



# 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** Propofol Injectable Emulsion (Hospira, Inc.)  
**Product Code(s)** PZ03545  
**Trade Name:** Propofol Injectable Emulsion  
**Chemical Family:** Not determined

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

**Recommended Use** Pharmaceutical product

### 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.

**Hazardous to the aquatic environment - acute** Category 3 - (H402)

**Hazardous to the aquatic environment - chronic** Category 3 - (H412)

### 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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**Hazard statements** H412 - Harmful to aquatic life with long lasting effects

**Precautionary Statements - EU (§28, 1272/2008)** P273 - Avoid release to the environment  
P501 - Dispose of contents/container in accordance with local, regional, national, and international regulations as applicable

**Supplemental Hazard** Compound, not fully tested, additional hazards may exist.

## 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 [CLP]	Specific concentration limit (SCL)	M-Factor	M-Factor (long-term)
Propofol (CAS #: 2078-54-8)	1		218-206-6	Acute Tox.4 (H302) Eye Irrit.2A (H319) Skin Irrit.2 (H315) STOT SE 3 (H335) STOT SE 3 (H336) Aquatic Acute 1 (H400) Aquatic Chronic 1 (H410)	Not classified	1	1
BENZYL ALCOHOL (CAS #: 100-51-6)	<1		202-859-9 (603-057-00-5)	Acute Tox. 4 (H302) Skin Sens. 1B	Not classified	No data available	No data available

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				(H317) Eye Irrit. 2 (H319)			
Sodium hydroxide (CAS #: 1310-73-2)	**	-	215-185-5 (011-002-00-6)	Skin Corr.1A (H314)	Eye Irrit. 2 :: 0.5%<=C<2% Skin Corr. 1A :: C>=5% Skin Corr. 1B :: 2%<=C<5% Skin Irrit. 2 :: 0.5%<=C<2%	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
Soybean oil (CAS #: 8001-22-7)	*		232-274-4	Not classified	Not classified	No data available	No data available
Glycerin, USP (CAS #: 56-81-5)	*		200-289-5	Not classified	Not classified	No data available	No data available
Lecithin (CAS #: 8002-43-5)	*		232-307-2	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
Glycerin, USP 56-81-5	27200	10000	5.85	No data available	No data available
Propofol 2078-54-8	500	No data available	No data available	No data available	No data available
BENZYL ALCOHOL 100-51-6	1200 + 1230	2000	4.178	No data available	No data available
Sodium hydroxide 1310-73-2	325	1350	No data available	No data available	No data available
Sodium benzoate 532-32-1	4070	No data available	No data available	No data available	No data available

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  
\*\* to adjust pH

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Non-hazardous ingredients provided for completeness. 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.

## 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, CO2, 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	Fine particles (such as dust and mists) may fuel fires/explosions.
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Hazardous combustion products	Formation of toxic gases is possible during heating or fire.
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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

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

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## 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** 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). 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.

