

# Safety Data Sheet

According to Regulation (EC) No 1272/2008  
Revision 3: 09/06/2021

## SECTION 1. PRODUCT/ MIXTURE AND COMPANY IDENTIFICATION

### *1.1 Product Identifier*

|                               |                             |
|-------------------------------|-----------------------------|
| Product name                  | BLANCONE® HOME DAY or NIGHT |
| Other means of identification | Not Available               |

### *1.2 Details of the supplier of the safety data sheet*

|                       |   |
|-----------------------|---|
| Manufacturer/Supplier | IDS SpA   |
| Address               | Via S. Cristoforo 28/10 – 17100 Savona -<br>Italy |
| Telephone             | +39.019.862080,                                   |
| Fax                   | -   |
| Website               | -----   |
| Email                 | info@idsdental.it                                 |
| Emergency Telephone   | +39.019.862080                                    |

### *1.3 Description of the Product*

BLANCONE® HOME is a two-syringe product for teeth bleaching (Syringe 1: Whitening gel and Syringe 2: Activator gel). The content of the 2 syringes is mixed before the use and the first application is performed in office by dentist and afterwards the user continuous the application in home according to the instructions of the dentist.

## SECTION 2. HAZARDS IDENTIFICATION

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

**Hazardous mixture according to directive (EC) No 1272/2008.**

**Not classified as Dangerous Goods for transport purposes.**

|   |  |
|---|--|
| Classification according to regulation (EC)<br>No 1272/2008 [CLP] [1] | Eye Irritation Category 2<br>Skin Irritation, Category 2       |
| [1]   | Classification drawn from EC Directive<br>1272/2008 - Annex VI |

### *2.2 Label element(s)*

CLP label element  
Pictogram GHS07



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## Hazardous components

### SIGNAL WORD

**WARNING**

### Hazard statement(s)

**H319 H315**

Causes serious irritation on eye and skin

### Supplementary statement(s)

Not Applicable

### Precautionary statement(s) Prevention

**P280**

Wear protective gloves/protecting clothing/eye protection/face protection

### Precautionary statement(s) Response

**P305+P351+P338**

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

**P337+P313**

If eye irritation persists: Get medical advice/attention.

## Precautionary statement(s) Storage

|      |                                  |
|------|----------------------------------|
| P273 | Avoid release to the environment |
|------|----------------------------------|

## Precautionary statement(s) Disposal

|      |   |
|------|---|
| P501 | Dispose of in compliance with governmental regulation. (EC1975L0442-10/11/2003) |
|------|---|

## 2.3 Other hazards

Cumulative effects may result following exposure\*.

May produce skin discomfort\*.

**REACH** - Art.57-59: The mixture does not contain Substances of Very High Concern (SVHC) at the SDS print date.

## SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

### Description

Bleaching gel for application on the teeth.

### 3.1 Substances

Not Applicable

### 3.2 Mixtures/ Chemical characterization

BlancOne Home Day 16% Bleaching gel or

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BlancOne Home Night 10% Bleaching gel

| CAS No     | EC No     | REACH No              | Description            | % w/w  | Classification according to Regulation EC No 1272/2008 (GLP)   |
|------------|-----------|-----------------------|------------------------|--------|--|
| 124-43-6   | 204-701-4 | Not Available         | Urea hydrogen peroxide | ≤16    | Oxidizing Solid Category 3, Metal Corrosion Category 1, Acute Toxicity (Oral) Category 4, Acute Toxicity (Inhalation) Category 4, Skin Corrosion/Irritation Category 1B, Serious Eye Damage Category 1; H272, H290, H302, H332, H314, H318 [1] |
| 7681-49-4  | 231-667-8 |                       | Sodium Fluoride        | 0.11   | Eye Irr., Cat. 2; Skin Irr., Cat. 2; Acute Tox. (O), CAT 3; EUH032; H301; H315; H319   |
| 7757-79-1  | 231-818-8 | Not Available         | Potassium Nitrate      | < 5.00 | H272   |
| 1310-73-2  | 215-185-5 |                       | Sodium Hydroxide       | < 2.00 | Skin Corr., Cat. 1B; H314  |
| 122-99-6   | 204-589-7 | 01-2119488943-21-XXXX | Phenoxyethanol         | < 0.30 | Acute Tox. 4; Eye Irrit. 2; H302, H319   |
| 57-55-6    | 200-338-0 | 01-2119456809-23-XXXX | Propylene Glycol       | 13.33  | Not a hazardous substance or mixture according to Regulation (EC) No. 1272/2008  |
| 6381-92-6  | 205-358-3 | Not Available         | Disodium EDTA          | < 2.50 | Acute Tox. 4; STOT RE 2; H332, H373  |
| 9067-32-7  |           | Not Available         | Sodium Hyaluronate     | < 1.00 | Not a hazardous substance or mixture according to Regulation (EC) No. 1272/2008  |
| 12167-74-7 | 235-330-6 | Not Available         | Hydroxyapatite         |        | Not a hazardous substance or mixture according to Regulation (EC) No. 1272/2008  |

