

# SAFETY DATA SHEET

PROCLINIC EXPERT PC 16%

Document version nº 1

## SECTION 1: Identification of the mixture and of the company

### 1.1 Identification of the mixture:

16% PC Home Kit 3ml syringes

### 1.2 Use of the mixture:

Cosmetic: teeth whitening

### 1.3 Company Identification:

Data of the company responsible for marketing/manufacturer:

DENTALSUR 2003 S.L.

Av/ Ortega y Gasset 152, 29006 Málaga

Tlf.: + 34 952040 057

### 1.4 Emergency telephone:

National Institute of Toxicology and Forensic Sciences

+34 915 620 420 (Information in Spanish 24h / 365 days).

Only for the purpose of providing sanitary response in case of urgency.

## SECTION 2: Hazards Identification

### 2.1 Classification of the mixture:

#### 2.1.1 Directive 67/548 / EC and Directive 1999/45 / EC:

The classification of the mixture has been carried out in accordance with Royal Decree 363/1995 (Directive 67/548 / EC) and Royal Decree 255/2003 (Directive 1999/45 / EC), adapting its provisions to Regulation (EC) 1907 / 2006 (REACH Regulation) according to Royal Decree 1802/2008. Irritating

#### 2.1.2 Regulation 1272/2008 (CLP):

The classification of the mixture has been carried out according to Regulation 1272/2008 (CLP), determines:

Eye irritant 2

### 2.2 Label elements:

Based on Directive 67/548 / EC and Directive 1999/45 / EC and Regulation 1272/2008 (CLP), the elements of labeling are as follows:

Pictograms:  (Xi)

Do not eat. Irritating to eyes, avoid contact with eyes. Keep out of reach of children. In case of accident consult the Medical Service of Toxicological Information, telephone 91 562 04 20.

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### 2.3 Other hazards

Not relevant.

## SECTION 3: Composition and information of the components

| INCI                           | CAS nº                  | classification                                | %   |
|--------------------------------|-------------------------|-----------------------------------------------|-----|
|                                | (EINECS nº)             | Regulation(CE)<br>1272/2008 (CLP)             |     |
| Aqua                           | 7732-18-5               |                                               | <85 |
|                                | (231-791-2)             |                                               |     |
| Carbamide peroxide             | 7722-84-1               | H271,H302,H314,H332,<br>GHS07,GHS05,GHS03,Dgr | <20 |
|                                | (231-765-0)             |                                               |     |
| Carbomer                       | 9007-20-9               |                                               | <6  |
|                                | (618-435-5)             |                                               |     |
| Triethanolamine                | 102-71-6<br>(203-049-8) | H315, GHS07,Wng                               | <4  |
| Xylitol                        | 87-99-0                 |                                               | <2  |
|                                | (201-788-0)             |                                               |     |
| Methyl salicylate              | 119-36-8                | H302, GHS07, Wng                              | <1  |
|                                | (204-317-7)             |                                               |     |
| HydroxyPropyl Methyl Cellulose | 9004-65-3               |                                               | <1  |
| Aloe Vera                      | 64-17-5                 |                                               | <1  |

## SECTION 4: First aid measures

### 4.1 Description of first aid:

In case of accident or discomfort, see a doctor immediately (if possible, show him the label).  
Never give anything by mouth to people who are unconscious

#### By inhalation

Not relevant.

#### By skin contact

Not relevant.

#### By eye contact:

May cause irritation. Irrigate the eyes with plenty of clean, fresh water during

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at least 15 minutes, until irritation subsides. Immediately request specialized medical assistance.

### **By ingestion:**

Rinse mouth Give small amounts of water to drink. Do not induce vomiting.

### **4.2 Main symptoms and effects, both acute and delayed:**

There are no symptoms or delayed effects. In case of acute symptoms are indicated in sections 2 and 11

### **4.3 Indication of all medical care and special treatments to be given immediately:**

Not relevant.

## **SECTION 5: Fire Fighting Measures**

### **5.1 Extinguishing modes:**

Where appropriate, use water or aqueous mixtures. This product does not burn. Extinguishing modes that should not be used for safety reasons: dry powder, carbon dioxide (Co2)

### **5.2 Specific hazards arising from the mixture:**

Not relevant.