### 7.3. Specific end use(s)

**Specific use(s)** Pharmaceutical 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.

#### Propofol

Pfizer OEL TWA-8 Hr: 140 µg/m<sup>3</sup>

#### BENZYL ALCOHOL

Pfizer OEL TWA-8 Hr: 10 ppm

#### Soybean oil

Germany DFG

Germany TRGS

Switzerland

TWA-MAK: 5 mg/m<sup>3</sup>; I(4);respirable fraction

Peak: 20 mg/m<sup>3</sup>; respirable fraction

TWA-AGW; 5 mg/m<sup>3</sup> (exposure factor 4); respirable fraction

TWA-MAK: 5 mg/m<sup>3</sup>; inhalable dust

STEL-KZGW: 20 mg/m<sup>3</sup>; inhalable dust

#### Glycerin, USP

Czech Republic

10 mg/m<sup>3</sup>

Ceiling: 15 mg/m<sup>3</sup>

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Estonia	TWA: 10 mg/m <sup>3</sup> ;
Finland	TWA: 20 mg/m <sup>3</sup> ;
France	10 mg/m <sup>3</sup>
Germany DFG	TWA-MAK: 200 mg/m <sup>3</sup> ; I(2);inhalable fraction
	Peak: 400 mg/m <sup>3</sup> ; inhalable fraction
Germany TRGS	TWA-AGW; 200 mg/m <sup>3</sup> (exposure factor 2); inhalable fraction
Poland	TWA-NDS: 10 mg/m <sup>3</sup> ; inhalable fraction
Slovakia	TWA: 10 mg/m <sup>3</sup> ;
Spain	TWA-(VLA-ED): 10 mg/m <sup>3</sup> ; mist
Switzerland	TWA-MAK: 50 mg/m <sup>3</sup> ; inhalable dust
	STEL-KZGW: 100 mg/m <sup>3</sup> ; inhalable dust
OSHA PEL	TWA: 15 mg/m <sup>3</sup> mist, total particulate
	TWA: 5 mg/m <sup>3</sup> mist, respirable fraction
	(vacated) TWA: 10 mg/m <sup>3</sup> mist, total particulate
	(vacated) TWA: 5 mg/m <sup>3</sup> mist, respirable fraction
United Kingdom	TWA: 10 mg/m <sup>3</sup> ; mist
	STEL: 30 mg/m <sup>3</sup> ; mist

## BENZYL ALCOHOL

Bulgaria	TWA: 5.0 mg/m <sup>3</sup> ;
Czech Republic	40 mg/m <sup>3</sup>
	Ceiling: 80 mg/m <sup>3</sup>
Finland	TWA: 10 ppm;
	TWA: 45 mg/m <sup>3</sup> ;
Germany DFG	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;
	Sk
Germany TRGS	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>
Latvia	TWA: 5 mg/m <sup>3</sup> ;
Poland	TWA-NDS: 240 mg/m <sup>3</sup> ;
Russia	MAC: 5 mg/m <sup>3</sup>
	Skin
Switzerland	TWA-MAK: 5 ppm; aerosol, vapour
	TWA-MAK: 22 mg/m <sup>3</sup> ; aerosol, vapour
	Sk

## Sodium hydroxide

ACGIH OEL (Ceiling)	2 mg/m <sup>3</sup>
ACGIH TLV	Ceiling: 2 mg/m <sup>3</sup>
Austria	TWA-TMW: 2 mg/m <sup>3</sup> ; inhalable fraction
	STEL-KZGW: 4 mg/m <sup>3</sup> (8 X 5 min); inhalable fraction
Bulgaria	TWA: 2.0 mg/m <sup>3</sup> ; alkaline aerosols
Czech Republic	1 mg/m <sup>3</sup>
	Ceiling: 2 mg/m <sup>3</sup>
Denmark	Ceiling: 2 mg/m <sup>3</sup> ;
Estonia	TWA: 1 mg/m <sup>3</sup> ;
	STEL: 2 mg/m <sup>3</sup> ;
Finland	Ceiling: 2 mg/m <sup>3</sup> ;
France	2 mg/m <sup>3</sup>
Hungary	TWA-AK: 1 mg/m <sup>3</sup> ;
	STEL-CK: 2 mg/m <sup>3</sup> ;
Ireland	STEL: 2 mg/m <sup>3</sup> ;
Ceiling Limit Value	2 mg/m <sup>3</sup>
Latvia	TWA: 0.5 mg/m <sup>3</sup> ;
Poland	TWA-NDS: 0.5 mg/m <sup>3</sup> ;

