MAK: 5 ppm; I(2);  
Peak: 44 mg/m<sup>3</sup>;  
Peak: 10 ppm;

Germany TRGS

Sk  
TWA-AGW; 5 ppm (exposure factor 2);  
TWA-AGW; 22 mg/m<sup>3</sup> (exposure factor 2);  
Sk

Ceiling Limit Value

25 mg/m<sup>3</sup>  
TWA: 5 mg/m<sup>3</sup>;  
TWA-NDS: 240 mg/m<sup>3</sup>;  
MAC: 5 mg/m<sup>3</sup>

Latvia  
Poland  
Russia

Skin

Switzerland

TWA-MAK: 5 ppm; aerosol, vapour  
TWA-MAK: 22 mg/m<sup>3</sup>; aerosol, vapour  
Sk

## 8.2. Exposure controls

### 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

Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE). Contact your safety and health professional or safety equipment supplier for assistance in selecting the correct protective clothing/equipment based on an assessment of the workplace conditions, other chemicals used or present in the workplace and specific operational processes.

### Eye/face protection

Wear safety glasses or goggles if eye contact is possible. (Eye protection must meet the standards in accordance with EN166, ANSI Z87.1 or international equivalent.).

### Hand protection

Impervious disposable gloves (e.g. Nitrile, etc.) (double recommended) if skin contact with drug product is possible and for bulk processing operations. (Protective gloves must meet

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the standards in accordance with EN374, ASTM F1001 or international equivalent.).

## Skin and body protection

Impervious disposable protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations. (Protective clothing must meet the standards in accordance with EN13982, ANSI 103 or international equivalent.).

## Respiratory protection

Under normal conditions of use, 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 (e.g. particulate respirator with a full mask, P3 filter). (Respirators must meet the standards in accordance with EN136, EN143, ASTM F2704-10 or international equivalent.).

## Thermal hazards

No information available.

## Environmental exposure controls

No information available.

## Section 9: PHYSICAL AND CHEMICAL PROPERTIES

### 9.1. Information on basic physical and chemical properties

Physical state	Liquid
Color	Clear, colorless to pale yellow
Odor	No information available.
Odor threshold	No information available

#### Property

#### Values

Melting point / freezing point	No data available
Boiling point or initial boiling point and boiling range	98
Flammability (solid, gas)	No data available
Lower and upper explosion limit/flammability limit	
Lower explosion limit	No data available
Upper explosion limit	No data available
Flash point	50
Autoignition temperature	No data available
Decomposition temperature	
SADT (°C)	No data available
pH	6.2-6.9
pH (as aqueous solution)	No data available
Kinematic viscosity	No data available
Dynamic viscosity	No data available
Solubility	No data available Soluble
Vapor pressure	No data available
Density and/or relative density	No data available
Bulk density	No data available
Liquid Density	No data available
Vapor density	No data available
Particle characteristics	
Particle Size	No information available
Particle Size Distribution	No information available

### 9.2. Other information

Molecular formula	Mixture
Molecular weight	Mixture

#### 9.2.1. Information with regard to physical hazard classes

No information available

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**Oxidizing properties** None

## **9.2.2. Other safety characteristics**

No information available

## **Section 10: STABILITY AND REACTIVITY**

### **10.1. Reactivity**

**Reactivity** No information available.

### **10.2. Chemical stability**

**Stability** Stable under normal conditions.

### **Explosion data**

**Sensitivity to mechanical impact** No information available.

**Sensitivity to static discharge** No information available.

### **10.3. Possibility of hazardous reactions**

**Possibility of hazardous reactions** No information available.

### **10.4. Conditions to avoid**

**Conditions to avoid** Keep away from open flames, hot surfaces and sources of ignition.

### **10.5. Incompatible materials**

**Incompatible materials** As a precautionary measure, keep away from strong oxidizers.

### **10.6. Hazardous decomposition products**

**Hazardous decomposition products** May form toxic materials such as carbon monoxide and carbon dioxide.

## **Section 11: TOXICOLOGICAL INFORMATION**

### **11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008**

**General Information:** There are no data for this formulation. The following information is available for the individual ingredients.

**Long Term:** Animal studies have shown a potential to cause adverse effects on the fetus. Use of this drug is habit forming. Addiction may occur.

