According to Regulation (EC) No 1272/2008

Revision 1: 27/09/2023

SECTION 1. PRODUCT/ MIXTURE AND COMPANY IDENTIFICATION

1.1 Product Identifier	
Product name	BLANCONE® HOME FAST
Other means of identification	BLANCONE® HOME FAST Single
	REF: 015031
	BLANCONE® HOME FAST Multi
	REF: 015036

1.2 Details of the supplier of the safety data sheet			
Manufacturer/Supplier IDS SpA			
Address	Via S. Cristoforo 28/10 – 17100 Savona -		
	Italy		
Telephone	+39.019.862080,		
Fax	-		
Website			
Email	info@idsdental.it		
Emergency Telephone	+39.019.862080		

1.3 Description of the Product

BLANCONE® HOME FAST is a dual chamber syringe system for teeth bleaching at home under the supervision of a dental health professional. The first chamber contains the Whitening gel and the second chamber contains the Activator gel. The content of the 2 chambers is mixed just before the application of the final gel on the tray as both gels are passing through the mixing tip. The first application and presentation of the product is performed in office by a dental health professional and afterwards the user continuous the application in home according to the given instructions.

SECTION 2. HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

H372 Specific target organ toxicity - repeated exposure, Oral (Category 1), Thyroid H412 Harmful to aquatic life with long lasting effects (Category 3)

Not classified as Dangerous Goods for transport purposes.

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

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2.2 Label element(s)

CLP label element

Pictogram GHS07



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

Cosmetic bleaching gel for application on the teeth according to the European Directive 2011/84.

According to Regulation (EC) No 1272/2008 Revision 1: 27/09/2023

3.1 Substances

See section 3.2

3.2 Mixtures/ Chemical characterization

BlancOne Home FAST 6% Hydrogen Peroxide Bleaching gel after mixing

Hazardous components

Hazai	raous com	ponents			
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	Hydrogen peroxide	< 12	Acute Toxicity, Category 4, Oral, H302 Serious Eye Damage Category 1, H318 Skin Irritation, Category 2 Specific Target organ toxicity, Category 4, H413 Oxidizing liquids, Category 2
1310-73-2	215-185-5	Not Available	Sodium Hydroxide	< 2.00	Skin Corr.,Cat. 1A; H315,H319
122-99-6	204-589-7	Not Available	Phenoxyethanol	< 0.30	Acute Tox. 4; Eye Irrit. 2; H302, H319 ATE oral 1394 mg/Kg BW
6381-92-6	205-358-3	Not Available	Disodium EDTA	< 2.50	Acute Tox. 4; STOT RE 2; H332, H373
12167-74- 7	235-330-6	Not Available	Hydroxyapatite	< 1.50	Not a hazardous substance or mixture according to Regulation (EC) No. 1272/2008
112945- 52-5 / 7631-86-9	231-545-4	Not Available	Silicon Dioxide, chemically prepared	< 10.00	Not a hazardous substance or mixture according to Regulation (EC) No. 1272/2008
9003-01-4		Not Available	Polyacrylic acid	0.5% <c<4%< td=""><td>Harmful to aquatic life with long lasting effects H412</td></c<4%<>	Harmful to aquatic life with long lasting effects H412
7681-11-0	231-659-4	Not Available	Potassium Iodide	< 0.015%	Specific target organ toxicity - repeated exposure, Oral (Category 1), Thyroid, H372
N/A	N/A	Not Available	Ingredients determined to be Non- Hazardous	< 68.00	N/A

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.

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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, CO2

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.

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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

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

8.1 Control parameters			
Exposure Guidelines			
Component	ACGIH TLV	OSHA PEL	NIOSH IDLH
Hydrogen Peroxide	TWA: 1 ppm	(Vacated) TWA: 1 ppm (Vacated) TWA: 1.4 mg/m3 TWA: 1 ppm TWA: 1.4 mg/m3	IDLH: 75 ppm TWA: 1 ppm TWA: 1.4 mg/m3

ACGIH - American Conference of Governmental Industrial Hygienists

OSHA - Occupational Safety and Health Administration

NIOSH IDLH: The National Institute for Occupational Safety and Health Immediately

Dangerous to Life or Health

* 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

According to Regulation (EC) No 1272/2008 Revision 1: 27/09/2023

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 FAST Final Gel after mixing