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Romania	STEL-NDSch: 1 mg/m <sup>3</sup> ; TWA: 1 mg/m <sup>3</sup> ; STEL: 3 mg/m <sup>3</sup> ;
Slovakia	TWA: 2 mg/m <sup>3</sup> ;
Spain	STEL (VLA-EC): 2 mg/m <sup>3</sup> ;
Switzerland	TWA-MAK: 2 mg/m <sup>3</sup> ; inhalable dust
OSHA PEL	STEL-KZGW: 2 mg/m <sup>3</sup> ; inhalable dust TWA: 2 mg/m <sup>3</sup> (vacated) Ceiling: 2 mg/m <sup>3</sup> STEL: 2 mg/m <sup>3</sup> ;
United Kingdom	
<b>Sodium benzoate</b>	
ACGIH - Skin Absorbers	Skin - potential significant contribution to overall exposure by the cutaneous route
ACGIH TLV	TWA: 2.5 mg/m <sup>3</sup> Benzoate inhalable particulate matter pSk
Germany DFG	TWA-MAK: 10 mg/m <sup>3</sup> ; II(2);inhalable fraction Peak: 20 mg/m <sup>3</sup> ; inhalable fraction Sk
Germany TRGS	TWA-AGW; 10 mg/m <sup>3</sup> (exposure factor 2); inhalable fraction Sk
Russia	MAC: 5 mg/m <sup>3</sup>
Switzerland	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

## 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 gloves (e.g. Nitrile, etc.) are recommended if skin contact with drug product is possible and for bulk processing operations. (Protective gloves must meet the standards in accordance with EN374, ASTM F1001 or international equivalent.).

### Skin and body protection

Impervious 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.).

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<b>Respiratory protection</b>	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 half mask, P3 filter). (Respirators must meet the standards in accordance with EN140, EN143, ASTM F2704-10 or international equivalent.).
<b>Thermal hazards</b>	No information available.
<b>Environmental exposure controls</b>	No information available.

## Section 9: PHYSICAL AND CHEMICAL PROPERTIES

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

<b>Appearance</b>	Oily emulsion
<b>Physical state</b>	Liquid
<b>Color</b>	White
<b>Odor</b>	None.
<b>Odor threshold</b>	No information available
<b>Property</b>	<b>Values</b>
<b>Melting point / freezing point</b>	No data available
<b>Boiling point or initial boiling point and boiling range</b>	No data available
<b>Flammability (solid, gas)</b>	No data available
<b>Lower and upper explosion limit/flammability limit</b>	
Lower explosion limit	No data available
Upper explosion limit	No data available
<b>Flash point</b>	No data available
<b>Autoignition temperature</b>	No data available
<b>Decomposition temperature</b>	
SADT (°C)	No data available
<b>pH</b>	6 - 8.5
pH (as aqueous solution)	No data available
<b>Kinematic viscosity</b>	No data available
Dynamic viscosity	No data available
<b>Solubility</b>	No data available Soluble
<b>Vapor pressure</b>	No data available
<b>Density and/or relative density</b>	No data available
Bulk density	No data available
Liquid Density	No data available
<b>Vapor density</b>	No data available
<b>Particle characteristics</b>	
Particle Size	No information available
Particle Size Distribution	No information available

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

**Propofol**  
Measured Log P 3.8

### 9.2. Other information

<b>Molecular formula</b>	Mixture
<b>Molecular weight</b>	Mixture

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

No information available

#### 9.2.2. Other safety characteristics



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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 Fine particles (such as dust and mists) may fuel fires/explosions.

### 10.5. Incompatible materials

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

### 10.6. Hazardous decomposition products

Hazardous decomposition products No data available.

## Section 11: TOXICOLOGICAL INFORMATION

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

General Information: The following information is available for the individual ingredients.

#### Short term

May cause eye and skin irritation (based on components)

#### Known Clinical Effects:

Clinical use of this drug has caused slow heart rate (bradycardia) decrease in blood pressure (hypotension) respiratory depression skin rash cough drowsiness, sleepiness, dizziness, sedation, and gastrointestinal disturbance.

#### Acute toxicity

Based on available data, the classification criteria are not met.

#### Serious eye damage/eye irritation

Based on available data, the classification criteria are not met.

#### Skin corrosion/irritation

Based on available data, the classification criteria are not met.

#### Respiratory or skin sensitization

Based on available data, the classification criteria are not met.

#### STOT - single exposure

Based on available data, the classification criteria are not met.

#### STOT - repeated exposure

Based on available data, the classification criteria are not met.

#### Reproductive toxicity

Based on available data, the classification criteria are not met.

#### Germ cell mutagenicity

Based on available data, the classification criteria are not met.

#### Carcinogenicity

Based on available data, the classification criteria are not met.

