SAFETY DATA SHEET

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

1.1. Product identifier

Product Name 0.05% Chlorhexidine & 0.5% Cetrimide Aqueous Irrigations

Product Code(s) PZ00711
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
66 Hudson Boulevard East
New York, New York 10001
1-800-879-3477

Pfizer Ireland Pharmaceuticals
OSG Building
Ringaskiddy, Co. Cork.
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: Regulated according to Regulation (EC) 1272/2008 and/or other applicable regulations.

Hazardous to the aquatic environment - acute Category 3 - (H402)
Hazardous to the aquatic environment - chronic Category 3 - (H412)

OSHA Classification

Hazards not otherwise classified (HNOC)
Not applicable

Hazards classified under paragraph (d)(1)(ii) of 1910.1200
Not applicable

2.2. Label elements

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

Precautionary Statements - EU (§28, 1272/2008) P273 - Avoid release to the environment

Unknown acute toxicity

0.5 % of the mixture consists of ingredient(s) of unknown acute dermal toxicity.
0.55 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (dust/mist).

2.3. Other hazards

Other hazards An Occupational Exposure Value has been established for one or more of the ingredients (see Section 8).

PBT & vPvB The product does not contain any substance(s) classified as PBT or vPvB.

Endocrine Disruptor Information This product does not contain any known or suspected endocrine disruptors.

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. (Index No.)	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Specific concentration limit (SCL)	M-Factor	M-Factor (long-term)
Cetrimide (CAS #: 8044-71-1)	0.5		Not Listed	Acute Tox.4 (H302) Eye Dam.1 (H318)	Not classified	No data available	No data available
Chlorhexidine Gluconate (CAS #: 18472-51-0)	0.05		242-354-0	Acute Tox.4 (H302) Eye Dam.1 (H318) Aquatic Acute 1 (H400) Aquatic Chronic 1 (H410)	Not classified	10	10

NonHazardous

Chemical name	Weight-%	REACH registration number	EC No. (Index 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	Not classified	No data available	No data available
FD&C Yellow No. 6; (Sunset yellow) (CAS #: 2783-94-0)	*		220-491-7	Not classified	Not classified	No data available	No data available

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

Acute Toxicity Estimate

Chemical name	Oral LD50 mg/kg	Dermal LD50 mg/kg	Inhalation LC50 - 4 hour - dust/mist - mg/L	Inhalation LC50 - 4 hour - vapor - mg/L	Inhalation LC50 - 4 hour - gas - ppm
Water 7732-18-5	89838.9	No data available	No data available	No data available	No data available
Cetrimide 8044-71-1	1000	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
FD&C Yellow No. 6; (Sunset yellow) 2783-94-0	10000	2000	No data available	No data available	No data available

This product does not contain candidate substances of very high concern at a concentration >=0.1% (Regulation (EC) No. 1907/2006 (REACH), Article 59).

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.

Section 4: FIRST AID MEASURES

4.1. Description of first aid measures

Inhalation Remove to fresh air. Seek immediate medical attention/advice.

Eye contact Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids. Consult a physician.

Skin contact Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.

Ingestion Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

4.2. Most important symptoms and effects, both acute and delayed

Most important symptoms and effects For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.

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.

Explosion data
Sensitivity to mechanical impact No information available.
Sensitivity to static discharge No information available.

5.3. Advice for firefighters

Special protective equipment and precautions 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.
For emergency responders Use personal protection recommended in Section 8.

6.2. Environmental precautions

Environmental precautions Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

6.3. Methods and material for containment and cleaning up

Methods for containment Prevent further leakage or spillage if safe to do so.
Methods for cleaning up Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly.
Prevention of secondary hazards Clean contaminated objects and areas thoroughly observing environmental regulations.

6.4. Reference to other sections

Reference to other sections See section 8 for more information. See section 13 for more information.

Section 7: HANDLING AND STORAGE

7.1. Precautions for safe handling

Advice on safe handling Minimize generating airborne mists and vapors. Avoid breathing dust/fume/gas/mist/vapors/spray. Avoid contact with skin, eyes or clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash thoroughly after handling. Wash hands and any exposed skin after removal of PPE. 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) disinfectant. antiseptic.

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.

