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## 1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

**1.1. Product identifier** CURASEPT ADS PERIO, CURASEPT ADS IMPLANT mouthwashes

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

- CURASEPT ADS PERIO: solution with PVP/VA, Chlorhexidine Digluconate 0,12%, Hyaluronic Acid. Use is recommended in the event of periodontal therapy and plastic surgery, surgical therapy of recessions, after full mouth disinfection, periodontal regeneration, in the event of gingivitis and in general also as a completion of the normal dental hygiene.
- CURASEPT ADS IMPLANT: solution with PVP/VA, Chlorhexidine Digluconate 0,20%, Hyaluronic Acid for oral hygiene. Use is recommended for Insertion of dental implants, Immediate loading procedures, after complex dental extraction, procedure of bone regeneration, in the event of gingivitis and periodontitis and in all cases where a faster normalization of wounds is required assuring the success of dental procedures.

**1.3. Details of the supplier of the safety data sheet**

Manufacturer: Curaden Healthcare S.p.A. – Via Parini n. 19 – 21047 Saronno (VA) – Tel. +39 02/9622799

Distributor: Curaden Pharma GmbH, Industriestrasse 4, D-76297 Stutensee

**1.4 Emergency telephone number:** contact your local emergency telephone number

## 2. HAZARDS IDENTIFICATION

**2.1. Classification of the substance or mixture**

Dangerous substances contained:

Ingredients	Danger symbol	Hazard sentences
Sodium metabisulfite	Xi R 36/38	Irritant to eyes and skin

**2.2. Label elements:** this preparation is not classified as dangerous according to Directive 93/42/EEC and subsequent amendments

**2.3. Other hazards:** no data available

## 3. COMPOSITION/INFORMATION ON INGREDIENTS

**3.1. Substances**

### CURASEPT ADS PERIO

PURIFIED WATER, XYLITOL, PROPYLENE GLYCOL, PEG-40 HYDROGENATED CASTOR OIL, PVP/VA COPOLYMER (0,20%), ASCORBIC ACID, SODIUM HYALURONATE, CHLORHEXIDINE DIGLUCONATE (0,12%), SODIUM BENZOATE, AROMA, POLOXAMER 407, SODIUM METABISULFITE, SODIUM CITRATE, CITRIC ACID, C.I. 42090, C.I. 17200.

### CURASEPT ADS IMPLANT

PURIFIED WATER, XYLITOL, PROPYLENE GLYCOL, PEG-40 HYDROGENATED CASTOR OIL, PVP/VA COPOLYMER (0,20%), ASCORBIC ACID, SODIUM HYALURONATE, CHLORHEXIDINE DIGLUCONATE (0,20%), SODIUM BENZOATE, AROMA, POLOXAMER 407, SODIUM METABISULFITE, SODIUM CITRATE, CITRIC ACID, C.I. 42090, C.I. 17200.

**3.2. Mixtures:** not applicable

## 4. FIRST AID MEASURES

**4.1. Description of first aid measures**

**CONTACT WITH EYES:** rinse in copious water.

**INGESTION:** do not ingest.

**INHALING:** none

**4.2. Most important symptoms and effects, both acute and delayed:** no data available

**4.3. Indication of any immediate medical attention and special treatment needed:** No data available

## 5. FIGHTING MEASURES

**5.1. Extinguishing media:** use water, atomised water, CO<sub>2</sub>, powder, foam.

**5.2. Special hazards arising from the substance or mixture:** combustion releases sulphur oxides.

**5.3. Advice for firefighters:** breathing equipment and protective clothing should be available to people in charge of extinguishing fires.

## 6. ACCIDENTAL RELEASE MEASURES:

**6.1. Personal precautions, protective equipment and emergency procedures:** heed instructions for use shown on the label.

**6.2. Environmental precautions:** none in particular

**6.3. Methods and material for containment and cleaning up:** Disperse with water.

**6.4. Reference to other sections:** heed warnings shown on the label.

## 7. HANDLING AND STORAGE

**7.1. Precautions for safe handling:** none in particular.

**7.2. Conditions for safe storage, including any incompatibilities:** keep in the original bottles well closed in a cool and dry place at room temperature. Avoid high temperatures.