#### Aspiration hazard

Based on available data, the classification criteria are not met.

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

#### Glycerin, USP

Mouse Oral LD50 4090 mg/kg

Rat Oral LD50 12.6 g/kg

Rabbit Dermal LD50 > 10 g/kg

Rat Inhalation LC50 1hr > 570 mg/m<sup>3</sup>

Rat Dermal LD 50 > 21.9 g/kg

#### Lecithin

Rat Oral LD50 > 8 ml/kg

#### Propofol

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Rat Oral LD50 500 mg/kg  
Mouse Oral LD50 1100 mg/kg  
Rabbit Dermal LD50 > 2000 mg/kg

## **BENZYL ALCOHOL**

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

## **Sodium hydroxide**

Mouse IP LD50 40 mg/kg

## **Sodium benzoate**

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

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Water	> 90 mL/kg ( Rat )	-	-
Glycerin, USP	= 27200 mg/kg ( Rat )	> 10 g/kg ( Rabbit )	> 5.85 mg/L ( Rat ) 4 h
Propofol	= 500 mg/kg ( Rat )	-	-
BENZYL ALCOHOL	= 1230 mg/kg ( Rat )	= 2 g/kg ( Rabbit )	> 4178 mg/m <sup>3</sup> ( Rat ) 4 h
Sodium hydroxide	= 325 mg/kg ( Rat )	= 1350 mg/kg ( Rabbit )	-
Sodium benzoate	= 4070 mg/kg ( Rat )	-	-

## **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)**

### **Glycerin, USP**

Eye Irritation Rabbit Mild

### **Propofol**

Eye Irritation Rabbit Irritant

Skin Irritation Rabbit Irritant

Skin Irritation Rat Severe Irritant

### **BENZYL ALCOHOL**

Eye Irritation Rabbit Severe

Skin Irritation Rabbit Minimal

Skin Irritation Guinea Pig Moderate

### **Sodium hydroxide**

Eye Irritation Rabbit Severe

Skin Irritation Rabbit Severe

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

### **Sodium benzoate**

10 Day(s) Rat Oral 27370 mg/kg LOAEL Liver, Blood

10 Day(s) Mouse Oral 45 g/kg LOAEL Liver, Kidney, Blood, Ureter, Bladder

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

### **Propofol**

Reproductive & Fertility Rabbit Intravenous 15 mg/kg/day NOAEL No effects at maximum dose

Reproductive & Fertility Rat Intravenous 15 mg/kg/day NOAEL No effects at maximum dose

### **Sodium benzoate**

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

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

### Propofol

Bacterial Mutagenicity (Ames) *Salmonella* Negative  
Mitotic Gene Conversion *Saccharomyces cerevisiae* Negative  
*In Vitro* Cytogenetics Chinese Hamster Ovary (CHO) cells Negative  
*In Vitro* Chromosome Aberration Human Lymphocytes Negative  
*In Vivo* Micronucleus Mouse Negative

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

## 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 of the formulation have not been investigated. Classification is based on mixture calculation methods based on component data.

### 12.1. Toxicity

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

##### Glycerin, USP

*Oncorhynchus mykiss* (Rainbow Trout) N/A LC50 96 hours 50 mg/L  
*Daphnia magna* (Water Flea) N/A EC50 24 hours > 500 mg/L

##### Propofol

*Lepomis macrochirus* (Bluegill Sunfish) FDA / TAD LC50 96 hours 0.62 mg/L  
*Oncorhynchus mykiss* (Rainbow Trout) FDA / TAD LC50 96 hours 0.37 mg/L  
*Pseudokirchneriella subcapitata* (Green Alga) FDA / TAD ErC50 96 hours 11.6 mg/L  
*Pseudokirchneriella subcapitata* (Green Alga) FDA / TAD TAD NOEC 96 hours 0.49 mg/L  
*Microcystis aeruginosa* (Blue-green Alga) FDA / TAD 96 hours ErC50 2.66 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

