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

1.1. Product identifier

Product Name Chlorhexidine Aqueous Irrigations 0.1% w/v

Product Code(s) PZ00713
Trade Name: Not applicable
Chemical Family: Mixture

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

Recommended Use Pharmaceutical product used as disinfectant antiseptic

1.3. Details of the supplier of the safety data sheet

Pfizer Inc Pfizer Ireland Pharmaceuticals

66 Hudson Boulevard East OSG Building

New York, New York 10001 Ringaskiddy, Co. Cork.

1-800-879-3477 Ireland

+353 21 4378701

E-mail address pfizer-MSDS@pfizer.com

1.4. Emergency telephone number

Emergency Telephone Chemtrec 1-800-424-9300 International Chemtrec (24 hours):+1-703-527-3887

Section 2: HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture

GHS - Classification

Acute aquatic toxicity
Chronic aquatic toxicity
Category 3 - (H402)
Category 3 - (H412)

2.2. Label elements

Signal word Not required

Hazard statements H412 - Harmful to aquatic life with long lasting effects

Precautionary Statements

2.3. Other hazards

P273 - Avoid release to the environment

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.

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Endocrine Disruptor Information

Chemical name	EU - REACH (1907/2006) - Article 59(1)	EU - REACH (1907/2006) - Endocrine
	- Candidate List of Substances of Very	Disruptor Assessment List of
	High Concern (SVHC) for Authorisation	Substances
Nonoxynol 8	Endocrine disrupting properties	-

Section 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Substances

Not applicable

3.2 Mixtures

Hazardous

110201000							
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)
Chlorhexidine Gluconate (CAS #: 18472-51-0)	0.1		242-354-0	Acute Tox.4 (H302) Eye Dam.1 (H318) Aquatic Acute 1 (H400) Aquatic Chronic 1 (H410)	Not Listed	10	10
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
Nonoxynol 8 (CAS #: 27177-05-5)	*		248-293-6	Not classified as hazardous	Not Listed	No data available	No data available

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

Acute Toxicity Estimate

Chemical name	Oral LD50	Dermal LD50		Inhalation LC50 - 4 hour - 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
Chlorhexidine Gluconate 18472-51-0	2000	5000	No data available	No data available	No data available

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Additional information

* Proprietary

Non-hazardous ingredients provided for completeness. 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.

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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 eyes with water 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.

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

No data available

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

Not applicable.

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

nitrogen and products of chlorine

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.

6.2. Environmental precautions

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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 sectionsSee 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

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 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.

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.

8.2. Exposure controls

Engineering controls Engineering controls should be used as the primary means to control exposures. General

room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section.

Environmental exposure controls No information available.

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

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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

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the workplace and specific operational processes.

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

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

Hand protection Impervious disposable gloves (e.g. Nitrile, etc.) (double recommended) if skin contact with

drug product is possible and for bulk processing operations. (Protective gloves must meet the standards in accordance with EN374, ASTM F1001 or international equivalent.).

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.).

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

Skin and body protection

Respiratory protection

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 Blue

Odor No information available.
Odor threshold No information available

Molecular formulaMixtureMolecular weightMixture

Property Values

pHNo data availableMelting point / freezing pointNo data available

Boiling point / boiling range

Flash point

Evaporation rate

Flammability (solid, gas)

No information available
No data available
No data available

Flammability Limit in Air

Upper flammability limit: No data available

Lower flammability limit: No data available

17.535 mmHg@20C Vapor pressure No data available Vapor density Relative density No data available No data available Water solubility 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 No information available Particle Size Distribution No information available

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Partition Coefficient: (Method, pH, Endpoint, Value)

Chlorhexidine Gluconate Measured -1.81 Log P Chlorhexidine Measured Log P 0.08

Explosive properties

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

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 May cause eye irritation (based on components)

Based on available data, the classification criteria are not met. **Acute toxicity** Based on available data, the classification criteria are not met. Serious eye damage/eye irritation 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. Based on available data, the classification criteria are not met. Reproductive toxicity 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)

Chlorhexidine Gluconate

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No information available

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2000 mg/kg Rat Oral LD50

Rat Para-periosteal LD50 24.2 mg/kg

Mouse Oral LD50 1260 mg/kg

Mouse Intravenous LD50 12.9 mg/kg

Chlorhexidine

Rat Oral LD 50 5000 mg/kg Mouse Oral LD 50 2515 mg/kg

Methylene Blue

Rat Oral LD50 1180 mg/kg

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Water	> 90 mL/kg (Rat)	-	-
Chlorhexidine Gluconate	= 2 g/kg (Rat)	> 5000 mg/kg(Rabbit)	-

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

Chlorhexidine Gluconate

Eye Irritation Rabbit Severe

Chlorhexidine

Skin irritation Rabbit Slight Eye irritation Rabbit Severe

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

Chlorhexidine Gluconate

50 Day(s) Rat Oral 0.5 mg/kg/day NOAEL Lymphoid tissue

12 Month(s) Dog Oral 0.5 mg/kg/day NOAEL Liver

Chlorhexidine

6 Month(s) Dog Oral 5 mg/kg/day LOAEL Liver

12 Month(s) Dog Oral 5 mg/kg/day LOAEL Liver

13 Day(s) Rat Oral 37.5 mg/kg/day NOAEL

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

Chlorhexidine Gluconate

Embryo / Fetal Development Rat Oral > 100 mg/kg/day NOAEL Not teratogenic

Reproductive & Fertility Rat Oral 4.9 mg/kg/day NOAEL Fetotoxicity

Chlorhexidine

Embryo / Fetal Development Rat Oral 300 mg/kg/day NOAEL Fetotoxicity

Embryo / Fetal Development Rabbit Oral 40 mg/kg/day NOAEL Fetotoxicity

Reproductive & Fertility Rat Oral 4.9 mg/kg/day NOEL Fertility

Peri-/Postnatal Development Rat Oral 50 mg/kg/day NOAEL No effects at maximum dose