### **5.3 Recommendations for firefighters:**

Wear autonomous breathing systems and protective clothing. The case of fire and / or explosion avoid breathing fumes.

## **SECTION 6: Accidental release measures**

### **6.1 Personal precautions, protective equipment and emergency procedures:**

Not relevant.

### **6.2 Environmental precautions:**

Avoid contamination of surface or groundwater, as well as soil. Do not allow the product to reach the sewer system. In case of large spills or if the product contaminates lakes, rivers or sewers, inform the competent authorities, according to current legislation.

### **6.3 Methods and material for containment and cleaning up:**

Very diluted solution, the drain can be cleaned with plenty of water. Do not re-pack spilled product in its original container.

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## 6.4 Reference to other section.

For waste disposal see section 13.

## SECTION 7: Handling and storage

### 7.1 Precautions for safe handling:

Comply with current legislation on occupational safety and health. Do not eat, drink or smoke during handling. After handling, wash your hands with soap and water. Avoid contact with eyes.

### 7.2 Conditions for safe storage, including any incompatibilities:

Keep in a cool and well ventilated place. Keep away from heat and sources of ignition. Container condition should be checked regularly. Store in original container. Materials to avoid: combustible material reducing agents, organic materials, metal oxide bases, metal ions (for example Mn, reduced Fe, Cu, Ni, Cr, Zn, metal salts, oxide, dirt).

### 7.3 Final specific uses:

Keep in refrigeration (4°-8°).

## SECTION 8: Exposure controls / personal protection

### Control parameters (ACGIH / OSHA):

Undetermined.

### 8.2 Exposure controls:

Eye protection with chemical protection glasses. Hygiene measures: Wash your hands with soap and water, wear gloves.

Eye / face protection: Wear eye protection equipment tested and approved according to standards such as NIOSH (USA) or EN 166 (EU).

Skin protection: Handle with gloves. Gloves must be checked before use. Use the correct technique of removing gloves (without touching the outer surface of the glove) to avoid skin contact with this product. Dispose of contaminated gloves after use, in accordance with applicable laws and good laboratory practices. Wash and dry hands. The selected protective gloves must comply with the specifications of EU Directive 89/686 / EEC and the EN 374 standard derived therefrom. Body Protection: Choose the protection for the body according to its characteristics the concentration and the amount of hazardous substances, and the specific place of work., The type of protective equipment must be chosen according to the concentration and the amount of substance dangerous to the place work specific.

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Respiratory protection: Respiratory protection not required. Where protection is desired Use respirators and components tested and approved under appropriate standards such as NIOSH (USA) or CEN (EU).

### SECTION 9: Physical and chemical properties

|                                       |                  |
|---------------------------------------|------------------|
| <b>9.1 Apariencia:</b>                | Transparent gel. |
| <b>9.2 Smell:</b>                     | Not applicable   |
| <b>9.3 Solubility in water:</b>       | Soluble.         |
| <b>9.4 Boiling point:</b>             | Undetermined.    |
| <b>9.5 Decomposition temperature:</b> | Undetermined.    |
| <b>9.6 Pressure / vapor density:</b>  | Undetermined.    |
| <b>9.7 pH:</b>                        | Not applicable   |
| <b>9.8 Explosive limits:</b>          | non flammable    |

### SECTION 10: Stability and reactivity

#### 10.1 Reactivity:

No risk of ignition.

#### 10.2 Chemical stability:

Stable under normal conditions of use.

#### 10.3 Possibility of hazardous reactions.

Not applicable

#### 10.4 Conditions to avoid:

High temperatures.

#### 10.5 Incompatible materials:

Not applicable

#### 10.6 Hazardous decomposition products.

It does not produce irritating substances and decomposing toxic gas.

### SECTION 11: Toxicological information

#### 11.1 Local Effects:

Harmful if swallowed.

