



# SAFETY DATA SHEET

Revision date 02-Sep-2025

Version 5.01

Page 1 / 13

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

### 1.1. Product identifier

**Product Name** 0.015% Chlorhexidine & 0.15% Cetrimide Aqueous Irrigations  
**Product Code(s)** PZ00712  
**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: This mixture is classified as not hazardous according to regulation (EC) 1272/2008 [CLP].

#### 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

**Signal word** Not classified

**Hazard statements** Non-hazardous in accordance with international standards for workplace safety.

### 2.3. Other hazards

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

# SAFETY DATA SHEET

Product Name 0.015% Chlorhexidine & 0.15% Cetrimide Aqueous  
Irrigations  
Revision date 02-Sep-2025

Page 2 / 13  
Version 5.01

## 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)                | 0.15     |                           | Not Listed         | Acute Tox.4 (H302)<br>Eye Dam.1 (H318)   | Not classified                     | No data available | No data available    |
| Chlorhexidine Gluconate (CAS #: 18472-51-0) | 0.015    |                           | 242-354-0          | Acute Tox.4 (H302)<br>Eye Dam.1 (H318)<br>Aquatic Acute 1 (H400)<br>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

# SAFETY DATA SHEET

Product Name 0.015% Chlorhexidine & 0.15% Cetrimide Aqueous  
Irrigations  
Revision date 02-Sep-2025

Page 3 / 13

Version 5.01

| 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<br>7732-18-5                                 | 89838.9         | No data available | No data available                           | No data available                       | No data available                    |
| Cetrimide<br>8044-71-1                             | 1000            | No data available | No data available                           | No data available                       | No data available                    |
| Chlorhexidine Gluconate<br>18472-51-0              | 2000            | 5000              | No data available                           | No data available                       | No data available                    |
| FD&C Yellow No. 6;<br>(Sunset yellow)<br>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  $\geq 0.1\%$  (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

|                     |  |
|---------------------|--|
| <b>Inhalation</b>   | Remove to fresh air. Seek immediate medical attention/advice.  |
| <b>Eye contact</b>  | Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids. Consult a physician.   |
| <b>Skin contact</b> | Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.  |
| <b>Ingestion</b>    | 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

|  |  |
|--|--|
| <b>Most important symptoms and effects</b> | 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

|                           |       |
|---------------------------|-------|
| <b>Note to physicians</b> | None. |
|---------------------------|-------|

## Section 5: FIRE-FIGHTING MEASURES

### 5.1. Extinguishing media

|                                     |  |
|-------------------------------------|--|
| <b>Suitable Extinguishing Media</b> | Dry chemical, CO <sub>2</sub> , alcohol-resistant foam or water spray. |
|-------------------------------------|--|

### 5.2. Special hazards arising from the substance or mixture

# SAFETY DATA SHEET

Product Name 0.015% Chlorhexidine & 0.15% Cetrimide Aqueous  
Irrigations  
Revision date 02-Sep-2025

Page 4 / 13

Version 5.01

**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)**

# SAFETY DATA SHEET

Product Name 0.015% Chlorhexidine & 0.15% Cetrimide Aqueous  
Irrigations  
Revision date 02-Sep-2025

Page 5 / 13

Version 5.01

**Specific use(s)** disinfectant, antiseptic.

## Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

### 8.1. Control parameters

#### 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<sup>3</sup> to < 100ug/m<sup>3</sup>)

#### Chlorhexidine Gluconate

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

#### Derived No Effect Level (DNEL) - Workers

| Chemical name                         | Oral | Dermal                 | Inhalation                     |
|---------------------------------------|------|------------------------|--------------------------------|
| Chlorhexidine Gluconate<br>18472-51-0 | -    | 6 mg/kg bw/day [4] [6] | 0.36 mg/m <sup>3</sup> [4] [6] |

#### Derived No Effect Level (DNEL) - General Public

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

#### Predicted No Effect Concentration (PNEC)

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

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

# SAFETY DATA SHEET

Product Name 0.015% Chlorhexidine & 0.15% Cetrimide Aqueous  
Irrigations  
Revision date 02-Sep-2025

Page 6 / 13

Version 5.01

## 8.2. Exposure controls

|  |   |
|--|---|
| <b>Engineering controls</b>            | 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.  |
| <b>Personal protective equipment</b>   | 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. |
| <b>Eye/face protection</b>             | 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.).  |
| <b>Hand protection</b>                 | 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.).   |
| <b>Skin and body protection</b>        | 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.).   |
| <b>Respiratory protection</b>          | 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.).                         |
| <b>Thermal hazards</b>                 | No information available.   |
| <b>Environmental exposure controls</b> | No information available.   |

## Section 9: PHYSICAL AND CHEMICAL PROPERTIES

### 9.1. Information on basic physical and chemical properties

|                       |                          |
|-----------------------|--------------------------|
| <b>Physical state</b> | Liquid                   |
| <b>Color</b>          | Yellow                   |
| <b>Odor</b>           | None.                    |
| <b>Odor threshold</b> | No information available |

