



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

Hospira UK Limited

275 North Field Drive Horizon
Lake Forest, Illinois 60045 Honey Lane
1-800-879-3477 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

Physical Hazards 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

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



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

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	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)	34	-	200-578-6	Flam. Liq. 2 (H225)	Not Listed	No data available	No data available
	Paricalcitol (CAS #: 131918-61-1)	<0.001		Not Listed	Not classified as hazardous	Not Listed	No data available	No data available
1	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)	56	-	231-791-2	Not classified as hazardous	Not Listed	No data available	No data available
Ī	Propylene glycol	*		200-338-0	Not classified	Not Listed	No data	No data

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(CAS #: 57-55-6)		as hazardous	available	available

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

Acute Toxicity Estimate
No information available

Chemical name	Oral LD50	Dermal LD50		Inhalation LC50 - 4 hour - vapor - mg/L	
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
Propylene glycol 57-55-6	20000	20800	No data available	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.

Section 4: FIRST AID MEASURES

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.

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

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

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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

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explosion-proof equipment.

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

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 ConditionsStore 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

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Exposure Limits

Hungary

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

Ethyl alcohol (ethanol)

STEL: 1000 ppm **ACGIH TLV** Austria 1000 ppm

1900 mg/m³ STEL 2000 ppm STEL 3800 mg/m3 1000 mg/m³

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Bulgaria Czech Republic 1000 mg/m³

Ceiling: 3000 mg/m³

Denmark 1000 ppm 1900 mg/m³

Estonia 500 ppm 1000 mg/m³

STEL: 1000 ppm STEL: 1900 mg/m3

Finland 1000 ppm 1900 mg/m³

STEL: 1300 ppm STEL: 2500 mg/m³

1900 mg/m³ France 200 ppm Germany

380 mg/m³

Ceiling / Peak: 800 ppm Ceiling / Peak: 1520 mg/m³

Germany 200 ppm

380 mg/m³ 1900 mg/m³ STEL: 3800 mg/m3

STEL: 1000 ppm Ireland 1000 mg/m³ Latvia Netherlands 260 mg/m³ STEL: 1900 mg/m³

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Poland 1900 mg/m³ 1000 ppm Romania 1900 mg/m³

STEL: 5000 ppm STEL: 9500 mg/m³ TWA: 1000 mg/m³

Russia MAC: 2000 mg/m3

Slovakia 500 ppm

960 mg/m³ Spain STEL: 1000 ppm STEL: 1910 mg/m³

500 ppm Switzerland 960 mg/m³

STEL: 1000 ppm STEL: 1920 mg/m³

OSHA PEL 1000 ppm 1900 mg/m³

(vacated) TWA: 1000 ppm

(vacated) TWA: 1900 mg/m³ United Kingdom TWA: 1000 ppm

TWA: 1920 mg/m³ STEL: 3000 ppm STEL: 5760 mg/m³

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Propylene glycol

Ireland 10 mg/m³ 150 ppm 470 mg/m³

> STEL: 1410 mg/m³ STEL: 30 mg/m³ STEL: 450 ppm 7 mg/m³

 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

Pfizer Occupational Exposure Band

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(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

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revision when new information becomes available.

Paricalcitol

Pfizer Occupational Exposure

Band (OEB):

OEB 5 (control exposure to <1 ug/m³)

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. 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.).

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General hygiene considerations

Handle in accordance with good industrial hygiene and safety practice.

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Section 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

Physical stateLiquidColorColourlessOdorAlcohol.

Odor threshold No information available

Molecular formulaMixtureMolecular weightMixture

<u>Property</u> <u>Values</u>

pHNo data availableMelting point / freezing pointNo data available

Boiling point / boiling range

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 pressureNo data availableVapor densityNo data availableRelative densityNo data available

Water solubility Soluble

Solubility(ies)No data availablePartition coefficientNo data availableAutoignition temperatureNo data availableDecomposition temperatureNo data availableKinematic viscosityNo data availableDynamic viscosity2.76 cps @25C

Particle characteristics

Particle SizeNo information availableParticle Size DistributionNo information availableExplosive propertiesNo information available

Upper Explosive Limits (Liquid) (% by Vol.):19% (ethanol)Lower Explosive Limits (Liquid) (% by Vol.):3.3% (ethanol)

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

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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 hazard classes as defined in Regulation (EC) No 1272/2008

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 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. Based on available data, the classification criteria are not met. Respiratory or skin sensitization 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

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)		-	= 116.9 mg/L (Rat) 4 h	
			= 133.8 mg/L (Rat) 4 h	
Propylene glycol	= 20 g/kg (Rat)	= 20800 mg/kg (Rabbit)	-	

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

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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)

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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

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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

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IARC, US OSHA or NTP.

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. 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.

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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

No information available. PBT and vPvB assessment

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

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.

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

UN number: **UN 1170 UN** proper shipping name: Ethanol solution Transport hazard class(es): Not applicable Packing group:

Environmental Hazard(s): Not applicable

Special precautions for user: Not applicable

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 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

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 Schedule 4

Poisons (SUSMP)

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

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

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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

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

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

Updated Section 1 - Identification of the Substance/Preparation and the Reason for revision

Company/Undertaking. Updated Section 12 - Ecological Information.

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Prepared By Pfizer Global Environment, Health, and Safety

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

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