**Carbamide peroxide**  
**Triethanolamine**

LD50 oral (rabbit):9200mg/kg  
LD50 oral (mouses):6400mg/kg

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## 11.2 Chronic toxicity:

**Carbamide peroxide**

Not classifiable for human by IARC.  
MUTAGENIC EFFECTS: Not mutagenic

**Triethanolamine**

Not mutagenic, not genotoxic.

## 11.3 Effects on humans:

**Carbamide peroxide**

Not described

**Triethanolamine**

Positive reactions interpreted as allergic seem to be caused by the ASD exposure in cosmetics and / or topical therapeutic preparations, possibly on damaged skin .

## SECTION 12: Ecological information

### 12.1 Acute aquatic toxicity:

**Carbamide peroxide**

LC100Fish: 250 mg/l 1 hour

**Triethanolamine**

LC50 Fish: > 10 000mg/L48 hours

**12.2 Persistence and gradability:**

Not available.

**12.3 Biaccumulation potential**

Not available.

**12.4 Mobility in soil**

Not available.

**12.5 Results of PBT and vPvB assessment**

Not available.

**12.6 Other adverse effects**

Not available.

## SECTION 13: Disposal considerations

### 13.1 Waste disposal:

Empty uncleaned waste and packaging must be handled and disposed of in accordance with current local / national laws. If applicable, return to the manufacturer or dispose of in accordance with the applicable state, regional and local legal requirements and applicable environmental regulations. Empty containers can be returned to the manufacturer or should be recycled or disposed of through an approved waste management facility.

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**Disposal of empty containers:** Packaging can be managed and disposed of by incineration or in a landfill as domestic containers and in accordance with the current local / national laws.

### 13.2 Special disposal considerations

The remaining liquids can be discarded into a treatment plant after dilution with plenty of water, but in accordance with local regulations.

## SECTION 14: Transport information

DANGEROUS COMPONENTS: DOES NOT APPLY

### 14.1 Road transport (ADR) and rail (RID):

Suitable

### 14.2 Transport by sea (IMDG):

Suitable

### 14.3 Transport by air (ICAO / IATA)

Suitable

## SECTION 15: Regulatory information

The substance (s) is listed in the EINECS, ELINCS, NPL inventories, or else it is exempt.

- **Classification according to Regulation (EC) No. 1272/2008 on classification, packaging and labeling:**



Symbols and words:

Precautionary statements:

Irritating to eyes (R36)

### OTHER INFORMATION:

Do not eat.

Avoid contact with eyes.

In case of an accident consult the National Toxicological Information Service,  
Telephone 91 562 04 20

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### SECTION 16: Other information

The information contained in this document is offered based on the knowledge available about the product at the time of its edition. Any use of the product other than the one indicated or its combination with others is the responsibility of the user. The specifications of this safety data sheet describe the safety requirements of our product and do not represent a guarantee of its characteristics.

Composition communicated to the National Institute of Toxicology and Forensic Sciences. Information on applications, dosage and form of use in its corresponding safety data sheet and labeling.

Main bibliographical references and data sources:

1. Royal Decree 363/1995, of March 10, 1995, regulating the Notification of New Substances and Classification, Packaging and Labeling of Hazardous Substances.
2. Royal Decree 255/2003, of February 28, which approves the Regulation on classification, packaging and labeling of dangerous preparations.
3. Regulation (EC) number 1907/2006 of the European Parliament and of the Council of 18 December 2006, concerning the registration, the Evaluation, authorization and restriction of chemical substances and preparations (REACH), which creates the European Chemicals Agency, amends Directive 1999/45 / EC and repeals Regulation (EEC) No 793 / 93 of Consejo and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769 / EEC and Directives 91/155 / EEC, 93/67 / EEC, 93/105 / EC and 2000/21 / EC of the Commission.
4. Regulation (EC) number 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labeling and packaging of substances and mixtures, and amending and repealing Directives 67/548 / EEC and 1999 / 45 / CE and the Regulation (EC) number 1907/2006.
5. Occupational Exposure Limits for Chemical Agents adopted by the National Institute for Occupational Safety and Health (INSHT) for the year 2011.