**7.3. Specific end use(s):** not applicable

## 8. EXPOSURE CONTROL/PERSONAL PROTECTION

**8.1. Control parameters:** No data available

**8.2. Exposure controls:** No data available

## 9. PHYSICAL AND CHEMICAL PROPERTIES

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

#### Curasept ADS PERIO

**9.1: Appearance:** clear liquid

**9.2: Colour:** Light indigo

**9.3: Characteristic smell**

**9.4: Density (25°C) g/cm<sup>3</sup>:** 1.000 - 1.050

**9.5: pH (25°C):** 5.00 - 6.00

#### Curasept ADS IMPLANT

**9.1 Appearance:** clear liquid

**9.2 Colour:** Dark indigo

**9.3: Characteristic smell**


**9.4: Density (25°C) g/cm<sup>3</sup> :** 1.000 - 1.050

**9.5:pH (25°C):** 5.00 - 6.00

**9.2. Other information:** none in particular

## 10. STABILITY AND REACTIVITY

According to current knowledge, there is no particular problem of stability under normal conditions.

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## 11. TOXICOLOGICAL INFORMATION

### 11.1. Information on toxicological effects

#### **Toxicity for people**

**11.1.1 Contact with eyes:** possible irritation.

**11.1.2 Contact with skin:** no particular important effect

**11.1.3 Inhaling:** no effect.

**11.1.4 Ingestion:** accidental ingestion can cause nausea.

**11.1.5 Continuous exposure:** chlorhexidine digluconate does not have oncogenic, mutagenic or teratogenic power.

**11.1.6 Other information:** chlorhexidine digluconate has very limited irritant and skin sensitising properties, but it is ototoxic

#### **Toxicity for animals**

DL50 (oral, rat): 2000 mg/Kg (chlorhexidine digluconate)

LD50(Rat) (based on similar products): >5000 mg/kg (PVPva copolymer)

## 12. ECOLOGICAL INFORMATION

### 12.1. Toxicity

#### TOXICITY FOR AQUATIC ORGANISMS

CL50 (Brachydanio rerio, 96 h): 10,4 mg/lit (chlorhexidine digluconate)

CE50 (Daphnia pulex, 48 h): > 0,05 mg/lit < 0,10 mg/Lt (chlorhexidine digluconate)

CI50 (Scenedesmus subspicatus, 72 h): 0,011 mg/lit (chlorhexidine digluconate)

CI50 (Cloroficee, 10 gg): 4,4 mg/lit (chlorhexidine digluconate)

**12.2. Persistence and degradability:** use according to good working practices, not releasing the product in the environment

**12.3. Bioaccumulative potential :** no data available

**12.4. Mobility in soil:** no data available

**12.5. Results of PBT and vPvB assessment:** no data available

**12.6. Other adverse effects:** no data available

## 13. DISPOSAL CONSIDERATIONS

### 13.1. Waste treatment methods:

**ELIMINATING THE PRODUCT:** dispose of as urban refuse.

**ELIMINATING PACKAGING:** provide for separate refuse collection.

**ELIMINATION OF DEPLETED SOLUTIONS:** : dispose of as urban refuse.

## 14. TRANSPORT INFORMATION

This product, because of its characteristics, is not one for which the ADR regulations apply since it is not considered goods dangerous for transporting on roads. Comply with the regulations set out by RID for rail transport, IMDG for shipping, and ICAO/IATA for air transport


## 15. REGULATORY INFORMATION

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

Classification: CE/MDD – Class I: 93/42/EEC and subsequent amendments

**15.2. Chemical safety assessment:** no data available

## 16. OTHER INFORMATION

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#### 16.1 USES:

##### **CURASEPT ADS PERIO**

Rinse the mouth for at least a minute, using a tablespoon of undiluted product (10 ml) after normal oral hygiene. It is recommended to avoid eating or drinking or re-rinsing the mouth for at least a half an hour after rinsing. Continue application for about 30 days and if it should be necessary to extend the treatment consult your dentist.

##### **CURASEPT ADS IMPLANT**

Rinse the mouth for at least a minute, using a tablespoon of undiluted product (10 ml) after normal oral hygiene. Avoid eating, drinking, re-rinsing or smoking for at least half an hour after rinsing. Use for about 7-14 days or as directed by your dental professional.

**16.2 FURTHER INFORMATION ON THE PRODUCT:** Contact the manufacturer for any further information.

**The information contained in this safety sheet is base on our current knowledge. It is the user's responsibility to apply the standards of hygiene, safety and protection of the environment required by laws in force. The information contained in this sheet refers to the product in the state and condition in which it was supplied, and described its characteristics in relation to the safety requirements.**