

According to Regulation (EC) N° 453/2010

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Rev. nº 01

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

**1.1 Product Identifier:** Whiteness Perfect 10%, 16% and 22%.

**1.2 Recommended use and restrictions on use:** Dental bleaching gel for vital teeth.

1.3 Supplier's details: Dentscare Ltda, Avenida Edgar Nelson Meister, 474, Joinville, Brasil.

**1.4 Emergency telefone number:** xx55 47 3441 6100

## **SECTION 2: HAZARD IDENTIFICATION**

**2.1 Hazard classification:** Irritant (16% and 22%).

Carbamide Peroxide is not listed in the annex of directive 67/548/EEC. For the purposes of Risk classification equivalent contents of Hydrogen Peroxide (3 to 7%) were used). The classification foreseen for products containing Hydrogen Peroxide between 5% and 8% is Xi, R36. The contents of Sodium Fluoride are rather low and do not add risks to the product.

2.2 Label elements: Professional use only.



Irritant

2.3 Other hazards: Not Applicable.

### SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Chemical characterization: Mixture.

INGREDIENT:	CAS N. A:	CLASSIFICATION:	% CONCENTRATION:
Carbamide Peroxide	124-43-6		10-22%
Potassium Nitrate	7757-79-1		3%
Sodium Fluoride	007681-49-4	T; R 23/25	0,20%

## SECTION 4: FIRST AIND MEASURES

- 4.1 Description of first aid measures
- 4.1.2 Skin contact: Wash with water and soap. Seek medical assistance if the irritation develops or persists.
- **4.1.3 Eye contact:** Immediately wash the eyes with water for at least 15 minutes. Get immediate medical attention.
- **4.1.4 Ingestion:** If swallowed, do not induce vomiting. Give the victim water or milk. Seek medical assistance immediately. Never give anything by mouth to an unconscious person.



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- 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 required: No data available.

### **SECTION 5: FIRE-FIGHTING MEASURES**

- **5.1 Suitable extinguishing media:** No data available.
- **5.2 Special hazards arising from the substance or mixture:** No data available.
- **5.3 Special protective actions for fire-fighters:** No data available.

### SECTION 6: ACCIDENTAL RELEASE MEASURES

- 6.1 Personal precautions, protective equipment and emergency procedures
- **6.2 Environmental precautions:** Non-defined.
- **6.3 Methods and material for containment and cleaning up:** Wash with water and soap.
- **6.4 Reference to other sections:** Non-defined.

### **SECTION 7: HANDLING AND STORAGE**

- **7.1 Precautions for safe handling:** Handle the product according to the instructions for use. Maintain the packaging closed when it is not being used.
- **7.2 Conditions for safe storage including any incompatibilities:** Store the product at 5°-25°C/41°-77°F. Do not freeze the product. Keep it out of direct sunlight.
- **7.3 Specific end use(s):** The identified uses for this product are detailed in Section 1.2.

### SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

- **8.1 Control parameters:** Not Applicable.
- 8.2 Exposure controls
- 8.2.1 Eye/face protection: Wear a mask and goggles.
- **8.2.2 Skin protection hand protection:** Wear protective gloves.
- 8.2.3 Skin protection other: Wear protective clothes.
- **8.2.4 Respiratory protection:** Not required.
- **8.2.5 Thermal hazards:** Not required.

#### SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

- 9.1 Information on basic physical and chemical properties
- a) Appearance (form and colour): Colourless gel.
- b) Smell: Odourless, without a characteristic odour.
- c) Odour threshold: No data available.
- **d) pH:** 6-7.
- e) Melting point/Melting range: No data available.



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f) Boiling point/Boiling range: No data available.

g) Flash point: No data available.

h) Evaporation rate: No data available.

i) Flammability (solid, gaseous): No data available.

j) Lower/upper explosion limit: No data available.

k) Vapor pressure: No data available.

1) Vapor density: No data available.

m) Relative density: No data available.

n) Solubility (s): No data available.

o) Partition coefficient: n-octanol/water: No data available.

p) Autoignition temperature: No data available.

**q) Decomposition temperature:** No data available.

r) Viscosity: No data available.

s) Explosive properties: Not Applicable.

t) Oxidising properties: Not Applicable.

**9.2 Other information:** Not Applicable.

### **SECTION 10: STABILITY AND REACTIVITY**

10.1 Reactivity: Not Applicable.

**10.2 Chemical stability:** Stable when stored and handled according to the manufacturer's recommendations. Decomposes with evolution of Oxygen at temperatures above 176 °F.

10.3 Possibility of hazardous reactions: Not Applicable.

**10.4 Conditions to avoid:** Avoid contact with strong bases, metals and their salts, prolonged exposure to sunlight and excessive heat.

10.5 Incompatible materials: Not Applicable.

**10.6 Hazards decomposition products:** Decomposes with evolution of Oxygen at temperatures above 176 °F. It can release toxic and corrosive fumes if exposed to high temperatures (pyrolysis).

### SECTION 11: TOXICOLOGICAL INFORMATION

#### 11.1 Information on toxicological effects

11.1.1 Acute toxicity: Not Applicable.

11.1.2 Irritation: The product may be irritant in case of prolonged contact with soft tissues.

11.1.3 Corrosion: Not Applicable.

**11.1.4 Sensitization:** May be sensitizing.

11.1.5 Repeated dose: Not Applicable.

11.1.6 Carcinogenicity: Negative Carcinogenicity according to IUCLID and NTP.

11.1.7 Mutagenicity: Not Applicable.



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11.1.8 Reproductive toxicity: Not Applicable.

## SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity: Not defined.

12.2 Persistence and degradability: Not defined.

12.3 Bioaccumulative potential: Not defined.

12.4 Mobility in soil: Not defined.

12.5 Results of PBT and vPvB assessment: Not defined.

12.6 Other adverse effects: Not defined.

#### **SECTION 13: DISPOSAL CONSIDERATIONS**

13.1 Waste treatment methods: In accordance with the governmental regulations of your country.

### **SECTION 14: TRANSPORT INFORMATION**

14.1 UN-Number: Not Applicable.

**14.2 UN proper shipping name:** Not Applicable.

14.3 Transport hazard class(es): Not Applicable.

14.4 Packing group: Not Applicable.

14.5 Environmental hazards: Not Applicable.14.6 Special precautions for user: Not Applicable.

14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code: Not Applicable.

## **SECTION 15: REGULATORY INFORMATION**

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture: These Material

Safety Data were prepared according to Regulation (EC) N° 453/2010.

15.2 Chemical Safety Assessment: Not Applicable.

### **SECTION 16: OTHER INFORMATION**

The information and recommendations are based on the MSDS and information of the raw material manufacturers.

Dentscare Ltda CNPJ 05.106.945/000106, is not responsible for the accuracy of this information or the need for additional information.