



# SAFETY DATA SHEET

Revision date 26-Jun-2023

Version 2

Page 1 / 13

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

### 1.1. Product identifier

**Product Name** Doxercalciferol Injection (Hospira, Inc.)  
**Product Code(s)** PZ03552  
**Trade Name:** Doxercalciferol Injection  
**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

Hospira UK Limited  
Horizon  
Honey Lane  
Hurley  
Maidenhead, SL6 6RJ  
United Kingdom

**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.

**Physical Hazards** Flammable liquids Category 4 - (H227)

### 2.2. Label elements

**Signal word** Warning

**Hazard statements** H227 - Combustible liquid

### Precautionary Statements

P210 - Keep away from heat/sparks/open flames/hot surfaces. - No smoking  
P280 - Wear protective gloves/protective clothing/eye protection/face protection  
P370 + P378 - In case of fire: Use water fog, carbon dioxide, dry chemical or alcohol-resistant foam for extinction  
P403 + P235 - Store in a well-ventilated place. Keep cool  
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

# SAFETY DATA SHEET

Product Name Doxercalciferol Injection (Hospira, Inc.)  
Revision date 26-Jun-2023

Page 2 / 13  
Version 2

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)	7.4	-	200-578-6	Flam. Liq. 2 (H225)	Not Listed	No data available	No data available
Butylated hydroxytoluene (CAS #: 128-37-0)	*		204-881-4	Not classified as hazardous	Not Listed	No data available	No data available
Doxercalciferol (CAS #: 54573-75-0)	0.0002		Not Listed	Acute Tox 1 (H300)	Not Listed	No data available	No data available

#### 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
Sodium Phosphate Dibasic Heptahydrate (CAS #: 7782-85-6)	*		Not Listed	Not classified as hazardous	Not Listed	No data available	No data available
Polysorbate 20 (CAS #: 9005-64-5)	*		Not Listed	Not classified as hazardous	Not Listed	No data available	No data available
Sodium phosphate, monobasic (CAS #: 7558-80-7)	*		231-449-2	Not classified as hazardous	Not Listed	No data available	No data available
SODIUM CHLORIDE (CAS #: 7647-14-5)	*	-	231-598-3	Not classified as hazardous	Not Listed	No data available	No data available
Edetate disodium (CAS #: 139-33-3)	*		205-358-3	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  
No information available

# SAFETY DATA SHEET

Product Name Doxercalciferol Injection (Hospira, Inc.)  
Revision date 26-Jun-2023

Page 3 / 13  
Version 2

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
Ethyl alcohol (ethanol) 64-17-5	7060	No data available	116.9 133.8	No data available	No data available
Polysorbate 20 9005-64-5	37000	No data available	No data available	No data available	No data available
Sodium phosphate, monobasic 7558-80-7	8290	7940	0.83	No data available	No data available
SODIUM CHLORIDE 7647-14-5	3000	10000	No data available	No data available	No data available
Edetate disodium 139-33-3	2000	No data available	No data available	No data available	No data available
Butylated hydroxytoluene 128-37-0	2930	2000	No data available	No data available	No data available
Doxercalciferol 54573-75-0	3.5	No data available	No data available	No data available	No data available

## Additional information

\* Proprietary

In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret. Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety. 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, carbon dioxide, water spray or alcohol-resistant foam.
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# SAFETY DATA SHEET

Product Name Doxercalciferol Injection (Hospira, Inc.)  
Revision date 26-Jun-2023

Page 4 / 13  
Version 2

## 5.2. Special hazards arising from the substance or mixture

**Specific hazards arising from the chemical** Combustible liquid. May generate flammable vapors. Vapors are heavier than air and may travel along surfaces to remote ignition sources and flash back.