**Known Clinical Effects:** Therapeutic use of this substance has resulted in weakness, dizziness, drowsiness, ataxia, confusion, tremors, headache, and gastrointestinal disturbances.

<b>Acute toxicity</b>	Based on available data, the classification criteria are not met.
<b>Serious eye damage/eye irritation</b>	Based on available data, the classification criteria are not met.
<b>Skin corrosion/irritation</b>	Based on available data, the classification criteria are not met.
<b>Respiratory or skin sensitization</b>	Based on available data, the classification criteria are not met.
<b>STOT - single exposure</b>	Based on available data, the classification criteria are not met.
<b>STOT - repeated exposure</b>	Based on available data, the classification criteria are not met.
<b>Reproductive toxicity</b>	Classification is based on mixture calculation methods based on component data.
<b>Germ cell mutagenicity</b>	Based on available data, the classification criteria are not met.
<b>Carcinogenicity</b>	Based on available data, the classification criteria are not met.
<b>Aspiration hazard</b>	Based on available data, the classification criteria are not met.

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

#### **Propylene glycol**

Rat Oral LD 50 22,000 mg/kg  
Mouse Oral LD 50 24,900 mg/kg  
Rabbit Dermal LD 50 20,800 mg/kg

#### **Ethyl alcohol (ethanol)**

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

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Rat Inhalation LC50 10h 20,000 ppm

## **Sodium benzoate**

Rat Oral LD50 4,070 mg/kg  
Mouse Oral LD50 1600 mg/kg

## **Diazepam**

Rat Oral LD 50 710 mg/kg  
Rat Para-periosteal LD 50 32 mg/kg  
Rat Intraperitoneal LD 50 46.5 mg/kg  
Mouse Oral LD 50 48 mg/kg  
Mouse Intravenous LD 50 25 mg/kg

## **Benzoic acid**

Rat Oral LD 50 1700 mg/kg  
Mouse Oral LD 50 1940 mg/kg  
Rabbit Dermal LD50 > 5000 mg/kg  
Rat Inhalation LC50 > 0.026 mg/L

## **BENZYL ALCOHOL**

Rat Oral LD 50 1230 mg/kg  
Mouse Oral LD 50 1360 mg/kg  
Rabbit Dermal LD 50 2 gm/kg

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Water	> 90 mL/kg ( Rat )	-	-
Propylene glycol	= 20 g/kg ( Rat )	= 20800 mg/kg ( Rabbit )	-
Ethyl alcohol (ethanol)	= 7060 mg/kg ( Rat )	-	= 116.9 mg/L ( Rat ) 4 h = 133.8 mg/L ( Rat ) 4 h
Sodium benzoate	= 4070 mg/kg ( Rat )	-	-
Diazepam	= 249 mg/kg ( Rat )	-	-
Benzoic acid	= 1700 mg/kg ( Rat )	> 10000 mg/kg ( Rabbit )	> 12.2 mg/L ( Rat ) 4 h
BENZYL ALCOHOL	= 1230 mg/kg ( Rat )	= 2 g/kg ( Rabbit )	> 4178 mg/m <sup>3</sup> ( Rat ) 4 h

## **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)**

### **Propylene glycol**

Skin irritation Rabbit Mild  
Eye irritation Rabbit Mild

### **Ethyl alcohol (ethanol)**

Eye Irritation Rabbit Severe  
Skin Irritation Rabbit Mild

### **Benzoic acid**

Skin Sensitization - GPMT Guinea Pig Negative  
Skin Sensitization - Beuhler Guinea Pig Negative  
Eye Irritation Rabbit Severe

### **BENZYL ALCOHOL**

Eye Irritation Rabbit Severe  
Skin Irritation Rabbit Minimal  
Skin Irritation Guinea Pig Moderate

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

### **Sodium benzoate**

10 Day(s) Rat Oral 27370 mg/kg LOEL Liver, Blood  
10 Day(s) Mouse Oral 45 g/kg LOEL Liver, Kidney, Blood, Ureter, Bladder

