



SAFETY DATA SHEET

Revision date 18-Mar-2023

Version 2

Page 1 / 15

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)

2.2. Label elements

Signal word Warning

Hazard statements H226 - Flammable liquid and vapor
H361 - Suspected of damaging fertility or the unborn child

Precautionary Statements P201 - Obtain special instructions before use

SAFETY DATA SHEET

Product Name Diazepam Injection (Hospira, Inc.)
Revision date 18-Mar-2023

Page 2 / 15
Version 2

P202 - Do not handle until all safety precautions have been read and understood
P210 - Keep away from heat/sparks/open flames/hot surfaces. - 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 attention/advice
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 all local and national regulations



2.3. Other hazards

Other hazards

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

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	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Specific concentration limit (SCL)	M-Factor	M-Factor (long-term)
Ethyl alcohol (ethanol) (CAS #: 64-17-5)	8.98	-	200-578-6	Flam. Liq. 2 (H225)	Not Listed	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 Listed	No data available	No data available
Benzoic acid (CAS #: 65-85-0)	< 1		200-618-2	Skin Irrit. 2 (H315) Eye Dam. 1 (H318) STOT RE 1 (H372)	Not Listed	No data available	No data available
BENZYL ALCOHOL	< 1		202-859-9	Acute Tox. 4	Not Listed	No data	No data

SAFETY DATA SHEET

Product Name Diazepam Injection (Hospira, Inc.)
Revision date 18-Mar-2023

Page 3 / 15
Version 2

(CAS #: 100-51-6)				(H302) Acute Tox. 4 (H332)		available	available
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NonHazardous

Chemical name	Weight-%	REACH Registration Number	EC 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 as hazardous	Not Listed	No data available	No data available
Propylene glycol (CAS #: 57-55-6)	*		200-338-0	Not classified as hazardous	Not Listed	No data available	No data available
Sodium benzoate (CAS #: 532-32-1)	*		208-534-8	Not classified as hazardous	Not Listed	No data available	No data available

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

Acute Toxicity Estimate

Chemical name	Oral LD50	Dermal LD50	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	1230	2000	4.178	No data available	No data available

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

SAFETY DATA SHEET

Product Name Diazepam Injection (Hospira, Inc.)
Revision date 18-Mar-2023

Page 4 / 15
Version 2

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.

4.3. Indication of any immediate medical attention and special treatment needed

Note to physicians None.

Section 5: FIRE-FIGHTING MEASURES

5.1. Extinguishing media

Suitable Extinguishing Media Dry chemical, carbon dioxide, water spray or alcohol-resistant foam.

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.

Hazardous combustion products Formation of toxic gases is possible during heating or fire. May include oxides of carbon.

5.3. Advice for firefighters

Special protective equipment for fire-fighters Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Use personal protection equipment.

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. 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

SAFETY DATA SHEET

Product Name Diazepam Injection (Hospira, Inc.)
Revision date 18-Mar-2023

Page 5 / 15
Version 2

7.1. Precautions for safe handling

Advice on safe handling

Keep away from heat, sparks, flame and all other sources of ignition. Avoid breathing vapor or mist. Avoid contact with eyes, skin and clothing. When handling, use appropriate personal protective equipment (see Section 8). Use 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/m³

BENZYL ALCOHOL

Pfizer OEL TWA-8 Hr: 10 ppm

Propylene glycol

Ireland

10 mg/m³
150 ppm
470 mg/m³
STEL: 1410 mg/m³
STEL: 30 mg/m³
STEL: 450 ppm
Latvia 7 mg/m³
Poland 100 mg/m³
Russia MAC: 7 mg/m³
United Kingdom TWA: 150 ppm
TWA: 474 mg/m³
TWA: 10 mg/m³
STEL: 450 ppm
STEL: 1422 mg/m³
STEL: 30 mg/m³

Ethyl alcohol (ethanol)

ACGIH TLV

Austria

STEL: 1000 ppm
1000 ppm
1900 mg/m³
STEL 2000 ppm
STEL 3800 mg/m³
1000 mg/m³
1000 mg/m³
Ceiling: 3000 mg/m³
1000 ppm
1900 mg/m³
500 ppm
1000 mg/m³