For full text of H-statements and R-phrases: see SECTION 16.

## **SECTION 4. FIRST AID MEASURES**

### **General information**

The intended use is for application for the patient at dental office and patient home following the instructions of the dentist.

### **Skin contact**

Immediately rinse with a lot of water and a mild soap. If irritation develops consult a doctor.

### **Eye contact**

Rinse opened eye for several minutes under running water. Then consult a doctor.

### **After swallowing**

No risk at small doses at intended use. Rinse out mouth and then drink plenty of water. In case of high dose consult doctor.

## **SECTION 5. FIREFIGHTING MEASURES**

### **Suitable extinguishing agents**

Water spray. Use fire extinguishing methods suitable to surrounding conditions.

## **For safety reasons unsuitable extinguishing agents**

Water with full jet, CO<sub>2</sub>

## **Protective equipment**

No special measures.

## **SECTION 6. ACCIDENTAL RELEASE MEASURES**

### **Person-related safety precautions**

Wear protective equipment. Keep unprotected persons away. Dilute with plenty of water.

### **Measures for cleaning/collecting**

Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).

### **Measures for environmental protection (see section 12)**

Dispose contaminated material as waste according to item 13.

## **SECTION 7. HANDLING AND STORAGE**

### **Handling**

#### **Safe Handling**

- Avoid all personal contact, including inhalation.
- Wear protective clothing when risk of exposure occurs.
- Use in a well-ventilated area.
- Prevent concentration in hollows and sumps.
- DO NOT enter confined spaces until atmosphere has been checked.
- DO NOT allow material to contact humans, exposed food or food utensils.
- Avoid contact with incompatible materials.
- When handling, DO NOT eat, drink or smoke.
- Keep containers securely sealed when not in use.
- Avoid physical damage to containers.
- Always wash hands with soap and water after handling.
- Work clothes should be laundered separately. Launder contaminated clothing before re-use.
- Use good occupational work practice.
- Observe manufacturer's storage and handling recommendations contained within this SDS.
- Atmosphere should be regularly checked against established exposure standards to ensure safe working conditions are maintained.

#### **Information about fire - and explosion protection**

Ensure good ventilation/exhaustion at the workplace. No special measures required.

### **Storage**

#### **Requirements to be met by storerooms and receptacles**

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Store in dry and well ventilated area at 5°C to 25°C. Avoid the direct contact with light and heat

## Information about storage in one common storage facility

- Store away from flammable substances.
- Store away from reducing agents.
- Store away from metals.

## Further information about storage conditions

- Keep receptacle tightly sealed.
- Protect from heat and direct sunlight.
- Store in a cool place.
- Heat will increase pressure and may lead to the receptacle bursting.

## **SECTION 8. EXPOSURE CONTROLS/ PERSONAL PROTECTION**

### General protective measures

Avoid contact with eyes and skin

### Hygienic measures

Immediately remove all soiled and contaminated clothing

| <b>8.1 Control parameters</b> |                  |                       |                     |                      |
|-------------------------------|------------------|-----------------------|---------------------|----------------------|
| <b>Exposure limits (EH40)</b> |                  |                       |                     |                      |
| <b>CAS No</b>                 | <b>Substance</b> | <b>TEEL-1*</b>        | <b>TEEL-2*</b>      | <b>TEEL-3*</b>       |
| -                             | Urea peroxide    | 1.2 mg/m <sup>3</sup> | 13mg/m <sup>3</sup> | 79 mg/m <sup>3</sup> |

**\*TEEL-3** is the airborne concentration (expressed as ppm [parts per million] or mg/m<sup>3</sup> [milligrams per cubic meter]) of a substance above which it is predicted that the general population, including susceptible individuals, when exposed for more than one hour, could experience life-threatening adverse health effects or death.