### **Diazepam**

6 Week(s) Mouse Oral 0.5 mg/kg LOEL Male reproductive system  
3 Month(s) Rat Oral 100 mg/kg/day NOEL None identified  
3 Month(s) Non-human Primate Oral 5 mg/kg/day LOEL None identified  
6 Month(s) Dog Oral 20 mg/kg/day LOEL Liver  
6 Month(s) Rat Oral 162 mg/kg/day LOEL Kidney

### **Benzoic acid**

250 Day(s) Dog Oral 1000 mg/kg/day NOEL None identified  
18 Month(s) Mouse Oral 80 mg/kg/day NOEL None identified  
18 Month(s) Rat Oral 80 mg/kg/day NOEL

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

### **Sodium benzoate**

Embryo / Fetal Development Rat Oral 44 g/kg LOEL Developmental toxicity

### **Diazepam**

Embryo / Fetal Development Mouse Oral 100 mg/kg/day NOEL Teratogenic, Fetotoxicity  
Embryo / Fetal Development Rat Oral 100 mg/kg LOEL Embryotoxicity  
Embryo / Fetal Development Dog Oral 5 mg/kg/day NOEL Not Teratogenic  
Embryo / Fetal Development Hamster Intraperitoneal 280 mg/kg LOEL Teratogenic  
Embryo / Fetal Development Rabbit Oral 8 mg/kg NOEL Not Teratogenic

### **Benzoic acid**

Reproductive & Fertility Rat Oral 5 mg/kg/day NOEL Fertility, Not teratogenic  
Fertility and Embryonic Development Rat Oral 500 mg/kg/day NOEL No effects at maximum dose

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

### **Diazepam**

Bacterial Mutagenicity (Ames) *Salmonella*, *E. coli* Negative  
*In Vitro* Micronucleus Mouse Positive  
*In Vivo* Chromosome Aberration Mouse Negative  
*In Vivo* Micronucleus Mouse Negative  
*In Vivo* Direct DNA Damage Rat Negative

### **Benzoic acid**

Bacterial Mutagenicity (Ames) *Salmonella* Negative  
Chromosome Aberration Chinese Hamster Ovary (CHO) cells Negative  
Sister Chromatid Exchange Human Lymphocytes Negative

## **Carcinogenicity: (Duration, Species, Route, Dose, End Point, Effect(s))**

### **Diazepam**

2 Year(s) Rat Liver, Tumors  
2 Year(s) Mouse Not carcinogenic  
2 Year(s) Hamster Not carcinogenic  
80 Week(s) Male Mouse Oral 75 mg/kg/day LOEL Malignant tumors

### **Carcinogenicity**

Carcinogenicity of the mixture has not been determined. Consumption of alcoholic beverages is considered carcinogenic to humans (Group 1) by IARC, though ethanol itself has not been classified by this agency. No other components are listed as carcinogens by IARC, US OSHA or NTP.

### **Ethyl alcohol (ethanol)**

IARC Group 1  
NTP Known

### **Diazepam**

IARC Group 3

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## 11.2. Information on other hazards