Bulgaria

Czech Republic

Denmark

Estonia

SAFETY DATA SHEET

Product Name Diazepam Injection (Hospira, Inc.)
Revision date 18-Mar-2023

Page 6 / 15
Version 2

Finland	STEL: 1000 ppm STEL: 1900 mg/m ³ 1000 ppm 1900 mg/m ³ STEL: 1300 ppm STEL: 2500 mg/m ³
France	1900 mg/m ³
Germany	200 ppm 380 mg/m ³ Ceiling / Peak: 800 ppm Ceiling / Peak: 1520 mg/m ³
Germany	200 ppm 380 mg/m ³
Hungary	1900 mg/m ³ STEL: 3800 mg/m ³
Ireland	STEL: 1000 ppm
Latvia	1000 mg/m ³
Netherlands	260 mg/m ³ STEL: 1900 mg/m ³
Poland	H* 1900 mg/m ³
Romania	1000 ppm 1900 mg/m ³ STEL: 5000 ppm STEL: 9500 mg/m ³
Russia	TWA: 1000 mg/m ³ MAC: 2000 mg/m ³
Slovakia	500 ppm 960 mg/m ³
Spain	STEL: 1000 ppm STEL: 1910 mg/m ³
Switzerland	500 ppm 960 mg/m ³ STEL: 1000 ppm STEL: 1920 mg/m ³
OSHA PEL	1000 ppm 1900 mg/m ³ (vacated) TWA: 1000 ppm (vacated) TWA: 1900 mg/m ³
United Kingdom	TWA: 1000 ppm TWA: 1920 mg/m ³ STEL: 3000 ppm STEL: 5760 mg/m ³
Sodium benzoate	
ACGIH - Skin Absorbers	Skin - potential significant contribution to overall exposure by the cutaneous route
ACGIH TLV	2.5 mg/m ³ S*
Germany	10 mg/m ³ Ceiling / Peak: 20 mg/m ³ Skin
Germany	10 mg/m ³ H*
Russia	MAC: 5 mg/m ³
Switzerland	0.2 ppm 1 mg/m ³ 10 mg/m ³ STEL: 0.8 ppm STEL: 4 mg/m ³ STEL: 20 mg/m ³

SAFETY DATA SHEET

Product Name Diazepam Injection (Hospira, Inc.)
Revision date 18-Mar-2023

Page 7 / 15
Version 2

Diazepam	H*
Bulgaria	STEL: 0.5 mg/m ³ 0.1 mg/m ³
Benzoic acid	
ACGIH - Skin Absorbers	Skin - potential significant contribution to overall exposure by the cutaneous route
ACGIH TLV	0.5 mg/m ³
Germany	S* 0.1 ppm can occur as vapor and aerosol at the same time 0.5 mg/m ³ can occur as vapor and aerosol at the same time 0.39 ppm can occur as vapor and aerosol at the same time 2 mg/m ³ can occur as vapor and aerosol at the same time Ceiling / Peak: 2 mg/m ³ Ceiling / Peak: 0.4 ppm Ceiling / Peak: 0.78 ppm Ceiling / Peak: 4 mg/m ³
Germany	Skin 0.1 ppm 0.5 mg/m ³
Latvia	H*
Russia	5 mg/m ³
Switzerland	MAC: 5 mg/m ³ 0.2 ppm 1 mg/m ³ 10 mg/m ³ STEL: 0.8 ppm STEL: 4 mg/m ³ STEL: 20 mg/m ³ H*
BENZYL ALCOHOL	
Bulgaria	5.0 mg/m ³
Czech Republic	40 mg/m ³ Ceiling: 80 mg/m ³
Finland	10 ppm 45 mg/m ³
Germany	22 mg/m ³ can occur as vapor and aerosol at the same time 5 ppm can occur as vapor and aerosol at the same time Ceiling / Peak: 44 mg/m ³ Ceiling / Peak: 10 ppm Skin
Germany	5 ppm 22 mg/m ³
Ceiling Limit Value	H* 25 mg/m ³
Latvia	5 mg/m ³
Poland	240 mg/m ³
Russia	MAC: 5 mg/m ³ Skin
Switzerland	5 ppm 22 mg/m ³ H*

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.

Environmental exposure controls

No information available.

SAFETY DATA SHEET

Product Name Diazepam Injection (Hospira, Inc.)
Revision date 18-Mar-2023

Page 8 / 15
Version 2

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

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
Molecular formula	Mixture
Molecular weight	Mixture
Property	Values
pH	6.2-6.9
Melting point / freezing point	No data available
Boiling point / boiling range	98
Flash point	50
Evaporation rate	No data available
Flammability (solid, gas)	No data available
Flammability Limit in Air	
Upper flammability limit:	No data available
Lower flammability limit:	No data available
Vapor pressure	No data available
Vapor density	No data available
Relative density	No data available
Water solubility	Soluble
Solubility(ies)	No data available
Partition coefficient	No data available
Autoignition temperature	No data available
Decomposition temperature	No data available
Kinematic viscosity	No data available
Dynamic viscosity	No data available

SAFETY DATA SHEET

Product Name Diazepam Injection (Hospira, Inc.)
Revision date 18-Mar-2023

Page 9 / 15
Version 2

Particle characteristics

Particle Size	No information available
Particle Size Distribution	No information available
Explosive properties	No information available

9.2. Other information

No information available

9.2.1. Information with regard to physical hazard classes

No information available

Oxidizing properties None

9.2.2. Other safety characteristics

No information available

Section 10: STABILITY AND REACTIVITY

10.1. Reactivity

Reactivity No data available.

10.2. Chemical stability

Stability Stable under normal conditions.

Explosion data

Sensitivity to Mechanical Impact No data available.

Sensitivity to Static Discharge No data 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 heat, spark, flames and all other 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.
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	Classification is based on mixture calculation methods based on component data.
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.