**\*TEEL-2** is the airborne concentration (expressed as ppm or mg/m<sup>3</sup>) of a substance above which it is predicted that the general population, including susceptible individuals, when exposed for more than one hour, could experience irreversible or other serious, long-lasting, adverse health effects or an impaired ability to escape.

**\*TEEL-1** is the airborne concentration (expressed as ppm or mg/m<sup>3</sup>) of a substance above which it is predicted that the general population, including susceptible individuals, when exposed for more than one hour, could experience notable discomfort, irritation, or certain asymptomatic, nonsensory effects. However, these effects are not disabling and are transient and reversible upon cessation of exposure.

| <b>Exposure Limits / Engineering Controls Chemical Components</b> | <b>ACGIH – TLV*</b>   | <b>NIOSH – REL*</b>   | <b>OSHA – Final PELs*</b> |
|---|-----------------------|-----------------------|---------------------------|
| Carbamide Peroxide  | None listed           | None listed           | None listed               |
| Sodium Fluoride   | 2.5 mg/m <sup>3</sup> | 2.5 mg/m <sup>3</sup> | 2.5 mg/m <sup>3</sup>     |

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\* **TLV – Threshold Limit Value** (should not be exceeded at any time) / **REL – Recommended Exposure Limit** (should not be exceeded at any time) / **PEL – Permissible Exposure Limit** (averaged over an 8-hour workshift)

## 8.2. Personal Protective Equipment (PPE) Information

**Eyes:** Wear appropriate protective eyeglasses or chemical safety goggles as described by OSHA's eye and face protection regulations in 29 CFR 1910.133 or European Standard EN166.

**Skin:** S36/37: Wear suitable protective clothing and gloves.

**Clothing:** Wear appropriate protective clothing to prevent skin exposure.

**Respiratory:** S38: In case of insufficient ventilation, wear suitable respiratory equipment.

## SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

### BLANCONE HOME DAY or NIGHT

**Form:** Opaque Gel

**Colour:** Colourless

**Odour:** Characteristic

|                     | Value                            | Temperature |
|---------------------|----------------------------------|-------------|
| pH-value            | 5.0-7.5                          |             |
| Boiling point       | n/a                              |             |
| Vapour pressure     | n/a                              | 20°C        |
| Density             | 1.100-1.300<br>g/cm <sup>3</sup> | 25°C        |
| Solubility in water | Yes                              |             |
| Viscosity           | 30,000-70,000<br>cPs             | 25°C        |

## SECTION 10. STABILITY AND REACTIVITY

### **Stability**

Product is stable at room temperature in closed containers under normal storage and handling conditions.

### **Dangerous reactions**

Reacts with various metals

Reacts with reducing agents Reacts with catalysts

Acts as an oxidizing agent on organic materials such as wood, paper and fats

## **Hazardous decomposition products**

Decomposition by combustion, may release oxides of carbon and nitrogen.

## **SECTION 11. TOXICOLOGICAL INFORMATION**

### *11.1 Information on toxicological effects*

|              |   |
|--------------|---|
| Inhaled      | The material is not thought to produce adverse health effects or irritation of the respiratory tract. Nevertheless, good hygiene practice requires that exposure be kept to a minimum and that suitable control measures be used in an occupational setting   |
| Ingestion    | The material has <b>NOT</b> been classified by EC Directives or other classification systems as "harmful by ingestion". This is because of the lack of corroborating animal or human evidence. The material may still be damaging to the health of the individual, following ingestion, especially where pre-existing organ (e.g liver, kidney) damage is evident. Present definitions of harmful or toxic substances are generally based on doses producing mortality rather than those producing morbidity (disease, ill-health). Gastrointestinal tract discomfort may produce nausea and vomiting. In an occupational setting however, ingestion of insignificant quantities is not thought to be cause for concern.  |
| Skin contact | Limited evidence exists, or practical experience predicts, that the material either produces inflammation of the skin in a substantial number of individuals following direct contact, and/or produces significant inflammation when applied to the healthy intact skin, for up to four hours, such inflammation being present twenty-four hours or more after the end of the exposure period. Skin irritation may also be present after prolonged or repeated exposure; this may result in a form of contact dermatitis (nonallergic). The dermatitis is often characterised by skin redness (erythema) and swelling (oedema) which may progress to blistering (vesiculation), scaling and thickening of the epidermis. At the microscopic level there may be intercellular oedema of the spongy layer of the skin (spongiosis) and intracellular oedema of the epidermis. Open cuts, abraded or irritated skin should not be exposed to this material<br>Entry into the blood-stream through, for example, cuts, abrasions, puncture wounds or lesions, may produce systemic injury with harmful effects. Examine the |