Form: Opaque Gel

Colour: White - off white

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 g/cm3	25°C
Solubility in water	Yes	
Viscosity	30,000-70,000	25°C
	cPs	

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

<u>Hazardous</u> decomposition products

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

SECTION 11. TOXICOLOGICAL INFORMATION

Safety Data Sheet
According to Regulation (EC) No 1272/2008
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11.1 Information on toxicological effects

Inhaled Ingestion	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. The material has NOT 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 Entry into the blood-stream through, for example, cuts, abrasions, puncture wounds or lesions, may produce systemic injury with harmful effects. Examine the skin prior to the use of the material and ensure that any external damage is suitably protected. IRRITANT
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. Repeated or prolonged eye contact may cause inflammation characterised by temporary redness (similar to windburn) of the conjunctiva (conjunctivitis); Temporary impairment of vision and/or other transient eye damage/ulceration may occur. STRONG IRRITANT WITH DANGER OF SEVER EYE INJURY
Chronic	Limited evidence suggests that repeated or long-term occupational exposure may produce cumulative health effects involving organs or biochemical systems.

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Acute Toxicity

Product Information

Oral LD50	Category 4. ATE = 300 - 2000 mg/kg
Dermal LD50	Based on ATE data, the classification criteria are not met. ATE > 2000 mg/kg
Vapor LC50	Category 4. ATE = 10 - 20 mg/l. Based on ATE data, the classification
	criteria are not met.
	ATE > 20 mg/l

Component Information

Component	LD50 Oral	LD50 Dermal	LC50 Inhalation
Hydrogen peroxide	376 mg/kg (Rat) (90%) 910 mg/kg (Rat) (20-60%) 1518 mg/kg (Rat) (8-20% sol)	>2000 mg/kg (Rabbit)	LC50 = 2000 mg/m3 (Rat) 4 h

Toxicologically Synergistic Products: No information available

Delayed and immediate effects as well as chronic effects from short and long-term exposure

Irritation	Causes burns by all exposure routes
Sensitization	No information available
Carcinogenicity	The table below indicates whether each agency has listed any ingredient as
	a carcinogen

Component	CAS-No	IARC	NTP	ACGIH	OSHA
Hydrogen peroxide	7722-84-1	Not listed	Not listed	A3	Not listed
Disodium EDTA	6381-92-6	Not listed	Not listed	Not listed	Not listed
Water	7732-18-5	Not listed	Not listed	Not listed	Not listed

IARC: (International Agency for Research on Cancer)

Group 1 - Carcinogenic to Humans

Group 2A - Probably Carcinogenic to Humans

Group 2B - Possibly Carcinogenic to Humans

ACGIH: (American Conference of Governmental Industrial Hygienists)

A1 - Known Human Carcinogen

A2 - Suspected Human Carcinogen

According to Regulation (EC) No 1272/2008 Revision 1: 27/09/2023

A3 - Animal Carcinogen

SECTION 12. ECOLOGICAL/ENVIROMENTAL 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

Product	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).
Uncleaned packaging	Empty contaminated packaging thoroughly. They may be recycled after thorough and proper cleaning. Recommended cleansing agents: Water, if necessary together with cleansing agents.
Waste treatment options	Not Available
Sewage disposal options	Not Available

SECTION 14. TRANSPORT INFORMATION

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

United States of America Inventory

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Component	CAS-No	TSCA	TSCA Inventory notification - Active/Inactive	TSCA - EPA Regulatory Flags
Hydrogen peroxide	7722-84-1	X	ACTIVE	-

TSCA - Toxic Substances Control Act, (40 CFR Part 710)

X - Listed

'-' - Not Listed

International Inventories

Canada (DSL/NDSL), Europe (EINECS/ELINCS/NLP), Philippines (PICCS), Japan (ENCS), Australia (AICS), China (IECSC), Korea (ECL).

Component	CAS-No	DSL	NDSL	EINECS	PICCS	ENCS	AICS	IECSC	KECL
Hydrogen	7722-84-1	X	-	231-765-0	X	X	X	X	KE-20204
peroxide									

SECTION 16. OTHER INFORMATION

16.1 Full text Hazard (H) and Risk (R) codes (not classification of ready mixed product)

H-phrases	
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.
H372	Causes damage to organs (Thyroid) through prolonged or repeated exposure if swallowed
H412	Harmful to aquatic life with long lasting effects
	(Category 3).

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.