SAFETY DATA SHEET

Product Name Diazepam Injection (Hospira, Inc.)
Revision date 18-Mar-2023

Page 10 / 15
Version 2

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
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 ³ (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

SAFETY DATA SHEET

Product Name Diazepam Injection (Hospira, Inc.)
Revision date 18-Mar-2023

Page 11 / 15
Version 2

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

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 NOAEL 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 NOAEL None identified
18 Month(s) Mouse Oral 80 mg/kg/day NOAEL None identified
18 Month(s) Rat Oral 80 mg/kg/day NOAEL

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 NOAEL Teratogenic, Fetotoxicity
Embryo / Fetal Development Rat Oral 100 mg/kg LOAEL Embryotoxicity
Embryo / Fetal Development Dog Oral 5 mg/kg/day NOAEL Not Teratogenic
Embryo / Fetal Development Hamster Intraperitoneal 280 mg/kg LOAEL Teratogenic
Embryo / Fetal Development Rabbit Oral 8 mg/kg NOAEL 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 NOAEL 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 LOAEL 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.

Diazepam

IARC Group 3 (Not Classifiable)

SAFETY DATA SHEET

Product Name Diazepam Injection (Hospira, Inc.)
Revision date 18-Mar-2023

Page 12 / 15
Version 2

11.2. Information on other hazards

11.2.1. Endocrine disrupting properties

Endocrine disrupting properties No information available.

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

SAFETY DATA SHEET

Product Name Diazepam Injection (Hospira, Inc.)
Revision date 18-Mar-2023

Page 13 / 15
Version 2

PBT and vPvB assessment

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

12.6. Endocrine disrupting properties

Endocrine disrupting properties No information available.

12.7. Other adverse effects

No information available.

Section 13: DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural 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
Special precautions for user: 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

SAFETY DATA SHEET

Product Name Diazepam Injection (Hospira, Inc.)
Revision date 18-Mar-2023

Page 14 / 15
Version 2

EINECS	231-791-2
AICS	Present
Propylene glycol	
CERCLA/SARA Section 313 de minimus %	Not Listed
California Proposition 65	Not Listed
TSCA	Present
EINECS	200-338-0
AICS	Present
Ethyl alcohol (ethanol)	
CERCLA/SARA Section 313 de minimus %	Not Listed
California Proposition 65	carcinogen 7/1/1988 when associated with alcohol abuse carcinogen 4/29/2011 developmental toxicity 10/1/1987
TSCA	Present
EINECS	200-578-6
AICS	Present
Sodium benzoate	
CERCLA/SARA Section 313 de minimus %	Not Listed
California Proposition 65	Not Listed
TSCA	Present
EINECS	208-534-8
AICS	Present
Diazepam	
CERCLA/SARA Section 313 de minimus %	Not Listed
California Proposition 65	developmental toxicity 1/1/1992 developmental toxicity 10/1/1992 Schedule IV Controlled Substance
U.S. - DEA (Drug Enforcement Administration)	
TSCA	Present
EINECS	207-122-5
Standard for Uniform Scheduling of Medicines and Poisons (SUSMP)	Schedule 4
Benzoic acid	
CERCLA/SARA Section 313 de minimus %	Not Listed
Hazardous Substances RQs	5000 lb
California Proposition 65	Not Listed
TSCA	Present
EINECS	200-618-2
AICS	Present
BENZYL ALCOHOL	
CERCLA/SARA Section 313 de minimus %	Not Listed
California Proposition 65	Not Listed
TSCA	Present
EINECS	202-859-9
AICS	Present

France

Occupational Illnesses (R-463-3, France)

Chemical name	French RG number	Title
Propylene glycol 57-55-6	RG 84	-
Ethyl alcohol (ethanol) 64-17-5	RG 84	-
BENZYL ALCOHOL 100-51-6	RG 84	-

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:

SAFETY DATA SHEET

Product Name Diazepam Injection (Hospira, Inc.)
Revision date 18-Mar-2023

Page 15 / 15
Version 2

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	Use restricted. See item 75.	

Persistent Organic Pollutants

Not applicable

Ozone-depleting substances (ODS) regulation (EC) 1005/2009

Not applicable

Plant protection products directive (91/414/EEC)

Chemical name	Plant protection products directive (91/414/EEC)
Benzoic acid - 65-85-0	Plant protection agent

Legend:

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory

EINECS/ELINCS - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances

AICS - Australian Inventory of Chemical Substances

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 H-Statements referred to under section 3

Acute toxicity, oral-Cat.4; H302 - Harmful if swallowed. Acute toxicity, inhalation-Cat.4; H332 - Harmful if inhaled. Reproductive toxicity-Cat.2; H361 - Suspected of damaging fertility or the unborn child. Specific target organ toxicity, repeated exposure-Cat.1; H372 - Causes damage to organs through prolonged or repeated exposure. Serious eye damage/eye irritation-Cat.1; H318 - Causes serious eye damage. Skin corrosion/irritation-Cat.2; H315 - Causes skin irritation. Flammable liquids-Cat.3; H226 - Flammable liquid and vapor Hazardous to the aquatic environment, acute toxicity-Cat.2; H401 - Toxic to aquatic life Hazardous to the aquatic environment, chronic toxicity-Cat.2; 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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