Cetrimide
Pfizer Occupational Exposure Band (OEB): OEB 3 (control exposure to the range of 10ug/m^3 to < 100ug/m^3)

Chlorhexidine Gluconate
Pfizer Occupational Exposure Band (OEB): OEB 4 (control exposure to the range of 1ug/m^3 to <10ug/m^3)

Derived No Effect Level (DNEL) - Workers

Chemical name	Oral	Dermal	Inhalation
Chlorhexidine Gluconate 18472-51-0	-	6 mg/kg bw/day [4] [6]	0.36 mg/m^3 [4] [6]

Derived No Effect Level (DNEL) - General Public

Chemical name	Oral	Dermal	Inhalation
Chlorhexidine Gluconate 18472-51-0	0.03 mg/kg bw/day [4] [6] 2 mg/kg bw/day [4] [7]	-	0.09 mg/m^3 [4] [6]

Predicted No Effect Concentration (PNEC)

Chemical name	Freshwater	Freshwater (intermittent release)	Marine water	Marine water (intermittent release)	Air
Chlorhexidine Gluconate 18472-51-0	0.00124 mg/L	0.00124 mg/L	0.000124 mg/L	-	-

Chemical name	Freshwater sediment	Marine sediment	Sewage treatment	Soil	Food chain
Chlorhexidine Gluconate 18472-51-0	0.866 mg/kg sediment dw	0.0866 mg/kg sediment dw	0.25 mg/L	5.26 mg/kg soil dw	-

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.

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 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.).

Thermal hazards No information available.

Environmental exposure controls No information available.

Section 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

Physical state	Liquid
Color	Yellow
Odor	None.
Odor threshold	No information available

Property	**Values**
Melting point / freezing point	No data available
Boiling point or initial boiling point and boiling range	No data available
Flammability (solid, gas)	No data available
Lower and upper explosion limit/flammability limit	
Lower explosion limit	No data available

Upper explosion limit	No data available
Flash point	No data available
Autoignition temperature	No data available
Decomposition temperature	
SADT (°C)	No data available
pH	No data available
pH (as aqueous solution)	No data available
Kinematic viscosity	No data available
Dynamic viscosity	No data available
Solubility	No data available
Vapor pressure	No data available
Density and/or relative density	No data available
Bulk density	No data available
Liquid Density	No data available
Vapor density	No data available
Particle characteristics	
Particle Size	No information available
Particle Size Distribution	No information available

Partition Coefficient: (Method, pH, Endpoint, Value)
Chlorhexidine Gluconate
Measured -1.81 Log P
Chlorhexidine
Measured Log P 0.08

9.2. Other information

Molecular formula	Mixture
Molecular weight	Mixture

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 information available.
10.2. Chemical stability
Stability Stable under normal conditions.
Explosion data
Sensitivity to mechanical impact No information available.
Sensitivity to static discharge No information 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
Known Clinical Effects: May cause eye and skin irritation May be harmful if swallowed (based on components) Hypersensitivity reactions may also occur in susceptible individuals.

Acute toxicity	Based on available data, the classification criteria are not met.
Serious eye damage/eye irritation	Based on available data, the classification criteria are not met.
Skin corrosion/irritation	Based on available data, the classification criteria are not met.
Respiratory or skin sensitization	Based on available data, the classification criteria are not met.
STOT - single exposure	Based on available data, the classification criteria are not met.
STOT - repeated exposure	Based on available data, the classification criteria are not met.
Reproductive toxicity	Based on available data, the classification criteria are not met.
Germ cell mutagenicity	Based on available data, the classification criteria are not met.
Carcinogenicity	Based on available data, the classification criteria are not met.
Aspiration hazard	Based on available data, the classification criteria are not met.

Acute Toxicity: (Species, Route, End Point, Dose)
Cetrimide
Rat Intravenous LD 50 15 mg/kg
Rat Oral LD50 1000 mg/kg
Chlorhexidine Gluconate
Rat Oral LD50 2000 mg/kg
Rat Para-periosteal LD50 24.2 mg/kg
Mouse Oral LD50 1260 mg/kg
Mouse Intravenous LD50 12.9 mg/kg
FD&C Yellow No. 6; (Sunset yellow)
Rat Oral LD50 > 10,000 mg/kg
Mouse Oral LD50 > 6,000 mg/kg
Chlorhexidine
Rat Oral LD 50 5000 mg/kg
Mouse Oral LD 50 2515 mg/kg

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Water	> 90 mL/kg (Rat)	-	-
Cetrimide	= 1000 mg/kg (Rat)	-	-
Chlorhexidine Gluconate	= 2 g/kg (Rat)	> 5000 mg/kg (Rabbit)	-
FD&C Yellow No. 6; (Sunset yellow)	> 10000 mg/kg (Rat)	> 2000 mg/kg (Rat)	-

Acute Toxicity Comments: A greater than symbol (>) indicates that the toxicity endpoint being tested was not achievable at the highest dose used in the test.

Unknown acute toxicity
0.5 % of the mixture consists of ingredient(s) of unknown acute dermal toxicity.
0.55 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (dust/mist).