#### Bacterial Inhibition: (Inoculum, Method, End Point, Result)

##### Propofol

Activated sludge N/A EC50 > 100 mg/L

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

##### Propofol

*Daphnia magna* (Water Flea) FDA / TAD 21 Day(s) LOEC 0.46 mg/L  
*Daphnia magna* (Water Flea) FDA / TAD 21 Day(s) NOEC 0.23 mg/L  
*Pseudokirchneriella subcapitata* (Green Alga) FDA / TAD 14 Day(s) NOEC 0.67 mg/L  
*Microcystis aeruginosa* (Blue-green Alga) FDA / TAD 21 Day(s) NOEC 1.9 mg/L

## 12.2. Persistence and degradability

**Persistence and degradability**

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

### Propofol

OECD 2.8 % in 28 Day(s) Not readily biodegradable

### BENZYL ALCOHOL

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

## 12.3. Bioaccumulative potential

### Bioaccumulation

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

### Propofol

Measured Log P 3.8

## 12.4. Mobility in soil

### Mobility in soil

### Sorption:

### Propofol (2078-54-8)

#### Method

FDA

FDA

#### Inoculum

Soil (various)

Soil (various)

#### End Point

Koc (Geometric mean)

Kd (Geometric mean)

#### Result

277

6

## 12.5. Results of PBT and vPvB assessment

### PBT and vPvB assessment

Chemical name	PBT and vPvB assessment
Glycerin, USP	Not PBT/vPvB
BENZYL ALCOHOL	Not PBT/vPvB
Sodium hydroxide	Not PBT/vPvB PBT assessment does not apply
Sodium benzoate	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.

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## 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.

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

Water

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

Soybean oil

CERCLA/SARA Section 313 de minimus %	Not Listed
California Proposition 65	Not Listed
TSCA	Present
EINECS	232-274-4
AICS	Present

Glycerin, USP

CERCLA/SARA Section 313 de minimus %	Not Listed
California Proposition 65	Not Listed
TSCA	Present
EINECS	200-289-5
AICS	Present

Lecithin

CERCLA/SARA Section 313 de minimus %	Not Listed
California Proposition 65	Not Listed
TSCA	Present
EINECS	232-307-2
AICS	Present

Propofol

CERCLA/SARA Section 313 de minimus %	Not Listed
California Proposition 65	Not Listed
TSCA	Present
EINECS	218-206-6
AICS	Present
Standard for Uniform Scheduling of Medicines and Poisons (SUSMP)	Schedule 4

BENZYL ALCOHOL

CERCLA/SARA Section 313 de minimus %	Not Listed
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<b>California Proposition 65</b>	Not Listed
<b>TSCA</b>	Present
<b>EINECS</b>	202-859-9
<b>AICS</b>	Present
Sodium hydroxide	
<b>CERCLA/SARA Section 313 de minimus %</b>	Not Listed
<b>Hazardous Substances RQs</b>	1000 lb
<b>California Proposition 65</b>	Not Listed
<b>TSCA</b>	Present
<b>EINECS</b>	215-185-5
<b>AICS</b>	Present
<b>Standard for Uniform Scheduling of Medicines and Poisons (SUSMP)</b>	Schedule 5 Schedule 6
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

## National regulations

### France

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

Chemical name	French RG number
BENZYL ALCOHOL 100-51-6	RG 84

### Germany

#### **Chemical Prohibition Ordinance (ChemVerbotsV)**

Not applicable

### **TRGS 905**

Not applicable

### 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
BENZYL ALCOHOL 100-51-6	75	-
Sodium hydroxide 1310-73-2	75	-

### **Persistent Organic Pollutants**

Not applicable

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## 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)
Lecithin 8002-43-5	Plant protection agent

Chemical name	Biocidal Products Regulation (EU) No 528/2012 (BPR)
Sodium benzoate 532-32-1	Simplified procedure - Category 1

## 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. H314 - Causes severe skin burns and eye damage. H315 - Causes skin irritation. H319 - Causes serious eye irritation. H335 - May cause respiratory irritation, H336 - May cause drowsiness or dizziness.

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

**Reason 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 11 - Toxicology Information. Updated Section 12 - Ecological Information. Updated Section 15 - Regulatory Information.

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

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