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|                      |   |
|----------------------|---|
|                      | skin prior to the use of the material and ensure that any external damage is suitably protected. <b>IRRITANT</b>  |
| Eye                  | Evidence exists, or practical experience predicts, that the material may cause eye irritation in a substantial number of individuals and/or may produce significant ocular lesions.<br>Repeated or prolonged eye contact may cause inflammation characterised by temporary redness (similar to windburn) of the conjunctiva (conjunctivitis);<br>Temporary impairment of vision and/or other transient eye damage/ulceration may occur. <b>STRONG IRRITANT WITH DANGER OF SEVERE EYE INJURY</b> |
| Chronic              | Limited evidence suggests that repeated or long-term occupational exposure may produce cumulative health effects involving organs or biochemical systems.   |
| Toxicity             | No data available   |
| Teratogenicity       | No data available   |
| Reproductive Effects | No data available   |
| Mutagenicity         | No data available   |

## SECTION 12. ECOLOGICAL/ENVIRONMENTAL INFORMATION

Under normal and foreseeable uses, there are no concerns for aquatic organisms exposed to product ingredients at the anticipated environmental concentrations. Relevant environmental data have been reviewed and these indicate that the product is compatible with down-the-drain disposal routes, including municipal wastewater treatment processes and septic tank systems. This product is intended for dispersive use and should not be disposed of directly into the environment.

## SECTION 13. DISPOSAL CONSIDERATIONS

|                                |   |
|--------------------------------|---|
| <b>Product</b>                 | <b>Small amounts may be diluted with plenty of water and washed away. Dispose of bigger amounts in accordance with governmental regulation. (EC 1975L0442-20/11/2003).</b>                    |
| <b>Uncleaned packaging</b>     | Empty contaminated packaging thoroughly. They may be recycled after thorough and proper cleaning.<br><u>Recommended cleansing agents:</u> Water, if necessary together with cleansing agents. |
| <b>Waste treatment options</b> | Not Available   |
| <b>Sewage disposal options</b> | Not Available   |



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## SECTION 14. TRANSPORT INFORMATION

|   |   |
|---|---|
| <b>14.1 Labels Required</b>               |   |
| <b>Marine Pollutant</b>                   | NO  |
| <b>HAZCHEM</b>                            | Not Applicable  |
| <b>14.2 General transport information</b> |   |
| <b>Land transport ADR/RID (GGV SE)</b>    | No dangerous good in sense of these transport regulations |
| <b>Inland waterways transport (ADN)</b>   | No dangerous good in sense of these transport regulations |
| <b>Sea transport IMDG (GGV See)</b>       | No dangerous good in sense of these transport regulations |
| <b>Air transport (ICAO)</b>               | No dangerous good in sense of these transport regulations |

## SECTION 15. REGULATORY INFORMATION

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

|  |  |
|--|--|
| UREA HYDROGEN PEROXIDE (124-43-6 IS FOUND ON THE FOLLOWING REGULATORY LISTS)                           |  |
| European Customs Inventory of Chemical Substances ECICS (English)<br>Regulation 1223/2009 on Cosmetics | European Union - European Inventory of Existing Commercial Chemical Substances (EINECS)<br>(English) |

## SECTION 16. OTHER INFORMATION

|   |   |
|---|---|
| <b>16.1 Full text Hazard (H) and Risk (R) codes (not classification of ready mixed product)</b> |   |
| <b>H-phrases</b>  |   |
| H225  | Highly flammable liquid and vapour            |
| H271  | May cause fire or explosion; strong oxidiser. |
| H272  | May intensify fire; oxidiser.                 |
| H290  | May be corrosive to metals.                   |
| H301  | Toxic if swallowed.                           |
| H302  | Harmful if swallowed                          |
| H314  | Causes severe skin burns and eye damage.      |
| H318  | Causes serious eye damage                     |
| H330  | Fatal if inhaled.                             |
| H332  | Harmful if inhaled.                           |
| H335  | May cause respiratory irritation.             |

**This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.**