Irritation / Sensitization: (Study Type, Species, Severity)
Cetrimide
Skin irritation Rabbit Corrosive
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)
Cetrimide
5 Month(s) Mouse Oral 5 mg/kg/day LOAEL Erythroid cells
6 Month(s) Mouse Oral 35 mg/kg/day LOAEL None identified
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))
Cetrimide
Embryo / Fetal Development Mouse Intraperitoneal 10.5 mg/kg/day LOAEL Fetotoxicity
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

Genetic Toxicity: (Study Type, Cell Type/Organism, Result)
Cetrimide
Bacterial Mutagenicity (Ames) *Salmonella* Negative
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.
FD&C Yellow No. 6; (Sunset yellow)
IARC Group 3

11.2. Information on other hazards
11.2.1. Endocrine disrupting properties
Endocrine disrupting properties Based on available data, the classification criteria are not met.

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

Biodegradation: (Method, Inoculum, Biodeg Study, Result, Endpoint, Duration, Classification)
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)
Chlorhexidine Gluconate
Measured -1.81 Log P
Chlorhexidine
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 Based on available data, the classification criteria are not met.

Chemical name	PBT and vPvB assessment
Chlorhexidine Gluconate	Not PBT/vPvB
FD&C Yellow No. 6; (Sunset yellow)	Not PBT/vPvB
Chlorhexidine	PBT assessment does not apply

12.6. Endocrine disrupting properties

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

12.7. Other adverse effects

Other adverse effects No information available.
PMT or vPvM properties Based on available data, the classification criteria are not met.

Chemical name	PMT and vPvM assessment
Chlorhexidine Gluconate	Not PMT/vPvM
Chlorhexidine	Not PMT/vPvM

Section 13: DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Waste from residues/unused products
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
Packing group: Not applicable
Environmental Hazard(s): 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

Cetrimide

CERCLA/SARA Section 313 de minimus %	Not Listed
California Proposition 65	Not Listed
EINECS	Not Listed
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 6 Schedule 7

FD&C Yellow No. 6; (Sunset yellow)

CERCLA/SARA Section 313 de minimus %	Not Listed
California Proposition 65	Not Listed
TSCA	Present
EINECS	220-491-7
AICS	Present
Standard for Uniform Scheduling of Medicines and Poisons (SUSMP)	Schedule 7

National regulations

Germany

Chemical Prohibition Ordinance (ChemVerbotsV)

Not applicable

TRGS 905 Not applicable

Switzerland

Ordinance on the Incentive Tax on Volatile Organic Compounds (OVOC) SR 814.018	Not applicable
Storage of Hazardous Material	Not applicable
WPO (GSchV) SR 814.201; WPA (GSchG) SR 814.20	Not applicable
Major Accidents Ordinance SR 814.012	Not applicable

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 contains one or more substance(s) subject to restriction (Regulation (EC) No. 1907/2006 (REACH), Annex XVII)

Chemical name	Restricted substance per REACH Annex XVII	Substance subject to authorization per REACH Annex XIV
FD&C Yellow No. 6; (Sunset yellow) 2783-94-0	75	-

Persistent Organic Pollutants
Not applicable

Ozone-depleting substances (ODS) Regulation (EU) 2024/590
Not applicable.

Biocidal Products Regulation (EU) No 528/2012 (BPR)

Chemical name	Biocidal Products Regulation (EU) No 528/2012 (BPR)
Chlorhexidine Gluconate 18472-51-0	Product-type 1: Human hygiene Product-type 2: Disinfectants and algaecides not intended for direct application to humans or animals Product-type 3: Veterinary hygiene

Explosives Precursors Marketing and Use (2019/1148)
Not applicable

Legend:
TSCA - United States Toxic Substances Control Act Section 8(b) Inventory
DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List
EINECS/ELINCS - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances
ENCS - Japan Existing and New Chemical Substances
IECSC - China Inventory of Existing Chemical Substances
KECL - Korean Existing Chemicals Inventory
PICCS - Philippines Inventory of Chemicals and Chemical Substances
AICS - Australian Inventory of Chemical Substances
NZIoC - New Zealand Inventory of Chemicals
TCSI - Taiwan Chemical Substance Inventory

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 any hazard and/or precautionary statements referred to under Sections 2-15
H318 - Causes serious eye damage. H302 - Harmful if swallowed. H400 - Very toxic to aquatic life. H410 - Very toxic to aquatic life with long lasting effects.

Data Sources: Publicly available toxicity information.

Reason for revision	Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking. Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 11 - Toxicology Information. Updated Section 12 - Ecological Information. Updated Section 15 - Regulatory Information. Updated Section 16 - Other Information.
Revision date	02-Sep-2025
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.