

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

1.1. Product identifier

Product Name Clindamycin phosphate injection, solution (Hospira, Inc.)

Product Code(s)
Synonyms
PNU-28508E
Trade Name:
Chemical Family:
Mixture

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

Recommended Use Pharmaceutical product used as antibiotic agent

1.3. Details of the supplier of the safety data sheet

Hospira, A Pfizer Company

275 North Field Drive

Hospira UK Limited
Horizon

Lake Forest, Illinois 60045
1-800-879-3477
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

Skin corrosion/irritationCategory 3Serious eye damage/eye irritationCategory 2ASkin sensitizationCategory 1

2.2. Label elements

Signal word Warning

Hazard statements H319 - Causes serious eye irritation

H316 - Causes mild skin irritation

H317 - May cause an allergic skin reaction

Precautionary Statements P261 - Avoid breathing dust/fume/gas/mist/vapors/spray

P264 - Wash hands thoroughly after handling

P272 - Contaminated work clothing must not be allowed out of the workplace P280 - Wear protective gloves/protective clothing/eye protection/face protection

P302+ P352 - IF ON SKIN: Wash with plenty of soap and water

P333 + P313 - If skin irritation or rash occurs: Get medical advice/attention

Product Name Clindamycin phosphate injection, solution (Hospira, Inc.)

Revision date 30-Jun-2022 Version 1.01

P363 - Wash contaminated clothing before reuse

P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes.

Remove contact lenses, if present and easy to do. Continue rinsing

P337 + P313 - If eye irritation persists: Get medical advice/attention

P501 - Dispose of contents/container in accordance with all local and national regulations

Page 2/14



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)
Clindamycin Phosphate (CAS #: 24729-96-2)	15		246-433-0	Acute Tox.4 (H302) Eye Irrit.2A (H319) Skin Irrit.3 (H316) Skin Sens.1 (H317)	Not Listed	No data available	No data available
BENZYL ALCOHOL (CAS #: 100-51-6)	<1.0		202-859-9	Acute Tox. 4 (H302) Acute Tox. 4 (H332)	Not Listed	No data available	No data available
Sodium hydroxide (CAS #: 1310-73-2)	**	-	215-185-5	Skin Corr.1A (H314)	Eye Irrit. 2 :: 0.5%<=C<2% Skin Corr. 1A :: C>=5% Skin Corr. 1B :: 2%<=C<5% Skin Irrit. 2 :: 0.5%<=C<2%	No data available	No data available

Product Name Clindamycin phosphate injection, solution (Hospira, Inc.) Revision date 30-Jun-2022

+ Hydrochloric Acid	**	-	231-595-7	Acute Tox. 3	Eye Irrit. 2 ::	No data	No data
(CAS #: 7647-01-0)				(H331)	10%<=C<25%	available	available
(, ,	Skin Corr. 1B ::		
				(H314)	C>=25%		
				Press. Gas	Skin Irrit. 2 ::		
				1 1033. 043	10%<=C<25%		
					STOT SE 3 ::		
					C>=10%		
NonHazardous							
Chemical name	Weight-%	REACH	EC No	Classification	Specific	M-Factor	M-Factor
	-	Registration		according to	concentration		(long-term)
		Number		Regulation	limit (SCL)		, , ,
				(EC) No.	` ′		
				1272/2008			
				[CLP]			
Water	*	-	231-791-2	Not classified	Not Listed	No data	No data
(CAS #: 7732-18-5)				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	Inhalation LC50 - 4	Inhalation LC50 - 4
			hour - dust/mist -	hour - vapor - mg/L	hour - gas - ppm
			mg/L		
Water	89838.9	No data available	No data available	No data available	No data available
7732-18-5					
Clindamycin Phosphate	1832	No data available	No data available	No data available	No data available
24729-96-2					
BENZYL ALCOHOL	1230	2000	4.178	No data available	No data available
100-51-6					
Sodium hydroxide	325	1350	No data available	No data available	No data available
1310-73-2					
+ Hydrochloric Acid	238	5010	No data available	No data available	563.3022
7647-01-0					

Additional information

- * Proprietary
- ** to adjust pH
- + Substance with a Union workplace exposure limit

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 Flush with water while holding eyelids open for at least 15 minutes. If irritation occurs or

persists, get medical attention.