### 11.2.1. Endocrine disrupting properties

**Endocrine disrupting properties** Based on available data, the classification criteria are not met.

### 11.2.2. Other information

**Other adverse effects** No information available.

## Section 12: ECOLOGICAL INFORMATION

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

### 12.1. Toxicity

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

##### Ethyl alcohol (ethanol)

*Oncorhynchus mykiss* (Rainbow Trout) NPDES LC50 96 Hours 12,900 mg/L

Fingerling Trout NPDES LC50 24 Hours 11200 mg/L

*Pimephales promelas* (Fathead Minnow) NPDES LC50 96 Hours 14200 mg/L

##### Diazepam

*Oncorhynchus mykiss* (Rainbow Trout) OECD LC50 96 hours 84 mg/L

*Oncorhynchus mykiss* (Rainbow Trout) OECD NOEC 96 hours 50 mg/L

*Desmodesmus subcapitata* (Green Alga) OECD ErC50 72 hours 3.11 mg/L

*Desmodesmus subcapitata* (Green Alga) OECD NOEC 72 hours 0.1 mg/L

##### Benzoic acid

*Daphnia magna* (Water Flea) EC-50 24 hours 500 mg/L

Fish LC50 96 180 mg/L

##### BENZYL ALCOHOL

*Pimephales promelas* (Fathead Minnow) EPA LC50 96 hours 460 - 770 mg/L

*Daphnia magna* (Water Flea) NPDES OECD EC50 48 Hours 230 mg/L

*Pseudokirchneriella subcapitata* (Green Alga) OECD EC50 72 hours 500 mg/L

#### Chronic Aquatic Toxicity: (Species, Method, Duration, Endpoint, Result, Adverse Endpoint)

##### Diazepam

*Daphnia magna* (Water Flea) OECD Day(s) NOEC 0.91 mg/L Reproduction

*Brachydanio rerio* (Zebra fish) OECD 35 Day(s) NOEC 0.273 mg/L Survival

### 12.2. Persistence and degradability

#### Persistence and degradability

#### Biodegradation: (Method, Inoculum, Biodeg Study, Result, Endpoint, Duration, Classification)

##### BENZYL ALCOHOL

OECD Activated sludge Ready 92 % After 28 Day(s) Ready

### 12.3. Bioaccumulative potential

**Bioaccumulation** No information available.

### 12.4. Mobility in soil

**Mobility in soil** No information available.

### 12.5. Results of PBT and vPvB assessment

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## PBT and vPvB assessment

Chemical name	PBT and vPvB assessment
Propylene glycol	Not PBT/vPvB PBT assessment does not apply
Ethyl alcohol (ethanol)	Not PBT/vPvB PBT assessment does not apply
Sodium benzoate	Not PBT/vPvB
Benzoic acid	Not PBT/vPvB
BENZYL ALCOHOL	Not PBT/vPvB

## 12.6. Endocrine disrupting properties

**Endocrine disrupting properties** Based on available data, the classification criteria are not met.

## 12.7. Other adverse effects

**Other adverse effects** No information available.

**PMT or vPvM properties** Based on available data, the classification criteria are not met.

## Section 13: DISPOSAL CONSIDERATIONS

### 13.1. Waste treatment methods

#### Waste from residues/unused products

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 wastewater 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.

## Section 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. 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.**

**UN number:** Not applicable  
**UN proper shipping name:** Not applicable  
**Transport hazard class(es):** Not applicable  
**Packing group:** Not applicable  
**Environmental Hazard(s):** Not applicable

## Section 15: REGULATORY INFORMATION

### 15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

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## Water

<b>CERCLA/SARA Section 313 de minimus %</b>	Not Listed
<b>California Proposition 65</b>	Not Listed
<b>TSCA</b>	Present
<b>EINECS</b>	231-791-2
<b>AICS</b>	Present

## Propylene glycol

<b>CERCLA/SARA Section 313 de minimus %</b>	Not Listed
<b>California Proposition 65</b>	Not Listed
<b>TSCA</b>	Present
<b>EINECS</b>	200-338-0
<b>AICS</b>	Present

## Ethyl alcohol (ethanol)

<b>CERCLA/SARA Section 313 de minimus %</b>	Not Listed
<b>California Proposition 65</b>	Carcinogen
	Developmental
<b>TSCA</b>	Present
<b>EINECS</b>	200-578-6
<b>AICS</b>	Present

## Sodium benzoate

<b>CERCLA/SARA Section 313 de minimus %</b>	Not Listed
<b>California Proposition 65</b>	Not Listed
<b>TSCA</b>	Present
<b>EINECS</b>	208-534-8
<b>AICS</b>	Present

## Diazepam

<b>CERCLA/SARA Section 313 de minimus %</b>	Not Listed
<b>California Proposition 65</b>	Developmental
<b>U.S. - DEA (Drug Enforcement Administration)</b>	Schedule IV Controlled Substance
<b>TSCA</b>	Present
<b>EINECS</b>	207-122-5
<b>Standard for Uniform Scheduling of Medicines and Poisons (SUSMP)</b>	Schedule 4

## Benzoic acid

<b>CERCLA/SARA Section 313 de minimus %</b>	Not Listed
<b>Hazardous Substances RQs</b>	5000 lb
<b>California Proposition 65</b>	Not Listed
<b>TSCA</b>	Present
<b>EINECS</b>	200-618-2
<b>AICS</b>	Present
<b>Standard for Uniform Scheduling of Medicines and Poisons (SUSMP)</b>	Schedule 5

