



SAFETY DATA SHEET

Revision date 19-Mar-2020

Version 1.01

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

1.1. Product identifier

Product Name Paricalcitol Injection (Hospira Inc.)
Product Code(s) PZ03129
Trade Name: Paricalcitol 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

1.4. Emergency telephone number

Emergency Telephone Chemtrec 1-800-424-9300 International Chemtrec (24 hours):+1-703-527-3887
E-mail address pfizer-MSDS@pfizer.com

Section 2: HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture

Flammable liquids Category 2

2.2. Label elements

Signal word Danger

Hazard statements H226 - Flammable liquid and vapor

Precautionary Statements P210 - Keep away from heat/sparks/open flames/hot surfaces. - No smoking
P233 - Keep container tightly closed

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P240 - Ground/bond container and receiving equipment
P241 - Use explosion-proof electrical/ventilating/lighting/equipment
P242 - Use only non-sparking tools
P243 - Take precautionary measures against static discharge
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
P370 + P378 - In case of fire: Use .? 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

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

Hazardous

Chemical Name	EC No	CAS No	Weight-%	Classification according to Regulation (EC) No. 1272/2008 [CLP]	REACH Registration Number
Ethyl alcohol (ethanol)	200-578-6	64-17-5	34	Flam. Liq. 2 (H225)	
Paricalcitol	Not Listed	131918-61-1	<0.001	Not Listed	

NonHazardous

Chemical Name	EC No	CAS No	Weight-%	Classification according to Regulation (EC) No. 1272/2008 [CLP]	REACH Registration Number
Water	231-791-2	7732-18-5	56	Not Listed	
Propylene glycol	200-338-0	57-55-6	*	Not Listed	

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

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.

Section 4: FIRST AID MEASURES

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4.1. Description of first aid measures

Inhalation	Remove to fresh air. Seek immediate medical attention/advice.
Eye contact	Flush eye(s) immediately with plenty of water. If irritation occurs or persists, get medical attention.
Skin contact	Wash off immediately with soap and plenty of water. If skin irritation persists, call a physician.
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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5.2. Special hazards arising from the substance or mixture

Specific hazards arising from the chemical	highly flammable. Vapors are heavier than air and may travel along surfaces to remote ignition sources and flash back. Material may burn with invisible flame. 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.
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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. 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.
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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.

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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

Flammable liquid and vapor- keep away from ignition sources and clean up spills promptly. Eliminate possible ignition sources (e.g., heat, sparks, flame, impact, friction, electricity), and follow appropriate grounding and bonding procedures. Avoid contact with eyes, skin, and clothing. Use appropriate personal protective equipment. Wash thoroughly after handling. Restrict access to work area. Avoid breathing vapor or mist. 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 heat 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.

Ethyl alcohol (ethanol)

ACGIH TLV	STEL: 1000 ppm
Austria	1000 ppm
	1900 mg/m ³
	STEL 2000 ppm
	STEL 3800 mg/m ³
Bulgaria	1000 mg/m ³
Czech Republic	1000 mg/m ³
	Ceiling: 3000 mg/m ³
Denmark	1000 ppm
	1900 mg/m ³
Estonia	500 ppm
	1000 mg/m ³
	STEL: 1000 ppm
	STEL: 1900 mg/m ³
Finland	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

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Hungary	380 mg/m ³ 1900 mg/m ³ STEL: 7600 mg/m ³
Ireland	STEL: 1000 ppm
Latvia	1000 mg/m ³
Netherlands	260 mg/m ³ STEL: 1900 mg/m ³ H*
Poland	1900 mg/m ³
Romania	1000 ppm 1900 mg/m ³ STEL: 5000 ppm
Russia	STEL: 9500 mg/m ³ TWA: 1000 mg/m ³ STEL: 2000 mg/m ³
Slovakia	500 ppm
Spain	960 mg/m ³ STEL: 1000 ppm
Switzerland	STEL: 1910 mg/m ³ 500 ppm 960 mg/m ³ STEL: 1000 ppm
OSHA PEL	STEL: 1920 mg/m ³ 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
Propylene glycol	
Ireland	10 mg/m ³ 150 ppm 470 mg/m ³ STEL: 1410 mg/m ³ STEL: 30 mg/m ³ STEL: 450 ppm
Latvia	7 mg/m ³
Poland	100 mg/m ³
Russia	MAC: 7 mg/m ³
United Kingdom	TWA: 150 ppm TWA: 474 mg/m ³ TWA: 10 mg/m ³ STEL: 450 ppm STEL: 1422 mg/m ³ STEL: 30 mg/m ³

Pfizer 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.