Skin contact Remove contaminated clothing and wash exposed area with soap and water. Obtain

medical assistance if irritation occurs.

PZ03369

Page 3 / 14 Version 1.01

Product Name Clindamycin phosphate injection, solution (Hospira, Inc.)

Revision date 30-Jun-2022 Version 1.01

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

Page 4/14

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, CO2, alcohol-resistant foam or water spray.

5.2. Special hazards arising from the substance or mixture

Specific hazards arising from the

chemical

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

Hazardous combustion products

Formation of toxic gases is possible during heating or fire.

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.

Use personal protection recommended in Section 8. For emergency responders

6.2. Environmental precautions

Place waste in an appropriately labeled, sealed container for disposal. Care should be **Environmental precautions**

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.

Clean contaminated objects and areas thoroughly observing environmental regulations. Prevention of secondary hazards

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

Product Name Clindamycin phosphate injection, solution (Hospira, Inc.)

Revision date 30-Jun-2022 Version 1.01

Advice on safe handling

Avoid breathing mist or aerosols. 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

Store as directed by product packaging. **Storage Conditions**

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.

Clindamycin Phosphate

Pfizer OEL TWA-8 Hr: 100 µg/m³

BENZYL ALCOHOL

Pfizer OEL TWA-8 Hr: 10 ppm

BENZYL ALCOHOL

Bulgaria 5.0 mg/m³ Czech Republic 40 ma/m³

Ceiling: 80 mg/m³

10 ppm Finland

45 mg/m³

22 mg/m³ can occur as vapor and aerosol at the same time Germany

5 ppm can occur as vapor and aerosol at the same time

Page 5/14

Ceiling / Peak: 44 mg/m³ Ceiling / Peak: 10 ppm

Skin

Germany 5 ppm

22 mg/m³

Ceiling Limit Value 25 mg/m³ 5 mg/m³ Latvia Poland 240 mg/m³ Russia MAC: 5 mg/m³

Skin

Switzerland 5 ppm

22 mg/m³

Sodium hydroxide

ACGIH OEL (Ceiling) 2 mg/m³

Ceiling: 2 mg/m³ **ACGIH TLV**

Austria 2 mg/m³

STEL 4 mg/m³ 2.0 mg/m³

Bulgaria Czech Republic 1 mg/m^3

Ceiling: 2 mg/m3

Denmark Ceiling: 2 mg/m³ 1 mg/m³ Estonia

STEL: 2 mg/m3

Page 6/14

Product Name Clindamycin phosphate injection, solution (Hospira, Inc.) Revision date 30-Jun-2022