The information contained in this document is offered based on the knowledge available about the product at the time of its edition. Any use of the product other than that indicated in section 1 or its combination with others is the responsibility of the user. The specifications of this safety data sheet describe the safety requirements of our product and do not represent a guarantee of its characteristics.

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### SECTION 1: Identification of the mixture and of the company

#### 1.1 Identification of the mixture:

10% PC Home Kit eml Syringes

#### 1.2 Use of the mixture:

Cosmetic: teeth whitening

#### 1.3 Company Identification:

Data of the company responsible for marketing/manufacturer:

DENTALSUR 2003 S.L.

Av/ Ortega y Gasset 152, 29006 Málaga

Tlf.: + 34 952040 057

#### 1.4 Emergency telephone:

National Institute of Toxicology and Forensic Sciences

+34 915 620 420 (Information in Spanish 24h / 365 days).

Only for the purpose of providing sanitary response in case of urgency.

### SECTION 2: Hazards Identification

#### 2.1 Classification of the mixture:

##### 2.1.1 Directive 67/548 / EC and Directive 1999/45 / EC:

The classification of the mixture has been carried out in accordance with Royal Decree 363/1995 (Directive 67/548 / EC) and Royal Decree 255/2003 (Directive 1999/45 / EC), adapting its provisions to Regulation (EC) 1907 / 2006 (REACH Regulation) according to Royal Decree 1802/2008. Irritating

##### 2.1.2 Regulation 1272/2008 (CLP):

The classification of the mixture has been carried out according to Regulation 1272/2008 (CLP), determines:

Eye irritant 2

#### 2.2 Label elements:

Based on Directive 67/548 / EC and Directive 1999/45 / EC and Regulation 1272/2008 (CLP), the elements of labeling are as follows:

Pictograms:  (Xi)

Do not eat. Irritating to eyes, avoid contact with eyes. Keep out of reach of children. In case of accident consult the Medical Service of Toxicological Information, telephone 91 562 04 20.

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### 2.3 Other hazards

Not relevant.

## SECTION 3: Composition and information of the components

| INCI                           | CAS nº                  | classification                                | %   |
|--------------------------------|-------------------------|-----------------------------------------------|-----|
|                                | (EINECS nº)             | Regulation(CE)<br>1272/2008 (CLP)             |     |
| Aqua                           | 7732-18-5               |                                               | <85 |
|                                | (231-791-2)             |                                               |     |
| Carbamide peroxide             | 7722-84-1               | H271,H302,H314,H332,<br>GHS07,GHS05,GHS03,Dgr | <15 |
|                                | (231-765-0)             |                                               |     |
| Carbomer                       | 9007-20-9               |                                               | <10 |
|                                | (618-435-5)             |                                               |     |
| Triethanolamine                | 102-71-6<br>(203-049-8) | H315, GHS07,Wng                               | <5  |
| Xylitol                        | 87-99-0                 |                                               | <3  |
|                                | (201-788-0)             |                                               |     |
| Methyl salicylate              | 119-36-8                | H302, GHS07, Wng                              | <3  |
|                                | (204-317-7)             |                                               |     |
| HydroxyPropyl Methyl Cellulose | 9004-65-3               |                                               | <1  |
| Aloe Vera                      | 64-17-5                 |                                               | <1  |

## SECTION 4: First aid measures

### 4.1 Description of first aid:

In case of accident or discomfort, see a doctor immediately (if possible, show him the label).  
Never give anything by mouth to people who are unconscious

#### By inhalation

Not relevant.

#### By skin contact

Not relevant.

#### By eye contact:

May cause irritation. Irrigate the eyes with plenty of clean, fresh water during

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at least 15 minutes, until irritation subsides. Immediately request specialized medical assistance.

### **By ingestion:**

Rinse mouth Give small amounts of water to drink. Do not induce vomiting.

### **4.2 Main symptoms and effects, both acute and delayed:**

There are no symptoms or delayed effects. In case of acute symptoms are indicated in sections 2 and 11

### **4.3 Indication of all medical care and special treatments to be given immediately:**

Not relevant.