Paricalcitol

Pfizer Occupational Exposure Band (OEB): OEB 5 (control exposure to <1ug/m³)

8.2. Exposure controls

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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. It is recommended that all operations be fully enclosed and no air recirculated.
Environmental exposure controls	No information available.
Personal protective equipment	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. Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).
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	Colourless
Molecular formula (MF):	Mixture
Molecular weight	Mixture
Odor	Alcohol.
Odor threshold	No data available

<u>Property</u>	<u>Values</u>
pH	
Melting point / freezing point	No data available
Boiling point / boiling range	No data available
Flash point	21.1
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

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Solubility(ies)	No data available
Autoignition temperature	No data available
Decomposition temperature	No data available
Kinematic viscosity	No data available
Dynamic viscosity	2.76 cps @25C
Explosive properties	No data available
Upper Explosive Limits (Liquid) (% by Vol.):	19% (ethanol)
Lower Explosive Limits (Liquid) (% by Vol.):	3.3% (ethanol)
Oxidizing properties	None

9.2. Other information

Liquid Density	No data available
Bulk density	No data 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 Oxides of carbon.

Section 11: TOXICOLOGICAL INFORMATION

11.1. Information on toxicological effects

General Information: The information included in this section describes the potential hazards of the individual ingredients

Short term May cause eye irritation (based on components)

Known Clinical Effects: Adverse effects associated with therapeutic use include diarrhea, increase in blood pressure (hypertension), dizziness, vomiting.

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

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

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Rat IV Minimum Lethal Dose > 16 ug/kg
Mouse IV Minimum Lethal Dose > 24 ug/kg

Chemical Name	Oral LD50	Dermal LD50	Inhalation LC50
Water	> 90 mL/kg (Rat)	-	-
Ethyl alcohol (ethanol)	= 7060 mg/kg (Rat)	-	= 124.7 mg/L (Rat) 4 h
Propylene glycol	= 20 g/kg (Rat)	= 20800 mg/kg (Rabbit)	-

Irritation / Sensitization: (Study Type, Species, Severity)

Ethyl alcohol (ethanol)

Eye Irritation Rabbit Severe
Skin Irritation Rabbit Mild

Propylene glycol

Skin Irritation Rabbit Mild
Eye Irritation Rabbit Mild

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

Paricalcitol

12 Month(s) Dog Intravenous 0.02 µg/kg/day NOAEL Blood

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

Paricalcitol

Embryo / Fetal Development Rabbit Intravenous 0.1 ug/kg/day NOAEL Fetotoxicity, Not teratogenic, Maternal toxicity

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

Paricalcitol

Bacterial Mutagenicity (Ames) Negative
Mouse Lymphoma Assay Negative
Chromosome Aberration Human Lymphocytes Negative
In Vivo Micronucleus Mouse Negative

Paricalcitol

104 Week(s) Mouse Subcutaneous 1 ug/kg/day LOEL Female reproductive system, Tumors
104 Week(s) Rat Subcutaneous 0.15 ug/kg/day LOEL Benign tumors

Carcinogenicity

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

Ethyl alcohol (ethanol)

IARC

Group 1 (Carcinogenic to Humans)

Section 12: ECOLOGICAL INFORMATION

Environmental Overview:

Environmental properties have not been thoroughly investigated. 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

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

12.2. Persistence and degradability

Persistence and degradability No information available.

Ethyl alcohol (ethanol)

Not 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

PBT and vPvB assessment No information available.

Chemical Name	PBT and vPvB assessment
Ethyl alcohol (ethanol)	The substance is not PBT / vPvB PBT assessment does not apply
Propylene glycol	The substance is not PBT / vPvB PBT assessment does not apply

12.6. Other adverse effects

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 waste water 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.

This material is regulated for transportation as a hazardous material/dangerous good.

UN number: UN 1170
UN proper shipping name: Ethanol solution
TDG 3
Packing group: II

Flash Point (°C): 21.1
Additional Information Limited Quantity Exceptions may apply for small quantities packed in combination packaging. See applicable DOT/IATA/IMDG modal regulations for specific instructions.

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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

Ethyl alcohol (ethanol)

CERCLA/SARA Section 313 de minimus %	Not Listed
California Proposition 65	carcinogen 4/29/2011 in alcoholic beverages carcinogen 7/1/1988 when associated with alcohol abuse developmental toxicity 10/1/1987 in alcoholic beverages
TSCA	Present
EINECS	200-578-6
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

Paricalcitol

CERCLA/SARA Section 313 de minimus %	Not Listed
California Proposition 65	Not Listed
EINECS	Not Listed
Standard for Uniform Scheduling of Medicines and Poisons (SUSMP)	Schedule 4

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

Flammable liquids-Cat.2; H226 - Flammable liquid and vapor

Data Sources: Pfizer proprietary drug development information. Publicly available toxicity information.

Reason for revision Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking. Updated Section 12 - Ecological Information.

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Prepared By Product Stewardship Hazard Communication
Pfizer Global Environment, Health, and Safety Operations

Pfizer Inc believes that the information contained in this Material Safety Data Sheet is accurate, and while it is provided in

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good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time.