version date 30-Jun-2022 Version 1.01

Finland Ceiling: 2 mg/m³ France 2 mg/m³

Hungary 1 mg/m³ STEL: 2 mg/m³

IrelandSTEL: 2 mg/m³Ceiling Limit Value2 mg/m³

 Latvia
 0.5 mg/m³

 Poland
 STEL: 1 mg/m³

 0.5 mg/m³
 0.5 mg/m³

Romania 1 mg/m³ STEL: 3 mg/m³

 Slovakia
 2 mg/m³

 Spain
 STEL: 2 mg/m³

 Switzerland
 2 mg/m³

 STEL: 2 mg/m³

OSHA PEL 2 mg/m³

(vacated) Ceiling: 2 mg/m³

Jnited Kingdom STEL: 2 mg/m³

United Kingdom
+ Hydrochloric Acid

European Union

ACGIH TI V

ACGIH TLV Ceiling: 2 ppm Austria 5 ppm

8 mg/m³ STEL 10 ppm STEL 15 mg/m³ STEL: 10 ppm

Bulgaria STEL: 10 ppm STEL: 15.0 mg/m³

5 ppm 8.0 mg/m³ 8 mg/m³

Czech Republic 8 mg/m³
Ceiling: 15 mg/m³

Estonia 5 ppm

8 mg/m³ STEL: 10 ppm STEL: 15 mg/m³ TWA: 5 ppm TWA: 8 mg/m³ STEL: 10 ppm

STEL: 15 mg/m³
Finland STEL: 5 ppm

STEL: 7.6 mg/m³
Germany 2 ppm

rmany 2 ppm 3.0 mg/m³

Ceiling / Peak: 4 ppm Ceiling / Peak: 6 mg/m³

Germany 2 ppm 3 mg/m³

Hungary 8 mg/m³

STEL: 16 mg/m³
Ireland 8 mg/m³

5 ppm STEL: 10 ppm STEL: 15 mg/m³

STEL: 10 ppm STEL: 15 mg/r Italy 5 ppm

8 mg/m³ STEL: 10 ppm STEL: 15 mg/m³

Ceiling Limit Value STEL: 15 mg

3.0 mg/m³ Latvia 5 ppm

Product Name Clindamycin phosphate injection, solution (Hospira, Inc.)

Revision date 30-Jun-2022 Version 1.01

8 mg/m³ STEL: 10 ppm Page 7 / 14

STEL: 15 mg/m³
Netherlands 8 mg/m³

Poland STEL: 15 mg/m³ STEL: 10 mg/m³

5 mg/m³
Romania 5 ppm
8 mg/m³

8 mg/m³ STEL: 10 ppm STEL: 15 mg/m³ MAC: 5 mg/m³

Russia MAC: 5 mg/m³ Slovakia 5 ppm

8.0 mg/m³ 5 ppm 7.6 mg/m³ STEL: 10 ppm

STEL: 15 mg/m³
Switzerland 2 ppm

3 mg/m³ STEL: 4 ppm STEL: 6 mg/m³ 5 ppm

U.S. - OSHA - Final PELs - Ceiling Limits 5 ppm 7 mg/m³

OSHA PEL (vacated) Ceiling: 5 ppm

(vacated) Ceiling: 7 mg/m³

Ceiling: 5 ppm Ceiling: 7 mg/m³ TWA: 1 ppm TWA: 2 mg/m³

STEL: 5 ppm STEL: 8 mg/m³

8.2. Exposure controls

United Kingdom

Spain

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.

Personal protective equipment Refer to applicable national standards and regulations in the selection and use of personal

protective equipment (PPE). Contact your safety and health professional or safety equipment supplier for assistance in selecting the correct protective clothing/equipment based on an assessment of the workplace conditions, other chemicals used or present in

the workplace and specific operational processes.

Eye/face protection Wear safety glasses or goggles if eye contact is possible. (Eye protection must meet the

standards in accordance with EN166, ANSI Z87.1 or international equivalent.).

Hand protection Impervious gloves (e.g. Nitrile, etc.) are recommended if skin contact with drug product is

possible and for bulk processing operations. (Protective gloves must meet the standards in

accordance with EN374, ASTM F1001 or international equivalent.).

Skin and body protection Impervious protective clothing is recommended if skin contact with drug product is possible

and for bulk processing operations. (Protective clothing must meet the standards in

accordance with EN13982, ANSI 103 or international equivalent.).

Respiratory protectionUnder normal conditions of use, if the applicable Occupational Exposure Limit (OEL) is

exceeded, wear an appropriate respirator with a protection factor sufficient to control

Product Name Clindamycin phosphate injection, solution (Hospira, Inc.)

Revision date 30-Jun-2022 Version 1.01

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.)

Page 8/14

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 Solution
Color Clear, colorless

Odor No information available.
Odor threshold No information available

Molecular formulaMixtureMolecular weightMixture

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

pHMelting point / freezing pointNo data availableNo data available

Boiling point / boiling range
Flash point No information available

Evaporation rate

No data available

Flammability (solid, gas)

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 No data available 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

Particle characteristics
Particle Size
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

9.2.2. Other safety characteristics

No information available

Section 10: STABILITY AND REACTIVITY

10.1. Reactivity

Product Name Clindamycin phosphate injection, solution (Hospira, Inc.)
Revision date 30-Jun-2022

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

10.5. Incompatible materials

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

10.6. Hazardous decomposition products

Hazardous decomposition products No data available.