## BENZYL ALCOHOL

<b>CERCLA/SARA Section 313 de minimus %</b>	Not Listed
<b>California Proposition 65</b>	Not Listed
<b>TSCA</b>	Present
<b>EINECS</b>	202-859-9
<b>AICS</b>	Present

## National regulations

### France

#### Occupational Illnesses (R-463-3, France)

Chemical name	French RG number
Propylene glycol 57-55-6	RG 84
Ethyl alcohol (ethanol) 64-17-5	RG 84

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BENZYL ALCOHOL 100-51-6	RG 84
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## Germany

### Chemical Prohibition Ordinance (ChemVerbotsV)

Not applicable

## TRGS 905

Not applicable

Chemical name	Netherlands - List of Carcinogens	Netherlands - List of Mutagens	Netherlands - List of Reproductive Toxins
Ethyl alcohol (ethanol) 64-17-5	Present	-	Fertility Category 1A Development Category 1A Can be harmful via breastfeeding

## Switzerland

Ordinance on the Incentive Tax on Volatile Organic Compounds (OVOC) SR 814.018 Not applicable

Storage of Hazardous Material

Not applicable

WPO (GSchV) SR 814.201; WPA (GSchG) SR 814.20

Not applicable

Major Accidents Ordinance SR 814.012

Not applicable

## European Union

Take note of Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work.

### Authorizations and/or restrictions on use:

This product contains one or more substance(s) subject to restriction (Regulation (EC) No. 1907/2006 (REACH), Annex XVII)

Chemical name	Restricted substance per REACH Annex XVII	Substance subject to authorization per REACH Annex XIV
Benzoic acid 65-85-0	75	-
BENZYL ALCOHOL 100-51-6	75	-

## Persistent Organic Pollutants

Not applicable

## Ozone-depleting substances (ODS) Regulation (EU) 2024/590

Not applicable.

## EU - Plant Protection Products (1107/2009/EC)

Chemical name	EU - Plant Protection Products (1107/2009/EC)
Benzoic acid 65-85-0	Plant protection agent

Chemical name	Biocidal Products Regulation (EU) No 528/2012 (BPR)
Ethyl alcohol (ethanol) 64-17-5	Product-type 1: Human hygiene Product-type 2: Disinfectants and algacides not intended for direct application to humans or animals Product-type 4: Food and feed area

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Sodium benzoate 532-32-1	Simplified procedure - Category 1
Benzoic acid 65-85-0	Product-type 3: Veterinary hygiene Product-type 4: Food and feed area

## Explosives Precursors Marketing and Use (2019/1148)

Not applicable

### Legend:

**TSCA** - United States Toxic Substances Control Act Section 8(b) Inventory  
**DSL/NDSL** - Canadian Domestic Substances List/Non-Domestic Substances List  
**EINECS/ELINCS** - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances  
**ENCS** - Japan Existing and New Chemical Substances  
**IECSC** - China Inventory of Existing Chemical Substances  
**KECL** - Korean Existing Chemicals Inventory  
**PICCS** - Philippines Inventory of Chemicals and Chemical Substances  
**AICS** - Australian Inventory of Chemical Substances  
**NZIoC** - New Zealand Inventory of Chemicals  
**TCSI** - Taiwan Chemical Substance Inventory

## 15.2. Chemical safety assessment

Chemical Safety Report No information available

## Section 16: OTHER INFORMATION

### Key or legend to abbreviations and acronyms used in the safety data sheet

#### Full text of any hazard and/or precautionary statements referred to under Sections 2-15

H302 - Harmful if swallowed. H332 - Harmful if inhaled. H361 - Suspected of damaging fertility or the unborn child. H372 - Causes damage to organs through prolonged or repeated exposure. H318 - Causes serious eye damage. H315 - Causes skin irritation. H226 - Flammable liquid and vapor H401 - Toxic to aquatic life H411 - Toxic to aquatic life with long lasting effects

**Data Sources:** The data contained in this SDS may have been gathered from confidential internal sources, raw material suppliers, or from the published literature.

**Reason for revision** Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 11 - Toxicology Information. Updated Section 12 - Ecological Information. Updated Section 16 - Other Information.

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**Prepared By** Pfizer Global Environment, Health, and Safety

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