Methylene Blue

Fertility and Embryonic Development Rat Oral 125 mg/kg/day NOAEL Developmental toxicity

Fertility and Embryonic Development Rat Oral 50 mg/kg/day LOAEL Maternal Toxicity

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

Chlorhexidine Gluconate

In Vivo Cytogenetics Hamster Negative

In Vivo Dominant Lethal Assay Mouse Negative

Bacterial Mutagenicity (Ames) Salmonella Negative

Chlorhexidine

Bacterial Mutagenicity (Ames) Salmonella, E. coli Negative

Carcinogenicity: (Duration, Species, Route, Dose, End Point, Effect(s))

Chlorhexidine

78 Week(s) Mouse Oral, in feed 800 mg/kg/day NOAEL Not carcinogenic 105 Week(s) Rat Oral, in feed 50 mg/kg/day NOAEL Not carcinogenic

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

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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: The environmental characteristics of this mixture have not been fully evaluated. Releases to

the environment should be avoided.

12.1. Toxicity

Aquatic Toxicity: (Species, Method, End Point, Duration, Result)

Chlorhexidine Gluconate

Brachydanio rerio (Zebra fish) LC50 96 hours 2.08 mg/L Daphnia magna (Water Flea) EC50 48 hours 0.087 mg/L

Desmodesmus subcapitata (Green Alga) ErC50 72 hours 0.081 mg/L

Chlorhexidine

Brachydanio rerio (Zebra fish) OECD LC50 96 hours 1.4 mg/L Daphnia magna (Water Flea) OECD EC50 48 hours 0.049 mg/L

Desmodesmus subcapitata (Green Alga) OECD ErC50 72 hours 0.046 mg/L Desmodesmus subcapitata (Green Alga) OECD EC10 72 hours 0.017 mg/L

Bacterial Inhibition: (Inoculum, Method, End Point, Result)

Chlorhexidine

Activated sludge OECD EC50 14 mg/L

Terrestrial Toxicity: (Species, Method, End Point, Duration, Result)

Chlorhexidine

Chironomus riparius (Midges) OECD NOEC N/A 2.44 mg/kg Eisenia foetida (Earthworm) OECD LC50 N/A 563 mg/kg

Chronic Aquatic Toxicity: (Species, Method, Duration, Endpoint, Result, Adverse Endpoint)

Chlorhexidine Gluconate

Daphnia magna (Water Flea) 21 Day(s) NOEC 0.02 mg/L

Chlorhexidine

Daphnia magna (Water Flea) OECD 21 Day(s) NOEC 0.012 mg/L Reproduction

12.2. Persistence and degradability

Persistence and degradability No information available.

Chlorhexidine Gluconate

Not readily biodegradable

Chlorhexidine

NA Activated sludge Ultimate (CO2 Evolution) 0 % After 28 Day(s) Not Ready

Photolysis: (Method, pH, Endpoint, Results)

Chlorhexidine

OECD N/A Half-Life (Summer) 8.6 and (Winter) 69.1 Day(s)

12.3. Bioaccumulative potential

Bioaccumulation

Partition Coefficient: (Method, pH, Endpoint, Value)

<u>Chlorhexidine Gluconate</u> Measured -1.81 Log P

Chlorhexidine

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Measured Log P 0.08

12.4. Mobility in soil

Mobility in soil No information available.

12.5. Results of PBT and vPvB assessment

PBT and vPvB assessment

Chemical name	PBT and vPvB assessment
Chlorhexidine Gluconate	The substance is not PBT / vPvB

12.6. Endocrine disrupting properties

Endocrine disrupting properties

Chemical name	EU - Endocrine Disrupters Candidate	EU - Endocrine Disruptors - Evaluated	
	List	Substances	
Nonoxynol 8	Group III Chemical	-	

12.7. Other adverse effects

No information available.

Section 13: DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural wastewater and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

Section 14: TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

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

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Water

CERCLA/SARA Section 313 de minimus % Not Listed California Proposition 65 Not Listed TSCA Present EINECS 231-791-2 AICS Present

Chlorhexidine Gluconate

CERCLA/SARA Section 313 de minimus % Not Listed
California Proposition 65 Not Listed
TSCA Present
EINECS 242-354-0
AICS Present
Standard for Uniform Scheduling of Medicines and
Poisons (SUSMP) Schedule 5
Schedule 7

Nonoxynol 8

CERCLA/SARA Section 313 de minimus % 1.0 %
California Proposition 65 Not Listed
TSCA Present
EINECS 248-293-6
AICS Present

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

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. Hazardous to the aquatic environment, acute toxicity-Cat.1; H400 - Very toxic to aquatic life. Hazardous to the aquatic environment, chronic toxicity-Cat.1; H410 - Very toxic to aquatic life with long lasting effects. Serious eye damage/eye irritation-Cat.1; H318 - Causes serious eye damage.

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Data Sources: Publicly available toxicity information.

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

Ingredients. Updated Section 16 - Other 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.