Section 11: TOXICOLOGICAL INFORMATION

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

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

ingredients

Short term Active ingredient may be harmful if swallowed. May cause eye irritation. May cause skin

irritation (based on components).

Known Clinical Effects: Individuals sensitive to this material or other materials in its chemical class may develop

allergic reactions. Clinical use of this drug has caused sore throat, fever, gastrointestinal disturbances, abnormal liver function tests, kidney dysfunction. Pseudomembranous colitis (manifested by watery diarrhea, urge to defecate, abdominal cramps, low-grade fever,

Page 9/14

Version 1.01

bloody stools, and abdominal pain) may also occur.

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

Serious eye damage/eye irritation
Skin corrosion/irritation
Classification is based on mixture calculation methods based on component data.
Classification is based on mixture calculation methods based on component data.
Classification is based on mixture calculation methods based on component data.

STOT - single exposure
STOT - repeated exposure
Reproductive toxicity
Germ cell mutagenicity
Carcinogenicity

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

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

Clindamycin Phosphate

Rat Oral LD 50 1832 mg/kg

Rat Para-periosteal LD 50 321 mg/kg Rat Intraperitoneal LD 50 745 mg/kg

Mouse Oral LD 50 2359 mg/kg

Mouse Intravenous LD 50 820 mg/kg

BENZYL ALCOHOL

Rat Oral LD 50 1230 mg/kg Mouse Oral LD 50 1360 mg/kg

Rabbit Dermal LD 50 2 gm/kg

Edetate disodium

Rat Oral LD50 2000-2200 mg/kg

Sodium hydroxide

Mouse IP LD50 40 mg/kg

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Water	> 90 mL/kg (Rat)	-	-

Product Name Clindamycin phosphate injection, solution (Hospira, Inc.)

Revision date 30-Jun-2022 Version 1.

Page 10 / 14 Version 1.01

Clindamycin Phosphate	= 1832 mg/kg (Rat)	-	-
BENZYL ALCOHOL	= 1230 mg/kg (Rat)	= 2 g/kg(Rabbit)	> 4178 mg/m³(Rat)4 h
Sodium hydroxide	= 325 mg/kg (Rat)	= 1350 mg/kg (Rabbit)	-
+ Hydrochloric Acid	238 - 277 mg/kg (Rat)	> 5010 mg/kg(Rabbit)	= 1.68 mg/L (Rat)1 h

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

Clindamycin Phosphate

Eye Irritation Rabbit Moderate Skin Irritation Rabbit Mild

BENZYL ALCOHOL

Eye Irritation Rabbit Severe
Skin Irritation Rabbit Minimal
Skin Irritation Guinea Pig Moderate

Sodium hydroxide

Eye Irritation Rabbit Severe Skin Irritation Rabbit Severe

+ Hydrochloric Acid

Skin irritation Severe Eye irritation Severe

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

Clindamycin Phosphate

6 Month(s) Rat Oral 600 mg/kg/day NOAEL No effects at maximum dose 6 Month(s) Dog Oral 600 mg/kg/day NOAEL Gastrointestinal system

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

Clindamycin Phosphate

Prenatal & Postnatal Development Rat Subcutaneous 250 mg/kg NOAEL Not teratogenic Prenatal & Postnatal Development Rat Oral 300 mg/kg/day NOAEL Not Teratogenic Prenatal & Postnatal Development Mouse Oral 600 mg/kg/day NOAEL Not Teratogenic

Prenatal & Postnatal Development Rabbit Subcutaneous 5 mg/kg/day NOAEL Not Teratogenic, Maternal Toxicity

Reproductive & Fertility Rat Oral 300 mg/kg/day NOAEL No effects at maximum dose

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

Clindamycin Phosphate

Bacterial Mutagenicity (Ames) Salmonella Negative

In Vitro Micronucleus Rat Negative

+ Hydrochloric Acid

Bacterial Mutagenicity (Ames) Salmonella Negative

In Vivo Micronucleus Rat Negative

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

OSHA.

+ Hydrochloric Acid

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

Product Name Clindamycin phosphate injection, solution (Hospira, Inc.) Revision date 30-Jun-2022

Other adverse effects No information available.