**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

### 7.1. Precautions for safe handling

#### Advice on safe handling

Restrict access to work area. Avoid breathing vapor or mist. Avoid contact with eyes, skin and 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

# SAFETY DATA SHEET

Product Name Doxercalciferol Injection (Hospira, Inc.)  
Revision date 26-Jun-2023

Page 5 / 13  
Version 2

## 8.1. Control parameters

### Exposure Limits

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

#### Ethyl alcohol (ethanol)

ACGIH TLV	STEL: 1000 ppm
Austria	1000 ppm 1900 mg/m <sup>3</sup> STEL 2000 ppm STEL 3800 mg/m <sup>3</sup>
Bulgaria	1000 mg/m <sup>3</sup>
Czech Republic	1000 mg/m <sup>3</sup> Ceiling: 3000 mg/m <sup>3</sup>
Denmark	1000 ppm 1900 mg/m <sup>3</sup>
Estonia	500 ppm 1000 mg/m <sup>3</sup>
Finland	STEL: 1000 ppm STEL: 1900 mg/m <sup>3</sup> 1000 ppm 1900 mg/m <sup>3</sup> STEL: 1300 ppm STEL: 2500 mg/m <sup>3</sup> 1900 mg/m <sup>3</sup>
France	200 ppm
Germany	380 mg/m <sup>3</sup> Ceiling / Peak: 800 ppm Ceiling / Peak: 1520 mg/m <sup>3</sup> 200 ppm 380 mg/m <sup>3</sup>
Germany	1900 mg/m <sup>3</sup>
Hungary	STEL: 3800 mg/m <sup>3</sup>
Ireland	STEL: 1000 ppm
Latvia	1000 mg/m <sup>3</sup>
Netherlands	260 mg/m <sup>3</sup> STEL: 1900 mg/m <sup>3</sup> H*
Poland	1900 mg/m <sup>3</sup>
Romania	1000 ppm 1900 mg/m <sup>3</sup> STEL: 5000 ppm STEL: 9500 mg/m <sup>3</sup>
Russia	TWA: 1000 mg/m <sup>3</sup> MAC: 2000 mg/m <sup>3</sup>
Slovakia	500 ppm 960 mg/m <sup>3</sup>
Spain	STEL: 1000 ppm STEL: 1910 mg/m <sup>3</sup>
Switzerland	500 ppm 960 mg/m <sup>3</sup> STEL: 1000 ppm STEL: 1920 mg/m <sup>3</sup>
OSHA PEL	1000 ppm 1900 mg/m <sup>3</sup> (vacated) TWA: 1000 ppm (vacated) TWA: 1900 mg/m <sup>3</sup>
United Kingdom	TWA: 1000 ppm TWA: 1920 mg/m <sup>3</sup>

# SAFETY DATA SHEET

Product Name Doxercalciferol Injection (Hospira, Inc.)  
Revision date 26-Jun-2023

Page 6 / 13  
Version 2

	STEL: 3000 ppm STEL: 5760 mg/m <sup>3</sup>
<b>Sodium phosphate, monobasic</b> Russia	MAC: 10 mg/m <sup>3</sup>
<b>SODIUM CHLORIDE</b> Latvia	5 mg/m <sup>3</sup>
Russia	MAC: 5 mg/m <sup>3</sup>
<b>Edetate disodium</b> Russia	MAC: 2 mg/m <sup>3</sup>
<b>Butylated hydroxytoluene</b> ACGIH TLV	2 mg/m <sup>3</sup>
Austria	10 mg/m <sup>3</sup>
Bulgaria	STEL: 50 mg/m <sup>3</sup> 10 mg/m <sup>3</sup>
Denmark	10 mg/m <sup>3</sup>
Finland	10 mg/m <sup>3</sup> STEL: 20 mg/m <sup>3</sup>
France	10 mg/m <sup>3</sup>
Germany	10 mg/m <sup>3</sup> can occur as vapor and aerosol at the same time Ceiling / Peak: 40 mg/m <sup>3</sup>
Germany	10 mg/m <sup>3</sup>
Ireland	2 mg/m <sup>3</sup> STEL: 6 mg/m <sup>3</sup>
Spain	10 mg/m <sup>3</sup>
Switzerland	10 mg/m <sup>3</sup> STEL: 40 mg/m <sup>3</sup>
OSHA PEL	(vacated) TWA: 10 mg/m <sup>3</sup>
United Kingdom	TWA: 10 mg/m <sup>3</sup> STEL: 30 mg/m <sup>3</sup>