## **SECTION 5: Fire Fighting Measures**

### **5.1 Extinguishing modes:**

Where appropriate, use water or aqueous mixtures. This product does not burn. Extinguishing modes that should not be used for safety reasons: dry powder, carbon dioxide (Co2)

### **5.2 Specific hazards arising from the mixture:**

Not relevant.

### **5.3 Recommendations for firefighters:**

Wear autonomous breathing systems and protective clothing. The case of fire and / or explosion avoid breathing fumes.

## **SECTION 6: Accidental release measures**

### **6.1 Personal precautions, protective equipment and emergency procedures:**

Not relevant.

### **6.2 Environmental precautions:**

Avoid contamination of surface or groundwater, as well as soil. Do not allow the product to reach the sewer system. In case of large spills or if the product contaminates lakes, rivers or sewers, inform the competent authorities, according to current legislation.

### **6.3 Methods and material for containment and cleaning up:**

Very diluted solution, the drain can be cleaned with plenty of water. Do not re-pack spilled product in its original container.

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### 6.4 Reference to other section.

For waste disposal see section 13.

## SECTION 7: Handling and storage

### 7.1 Precautions for safe handling:

Comply with current legislation on occupational safety and health. Do not eat, drink or smoke during handling. After handling, wash your hands with soap and water. Avoid contact with eyes.

### 7.2 Conditions for safe storage, including any incompatibilities:

Keep in a cool and well ventilated place. Keep away from heat and sources of ignition. Container condition should be checked regularly. Store in original container. Materials to avoid: combustible material reducing agents, organic materials, metal oxide bases, metal ions (for example Mn, reduced Fe, Cu, Ni, Cr, Zn, metal salts, oxide, dirt).

### 7.3 Final specific uses:

Keep in refrigeration (4°-8°).

## SECTION 8: Exposure controls / personal protection

### Control parameters (ACGIH / OSHA):

Undetermined.

### 8.2 Exposure controls:

Eye protection with chemical protection glasses. Hygiene measures: Wash your hands with soap and water, wear gloves.

Eye / face protection: Wear eye protection equipment tested and approved according to standards such as NIOSH (USA) or EN 166 (EU).

Skin protection: Handle with gloves. Gloves must be checked before use. Use the correct technique of removing gloves (without touching the outer surface of the glove) to avoid skin contact with this product. Dispose of contaminated gloves after use, in accordance with applicable laws and good laboratory practices. Wash and dry hands. The selected protective gloves must comply with the specifications of EU Directive 89/686 / EEC and the EN 374 standard derived therefrom. Body Protection: Choose the protection for the body according to its characteristics the concentration and the amount of hazardous substances, and the specific place of work., The type of protective equipment must be chosen according to the concentration and the amount of substance dangerous to the place work specific.

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Respiratory protection: Respiratory protection not required. Where protection is desired Use respirators and components tested and approved under appropriate standards such as NIOSH (USA) or CEN (EU).

### SECTION 9: Physical and chemical properties

|                                       |                  |
|---------------------------------------|------------------|
| <b>9.1 Apariencia:</b>                | Transparent gel. |
| <b>9.2 Smell:</b>                     | Not applicable   |
| <b>9.3 Solubility in water:</b>       | Soluble.         |
| <b>9.4 Boiling point:</b>             | Undetermined.    |
| <b>9.5 Decomposition temperature:</b> | Undetermined.    |
| <b>9.6 Pressure / vapor density:</b>  | Undetermined.    |
| <b>9.7 pH:</b>                        | Not applicable   |
| <b>9.8 Explosive limits:</b>          | non flammable    |

### SECTION 10: Stability and reactivity

#### 10.1 Reactivity:

No risk of ignition.

#### 10.2 Chemical stability:

Stable under normal conditions of use.

#### 10.3 Possibility of hazardous reactions.

Not applicable

#### 10.4 Conditions to avoid:

High temperatures.

#### 10.5 Incompatible materials:

Not applicable

#### 10.6 Hazardous decomposition products.

It does not produce irritating substances and decomposing toxic gas.

### SECTION 11: Toxicological information

#### 11.1 Local Effects:

Harmful if swallowed.