Section 12: ECOLOGICAL INFORMATION

Environmental Overview: Based on available data, the classification criteria are not met. 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) BENZYL ALCOHOL

460 - 770 mg/L Pimephales promelas (Fathead Minnow) EPA LC50 96 hours Daphnia magna (Water Flea) NPDES OECD EC50 48 Hours 230 mg/L Pseudokirchneriella subcapitata (Green Alga) OECD EC50 72 hours 500 mg/L

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

No information available. **Bioaccumulation**

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
BENZYL ALCOHOL	The substance is not PBT / vPvB
Sodium hydroxide	The substance is not PBT / vPvB PBT assessment does
	not apply
+ Hydrochloric Acid	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

PZ03369

Page 11/14 Version 1.01

Product Name Clindamycin phosphate injection, solution (Hospira, Inc.) Revision date 30-Jun-2022

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.

UN number:
UN proper shipping name:
Transport hazard class(es):
Packing group:
Environmental Hazard(s):
Not applicable
Not applicable
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
EINECS	231-791-2
AICS	Present
Clindamycin Phosphate	
CERCLA/SARA Section 313 de minimus %	Not Listed
California Proposition 65	Not Listed
EINECS	246-433-0
BENZYL ALCOHOL	
CERCLA/SARA Section 313 de minimus %	Not Listed
California Proposition 65	Not Listed
TSCA	Present
EINECS	202-859-9
AICS	Present
Sodium hydroxide	
CERCLA/SARA Section 313 de minimus %	Not Listed
Hazardous Substances RQs	1000 lb
California Proposition 65	Not Listed
TSCA	Present
EINECS	215-185-5
AICS	Present Schedule 5
Standard for Uniform Scheduling of Medicines and	Schedule 5
Poisons (SUSMP)	Scriedule 6
+ Hydrochloric Acid CERCLA/SARA Section 313 de minimus %	1.0 %
Hazardous Substances RQs	5000 lb
California Proposition 65	Not Listed
TSCA	Present
EINECS	231-595-7
	201-000-1

Present

PZ03369

AICS

Page 12 / 14 Version 1.01

Product Name Clindamycin phosphate injection, solution (Hospira, Inc.) Revision date 30-Jun-2022

Revision date 30-Jun-2022 Version 1.01

Standard for Uniform Scheduling of Medicines and Poisons (SUSMP)

Schedule 5 Schedule 6 Page 13 / 14

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

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)

Chemical name	Restricted substance per REACH	Substance subject to authorization per
	Annex XVII	REACH Annex XIV
Sodium hydroxide - 1310-73-2	Use restricted. See item 75.	
+ Hydrochloric Acid - 7647-01-0	Use restricted. See item 75.	

Persistent Organic Pollutants

Not applicable

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

Not applicable

Chemical name	Lower-tier requirements (tons)	Upper-tier requirements (tons)
+ Hydrochloric Acid - 7647-01-0	25	250

Chemical name	EU - Biocides
+ Hydrochloric Acid - 7647-01-0	Product-type 2: Disinfectants and algaecides not intended
·	for direct application to humans or animals

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 Serious eye damage/eye irritation-Cat.2A; H319 - Causes serious eye irritation Skin corrosion/irritation-Cat.3; H316 - Causes mild skin irritation Sensitization, skin-Cat.1; H317 - May cause an allergic skin reaction Skin corrosion/irritation-Cat.1A; Skin corrosion/irritation-Cat.1B; H314 - Causes severe skin burns and eye damage Acute toxicity, inhalation-Cat.3; H331 - Toxic if inhaled

Data Sources:

Publicly available toxicity information. Safety data sheets for individual ingredients. Pfizer proprietary drug development information.

Product Name Clindamycin phosphate injection, solution (Hospira, Inc.)

Revision date 30-Jun-2022 Version 1.01

Reason for revision Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on

Ingredients. Updated Section 7 - Handling and Storage. Updated Section 11 - Toxicology

Page 14/14

Information. Updated Section 12 - Ecological Information.

Revision date 30-Jun-2022

Prepared By Pfizer Global Environment, Health, and Safety

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