## Pfizer Occupational Exposure Band (OEB) Statement:

The purpose of the Occupational Exposure Band (OEB) classification system is to separate substances into different Hazard categories when the available data are sufficient to do so, but inadequate to establish an Occupational Exposure Limit (OEL). The OEB given is based upon an analysis of all currently available data; as such, this value may be subject to revision when new information becomes available.

### Sodium phosphate, monobasic

Pfizer Occupational Exposure Band (OEB):

OEB 1 (control exposure to the range of 1000ug/m<sup>3</sup> to 3000ug/m<sup>3</sup>)

### SODIUM CHLORIDE

Pfizer Occupational Exposure Band (OEB):

OEB 1 (control exposure to the range of 1000ug/m<sup>3</sup> to 3000ug/m<sup>3</sup>)

### Doxercalciferol

Pfizer Occupational Exposure Band (OEB):

OEB 5 (control exposure to <1ug/m<sup>3</sup>)

## 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 air contamination levels below the exposure limits or within the OEB range listed above in this section.

### Environmental exposure controls

No information available.

### 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.

# SAFETY DATA SHEET

Product Name Doxercalciferol Injection (Hospira, Inc.)  
Revision date 26-Jun-2023

Page 7 / 13  
Version 2

<b>Eye/face protection</b>	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.).
<b>Hand protection</b>	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.).
<b>Skin and body protection</b>	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.).
<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>General hygiene considerations</b>	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

<b>Physical state</b>	Liquid
<b>Color</b>	Colorless
<b>Odor</b>	Alcoholic.
<b>Odor threshold</b>	No information available
<b>Molecular formula</b>	Mixture
<b>Molecular weight</b>	Mixture
<b>Property</b>	<b>Values</b>
<b>pH</b>	No data available
<b>Melting point / freezing point</b>	No data available
<b>Boiling point / boiling range</b>	
<b>Flash point</b>	~62
<b>Evaporation rate</b>	No data available
<b>Flammability (solid, gas)</b>	No data available
<b>Flammability Limit in Air</b>	
Upper flammability limit:	No data available
Lower flammability limit:	No data available
<b>Vapor pressure</b>	No data available
<b>Vapor density</b>	No data available
<b>Relative density</b>	No data available
<b>Water solubility</b>	Soluble in water Soluble
<b>Solubility(ies)</b>	No data available
<b>Partition coefficient</b>	No data available
<b>Autoignition temperature</b>	No data available
<b>Decomposition temperature</b>	No data available
<b>Kinematic viscosity</b>	No data available
<b>Dynamic viscosity</b>	No data available
<b>Particle characteristics</b>	
Particle Size	No information available
Particle Size Distribution	No information available
<b>Explosive properties</b>	No information available
<b>Upper Explosive Limits (Liquid) (% by Vol.):</b>	19
<b>Lower Explosive Limits (Liquid) (% by Vol.):</b>	3.3

# SAFETY DATA SHEET

Product Name Doxercalciferol Injection (Hospira, Inc.)  
Revision date 26-Jun-2023

Page 8 / 13  
Version 2

## 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 No data available.

## Section 11: TOXICOLOGICAL INFORMATION

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

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

**Short term** May cause eye irritation (based on components)

**Known Clinical Effects:** Clinical use of this drug has caused effects on kidney, heart.

**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)

#### Ethyl alcohol (ethanol)

Mouse Oral LD50 3450 mg/kg

Rat Oral LD50 7060 mg/kg

Rat Inhalation LC50 10h 20,000 ppm



# SAFETY DATA SHEET

Product Name Doxercalciferol Injection (Hospira, Inc.)  
Revision date 26-Jun-2023