**Carbamide peroxide**  
**Triethanolamine**

LD50 oral (rabbit): 9200mg/kg  
LD50 oral (mouses): 6400mg/kg

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### 11.2 Chronic toxicity:

#### Carbamide peroxide

Not classifiable for human by IARC.  
MUTAGENIC EFFECTS: Not mutagenic

#### Triethanolamine

Not mutagenic, not genotoxic.

### 11.3 Effects on humans:

#### Carbamide peroxide

Not described

#### Triethanolamine

Positive reactions interpreted as allergic seem to be caused by the ASD exposure in cosmetics and / or topical therapeutic preparations, possibly on damaged skin .

## SECTION 12: Ecological information

### 12.1 Acute aquatic toxicity:

#### Carbamide peroxide

LC100Fish: 250 mg/l 1 hour

#### Triethanolamine

LC50 Fish: > 10 000mg/L48 hours

### 12.2 Persistence and gradability:

Not available.

### 12.3 Biaccumulation potential

Not available.

### 12.4 Mobility in soil

Not available.

### 12.5 Results of PBT and vPvB assessment

Not available.

### 12.6 Other adverse effects

Not available.

## SECTION 13: Disposal considerations

### 13.1 Waste disposal:

Empty uncleaned waste and packaging must be handled and disposed of in accordance with current local / national laws. If applicable, return to the manufacturer or dispose of in accordance with the applicable state, regional and local legal requirements and applicable environmental regulations. Empty containers can be returned to the manufacturer or should be recycled or disposed of through an approved waste management facility.

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**Disposal of empty containers:** Packaging can be managed and disposed of by incineration or in a landfill as domestic containers and in accordance with the current local / national laws.

### 13.2 Special disposal considerations

The remaining liquids can be discarded into a treatment plant after dilution with plenty of water, but in accordance with local regulations.

## SECTION 14: Transport information

DANGEROUS COMPONENTS: DOES NOT APPLY

### 14.1 Road transport (ADR) and rail (RID):

Suitable

### 14.2 Transport by sea (IMDG):

Suitable

### 14.3 Transport by air (ICAO / IATA)

Suitable

## SECTION 15: Regulatory information

The substance (s) is listed in the EINECS, ELINCS, NPL inventories, or else it is exempt.

- **Classification according to Regulation (EC) No. 1272/2008 on classification, packaging and labeling:**



Symbols and words:

Precautionary statements:

Irritating to eyes (R36)

### OTHER INFORMATION:

Do not eat.

Avoid contact with eyes.

In case of an accident consult the National Toxicological Information Service,  
Telephone 91 562 04 20

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### SECTION 16: Other information

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Composition communicated to the National Institute of Toxicology and Forensic Sciences. Information on applications, dosage and form of use in its corresponding safety data sheet and labeling.

Main bibliographical references and data sources:

1. Royal Decree 363/1995, of March 10, 1995, regulating the Notification of New Substances and Classification, Packaging and Labeling of Hazardous Substances.
2. Royal Decree 255/2003, of February 28, which approves the Regulation on classification, packaging and labeling of dangerous preparations.
3. Regulation (EC) number 1907/2006 of the European Parliament and of the Council of 18 December 2006, concerning the registration, the Evaluation, authorization and restriction of chemical substances and preparations (REACH), which creates the European Chemicals Agency, amends Directive 1999/45 / EC and repeals Regulation (EEC) No 793 / 93 of Consejo and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769 / EEC and Directives 91/155 / EEC, 93/67 / EEC, 93/105 / EC and 2000/21 / EC of the Commission.
4. Regulation (EC) number 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labeling and packaging of substances and mixtures, and amending and repealing Directives 67/548 / EEC and 1999 / 45 / CE and the Regulation (EC) number 1907/2006.
5. Occupational Exposure Limits for Chemical Agents adopted by the National Institute for Occupational Safety and Health (INSHT) for the year 2011.

The information contained in this document is offered based on the knowledge available about the product at the time of its edition. Any use of the product other than that indicated in section 1 or its combination with others is the responsibility of the user. The specifications of this safety data sheet describe the safety requirements of our product and do not represent a guarantee of its characteristics.

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