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	Curasept ADS Periodontal gel 0,5% Regenerating Topical Gum treatment	02/10/2017 Pagina 1 di 3

1. IDENTITY OF THE PREPARATION AND ITS PRODUCER

Trade Name: CURASEPT ADS® PERIODONTAL GEL 0,5% regenerating topical gum treatment

Description: periodontal gel

Manufacturer: Curaden Healthcare S.p.A. – Via Parini n. 19 – 21047 Saronno (VA) – Tel. +39 02/9622799 – E-mail: info@curaden.it

2. COMPOSITION/INFORMATION ON INGREDIENTS

2.1 INGREDIENTS

Purified water, Propylene Glycol, Xylitol, Hydroxyethylcellulose, Peg-40 Hydrogenated Castor oil, PVP-VA Copolymer, Sodium hyaluronate, Chlorhexidine Digluconate, Sodium Metabisulfite, Ascorbic Acid, Sodium Citrate, Aroma, Sodium Benzoate, Citric Acid, C.I. 42090, C.I. 17200.

2.2 Information about the ingredients

Dangerous substances contained:

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

3. HAZARDS IDENTIFICATION

Hazard instruction not necessary.

4. FIRST AID MEASURES

4.1 CONTACT WITH EYES: rinse in copious water.

4.2 INGESTION: do not ingest.

4.3 INHALING: none

5. FIRE FIGHTING MEASURES

5.1 EXTINGUISHING METHODS: use water, atomised water, CO₂, powder, foam.

5.2 MEANS OF PROTECTION IN CASE OF FIRE: breathing equipment and protective clothing should be available to people in charge of extinguishing fires.

5.3 EXTINGUISHING SYSTEMS TO AVOID: data not available

5.4 SPECIAL FIRE PREVENTION PROCEDURES: data not available

5.5 DANGERS DERIVING FROM THE RESULT OF COMBUSTION AND DECOMPOSITION: combustion releases sulphur oxides.

5.6 RISK OF EXPLOSION: none

6. ACCIDENTAL RELEASE MEASURES:

6.1 METHODS FOR CLEANING AND COLLECTING LEAKS: Disperse with water.

6.2 PERSONAL PRECAUTIONS: see point 8.

6.3 OTHER INSTRUCTIONS: heed warnings shown on the label.

7. HANDLING AND STORAGE

7.1 TECHNICAL MEASURES: none in particular.

7.2 STORAGE CONDITIONS: keep in the original bottles well closed in a cool and dry place at room temperature. Avoid high temperatures.

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8. EXPOSURE CONTROLS AND PERSONAL PROTECTION GEAR

8.1 PERSONAL PROTECTION: not applicable

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Appearance: gel

9.2 Color: blue

9.3 Characteristic smell

9.4 Specific weight: 1,020 - 1,050 g/cm³

9.5 pH: 5,50 – 7,00

10. STABILITY AND REACTIVITY

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

11. TOXICOLOGICAL INFORMATION

11.1 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

11.2 Toxicity for animals

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

12. ENVIRONMENTAL INFORMATION

12.1 PERSISTENCE AND DEGRADABILITY:

use according to good working practices, not releasing the product in the environment

12.2 TOXICITY FOR AQUATIC ORGANISMS

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

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

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

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

12.3 OTHER INFORMATION:

COD: 219000 mg/Lt (chlorhexidine digluconate)BOD5: 0 mg/Lt (chlorhexidine digluconate)

13. CONSIDERATIONS ON WASTE DISPOSAL

13.1 ELIMINATING THE PRODUCT: dispose of as urban refuse.

13.2 ELIMINATING PACKAGING: provide for separate refuse collection.

13.3 ELIMINATION OF DEPLETED SOLUTIONS: see point 13.1.

14. TRANSPORT INFORMATION

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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. REGULATIONS

Product manufactured in accordance with Medical Device Directive 93/42/EEC

16. OTHER INFORMATION

16.1 USES: oral care, apply a small amount of gel, with a finger or with an ultra soft toothbrush on the gums by massaging it delicately or apply a thin layer to the inner surface of the denture. To apply into interproximal spaces, use interdental brushes covered with gel.

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

The information contained in this safety sheet is based 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.