Page 9 / 13  
Version 2

## **SODIUM CHLORIDE**

Rat Sub-tenon injection (eye) LC50/1hr > 42 g/m<sup>3</sup>

Rat Oral LD 50 3 g/kg

Mouse Oral LD 50 4 g/kg

Rabbit Dermal LD 50 > 10 g/kg

## **Edetate disodium**

Rat Oral LD50 2000-2200 mg/kg

## **Butylated hydroxytoluene**

Rat Oral LD50 1700 mg/kg

Mouse Oral LD50 650 mg/kg

Rat Oral LD50 890 mg/kg

Mouse Intraperitoneal LD 50 138 mg/kg

## **Doxercalciferol**

Rat Oral LD50 3.5 mg/kg

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Water	> 90 mL/kg ( Rat )	-	-
Ethyl alcohol (ethanol)	= 7060 mg/kg ( Rat )	-	= 116.9 mg/L ( Rat ) 4 h = 133.8 mg/L ( Rat ) 4 h
Polysorbate 20	= 37000 mg/kg ( Rat )	-	> 5.1 mg/L ( Rat ) 4 h
Sodium phosphate, monobasic	= 8290 mg/kg ( Rat )	> 7940 mg/kg ( Rabbit )	> 0.83 mg/L ( Rat ) 4 h
SODIUM CHLORIDE	= 3 g/kg ( Rat )	> 10000 mg/kg ( Rabbit )	> 42 mg/L ( Rat ) 1 h
Edetate disodium	= 2 g/kg ( Rat )	-	-
Butylated hydroxytoluene	> 2930 mg/kg ( Rat )	> 2000 mg/kg ( Rat )	-
Doxercalciferol	= 3500 µg/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)**

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

Eye Irritation Rabbit Severe

Skin Irritation Rabbit Mild

## **SODIUM CHLORIDE**

Skin irritation Rabbit Mild

Eye irritation Rabbit Mild

## **Butylated hydroxytoluene**

Eye Irritation Rabbit Moderate

Skin Irritation Rabbit Moderate

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

### **Butylated hydroxytoluene**

4 Week(s) Rat Oral 5185 mg/kg LOAEL Liver

4 Day(s) Mouse Oral 2000 mg/kg LOAEL Liver, Kidney, Ureter, Bladder

### **Doxercalciferol**

52 Week(s) Monkey No route specified 0.6 µg/kg/day NOAEL Bone

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

### **Butylated hydroxytoluene**

Embryo / Fetal Development Rat Oral 6 g/kg LOEL Teratogenic,

# SAFETY DATA SHEET

Product Name Doxercalciferol Injection (Hospira, Inc.)  
Revision date 26-Jun-2023

Page 10 / 13  
Version 2

## Doxercalciferol

Fertility Rat Oral 2.5 µg/kg/day NOAEL No effects at maximum dose  
Embryo / Fetal Development Rabbit No route specified 0.1 µg/kg/day NOAEL No evidence of impaired fertility or harm to the fetus  
Embryo / Fetal Development Rat No route specified 20 µg/kg/day NOAEL Not Teratogenic, No fetotoxicity

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

### Doxercalciferol

Bacterial Mutagenicity (Ames) Bacteria Negative  
Mammalian Cell Mutagenicity Mouse Lymphoma Negative  
*In Vitro* Chromosome Aberration Human Lymphocytes Positive with activation  
*In Vivo* Micronucleus Mouse Negative

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

### Butylated hydroxytoluene

IARC Group 3 (Not Classifiable)

## 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:** Environmental properties have not been thoroughly investigated. The following information is available for the individual ingredients. Releases to the environment should be avoided.