#### Property

Melting point / freezing point  
Boiling point or initial boiling point and boiling range  
Flammability (solid, gas)  
Lower and upper explosion limit/flammability limit  
    Lower explosion limit  
    Upper explosion limit  
Flash point  
Autoignition temperature  
Decomposition temperature  
    SADT (°C)  
pH  
    pH (as aqueous solution)  
Kinematic viscosity

#### Values

No data available  
No data available  
No data available  
No data available  
No data available  
No data available  
No data available  
No data available  
No data available  
No data available  
No data available  
No data available

# SAFETY DATA SHEET

Product Name 0.015% Chlorhexidine & 0.15% Cetrimide Aqueous  
Irrigations  
Revision date 02-Sep-2025

Page 7 / 13

Version 5.01

|                                 |                          |
|---------------------------------|--------------------------|
| 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

## 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** May cause eye and skin irritation. May be harmful if swallowed (based on components).  
**Known Clinical Effects:** Hypersensitivity reactions may also occur in susceptible individuals.

# SAFETY DATA SHEET

Product Name 0.015% Chlorhexidine & 0.15% Cetrimide Aqueous  
Irrigations  
Revision date 02-Sep-2025

Page 8 / 13

Version 5.01

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

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

### **Cetrimide**

Rat Intravenous LD50 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

| 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.

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

### **Cetrimide**

Skin irritation Rabbit Corrosive

### **Chlorhexidine Gluconate**

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

## **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



# SAFETY DATA SHEET

Product Name 0.015% Chlorhexidine & 0.15% Cetrimide Aqueous  
Irrigations  
Revision date 02-Sep-2025

Page 9 / 13

Version 5.01

## 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

**Carcinogenicity** See below

### 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

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

##### Chlorhexidine Gluconate

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

### 12.2. Persistence and degradability

#### **Persistence and degradability**

##### Biodegradation:

##### Chlorhexidine Gluconate

Not readily biodegradable

### 12.3. Bioaccumulative potential

#### **Bioaccumulation**

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

##### Chlorhexidine Gluconate

Measured -1.81 Log P

### 12.4. Mobility in soil

# SAFETY DATA SHEET

Product Name 0.015% Chlorhexidine & 0.15% Cetrimide Aqueous  
Irrigations  
Revision date 02-Sep-2025

Page 10 / 13

Version 5.01

**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            |

## 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            |

## 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

# SAFETY DATA SHEET

Product Name 0.015% Chlorhexidine & 0.15% Cetrimide Aqueous  
Irrigations  
Revision date 02-Sep-2025

Page 11 / 13

Version 5.01

## Section 15: REGULATORY INFORMATION

### 15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

#### Water

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

#### Cetrimide

|   |            |
|---|------------|
| <b>CERCLA/SARA Section 313 de minimus %</b> | Not Listed |
| <b>California Proposition 65</b>            | Not Listed |
| <b>EINECS</b>                               | Not Listed |
| <b>AICS</b>                                 | Present    |

#### Chlorhexidine Gluconate

|   |  |
|---|--|
| <b>CERCLA/SARA Section 313 de minimus %</b>                             | Not Listed                             |
| <b>California Proposition 65</b>  | Not Listed                             |
| <b>TSCA</b>   | Present                                |
| <b>EINECS</b>   | 242-354-0                              |
| <b>AICS</b>   | Present                                |
| <b>Standard for Uniform Scheduling of Medicines and Poisons (SUSMP)</b> | Schedule 5<br>Schedule 6<br>Schedule 7 |

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

|   |            |
|---|------------|
| <b>CERCLA/SARA Section 313 de minimus %</b>                             | Not Listed |
| <b>California Proposition 65</b>  | Not Listed |
| <b>TSCA</b>   | Present    |
| <b>EINECS</b>   | 220-491-7  |
| <b>AICS</b>   | Present    |
| <b>Standard for Uniform Scheduling of Medicines and Poisons (SUSMP)</b> | 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 | Substance subject to authorization per |
|---------------|--------------------------------|--|
|---------------|--------------------------------|--|

# SAFETY DATA SHEET

Product Name 0.015% Chlorhexidine & 0.15% Cetrimide Aqueous  
Irrigations  
Revision date 02-Sep-2025

Page 12 / 13

Version 5.01

|   | Annex XVII | REACH Annex XIV |
|---|------------|-----------------|
| FD&C Yellow No. 6; (Sunset yellow)<br>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<br>18472-51-0 | Product-type 1: Human hygiene Product-type 2:<br>Disinfectants and algacides not intended for direct<br>application to humans or animals Product-type 3:<br>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

H302 - Harmful if swallowed. H318 - Causes serious eye damage. H400 - Very toxic to aquatic life. H410 - Very toxic to aquatic life with long lasting effects.

### Classification procedure

Calculation method

**Data Sources:** Publicly available toxicity information.

# SAFETY DATA SHEET

Product Name 0.015% Chlorhexidine & 0.15% Cetrimide Aqueous  
Irrigations  
Revision date 02-Sep-2025

Page 13 / 13

Version 5.01

---

## 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.**