### 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

### 12.2. Persistence and degradability

**Persistence and degradability** No information available.

### 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 Doxercalciferol Injection (Hospira, Inc.)  
Revision date 26-Jun-2023

Page 11 / 13  
Version 2

## PBT and vPvB assessment

Chemical name	PBT and vPvB assessment
Ethyl alcohol (ethanol)	The substance is not PBT / vPvB PBT assessment does not apply
Polysorbate 20	The substance is not PBT / vPvB PBT assessment does not apply
Sodium phosphate, monobasic	PBT assessment does not apply
SODIUM CHLORIDE	The substance is not PBT / vPvB PBT assessment does not apply
Edetate disodium	The substance is not PBT / vPvB PBT assessment does not apply
Butylated hydroxytoluene	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.

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

# SAFETY DATA SHEET

Product Name Doxercalciferol Injection (Hospira, Inc.)  
Revision date 26-Jun-2023

Page 12 / 13  
Version 2

<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
Ethyl alcohol (ethanol)	
<b>CERCLA/SARA Section 313 de minimus %</b>	Not Listed
<b>California Proposition 65</b>	carcinogen 7/1/1988 when associated with alcohol abuse carcinogen 4/29/2011 developmental toxicity 10/1/1987
<b>TSCA</b>	Present
<b>EINECS</b>	200-578-6
<b>AICS</b>	Present
Sodium Phosphate Dibasic Heptahydrate	
<b>CERCLA/SARA Section 313 de minimus %</b>	Not Listed
<b>California Proposition 65</b>	Not Listed
<b>EINECS</b>	Not Listed
<b>AICS</b>	Present
<b>Standard for Uniform Scheduling of Medicines and Poisons (SUSMP)</b>	Schedule 5
Polysorbate 20	
<b>CERCLA/SARA Section 313 de minimus %</b>	Not Listed
<b>California Proposition 65</b>	Not Listed
<b>TSCA</b>	Present
<b>EINECS</b>	Not Listed
<b>AICS</b>	Present
Sodium phosphate, monobasic	
<b>CERCLA/SARA Section 313 de minimus %</b>	Not Listed
<b>California Proposition 65</b>	Not Listed
<b>TSCA</b>	Present
<b>EINECS</b>	231-449-2
<b>AICS</b>	Present
SODIUM CHLORIDE	
<b>CERCLA/SARA Section 313 de minimus %</b>	Not Listed
<b>California Proposition 65</b>	Not Listed
<b>TSCA</b>	Present
<b>EINECS</b>	231-598-3
<b>AICS</b>	Present
Edetate disodium	
<b>CERCLA/SARA Section 313 de minimus %</b>	Not Listed
<b>California Proposition 65</b>	Not Listed
<b>TSCA</b>	Present
<b>EINECS</b>	205-358-3
<b>AICS</b>	Present
Butylated hydroxytoluene	
<b>CERCLA/SARA Section 313 de minimus %</b>	Not Listed
<b>California Proposition 65</b>	Not Listed
<b>TSCA</b>	Present
<b>EINECS</b>	204-881-4
<b>AICS</b>	Present
Doxercalciferol	
<b>CERCLA/SARA Section 313 de minimus %</b>	Not Listed
<b>California Proposition 65</b>	Not Listed
<b>EINECS</b>	Not Listed

Chemical name	French RG number	Title
Ethyl alcohol (ethanol) 64-17-5	RG 84	-
SODIUM CHLORIDE 7647-14-5	RG 78	-

# SAFETY DATA SHEET

Product Name Doxercalciferol Injection (Hospira, Inc.)  
Revision date 26-Jun-2023

Page 13 / 13  
Version 2

## 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 does not contain substances subject to authorization (Regulation (EC) No. 1907/2006 (REACH), Annex XIV) This product does not contain substances subject to restriction (Regulation (EC) No. 1907/2006 (REACH), Annex XVII)

## Persistent Organic Pollutants

Not applicable

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

Not applicable

Chemical name	Plant protection products directive (91/414/EEC)
SODIUM CHLORIDE - 7647-14-5	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.1; H300 - Fatal if swallowed Flammable liquids-Cat.2; H225 - Highly flammable liquid and vapor

**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 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 11 - Toxicology Information. Updated Section 12 - Ecological Information.

**Revision date** 26-Jun-2023

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

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