

according to Regulation (EC) No. 1907/2006

Omni WhiteSmile Home Bleaching 10% CP, 16% CP

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SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

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1.2. Relevant identified uses of the substance or mixture and uses advised against

Use of the substance/mixture

Omni WhiteSmile Home Bleaching is a ready-to-use tooth whitening gel for use in custom-made trays.

Omni WhiteSmile Home Bleaching should not be used: During pregnancy or breastfeeding, in children, in the case of known allergies to any of the ingredients, cervically exposed dentin, insufficient fillings, untreated primary or secondary treated primary or secondary caries, in persons under 18 years of age, under anesthesia.

Contains carbamide peroxide

1.3. Details of the supplier providing the safety data sheet

Company name: WHITEsmile GmbH Street: Weinheimer Str.6 Place: 69488 Birkenau Phone: +49 62 01 / 8 43 21-90

E-mail:

info@whitesmile.com Internet: https://www.whitesmile.com

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Regulation (EC) No 1272/2008

Hazard categories:

Serious eye damage/eye irritation: Eye irrit. 2 Hazard statements: Causes severe eye irritation. Wording of the hazard statements: see SECTION 16.

2.2. Label elements

Regulation (EC) No. 1272/2008

Hazard-determining components of labeling

Hydrogen peroxide solution ... % Signal word: Warning

Pictogram:



Hazard warnings

H319 Causes severe eye irritation.

Safety instructions

Wear protective gloves/protective clothing/eye protection. P280

IF FINGESTED: Rinse out mouth, DO NOT induce vomiting. P301+P330+P331

P302+P352 IF ON SKIN: Wash with plenty of soap and water.

P305+P35+P338 IF IN EYES: Rinse cautiously with water for several minutes.

SECTION 3: Composition/Information on ingredients

3.2 Mixtures

Chemical characterization

Mixture of carbamide peroxide (10%, 16%, 22%, 35%) and glycerin.



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Hazardous ingredients

EC no.	Term	
CAS No.	Classification according to Directive 67/548/EEC	
Index no.	Classification according to Regulation (EC) No 1272/2008 [CLP].	
REACH no.		
231-765-0	Hydrogen peroxide in solution %	10% = 3.6% HP 16% = 5.7%HP 22% = 7.7% HP 35% = 12.2% HP
7722-84-1	O - Oxidizing, C - Corrosive, Xn - Harmful R05-08-20/22-35	
	Ox. Liq. 1, Acute Tox. 4, Acute Tox. 4, Skin Corr. 1A, Aquatic Chronic 3; H271 H302	

Wording of H- and EUH-phrases: see section 16.

SECTION 4: First aid measures

4.1. Description of first aid measures

General instructions

Remove contaminated clothing and wash before wearing again.

After inhalation

Provide fresh air.

After skin contact

After contact with skin, wash immediately with plenty of soap and water.

After eye contact

In case of contact with eyes, rinse immediately with plenty of running water for 10 to 15 minutes with the eyelids open and seek medical advice. Remove contact lenses if possible. Continue rinsing. Seek medical advice immediately.

After ingestion

If swallowed, rinse mouth with water (only if victim is conscious). Do not induce vomiting.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing agents

Water, foam, carbon dioxide (CO2).

5.2. Special hazards arising from the substance or mixture

In the event of fire, the following may be generated: Gases/vapors, harmful to health

5.3. Advice for firefighters

Collect contaminated extinguishing water separately. Do not allow to enter drains or water courses.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General notes

Safe handling: see section 7 Personal protective equipment: see section 8

6.2. Environmental precautions

Do not allow to enter drains or water courses.



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6.3. Methods and material for containment and cleaning up

Further information

Absorb with liquid-binding material (sand, diatomaceous earth, acid binders, universal binders). Pick up mechanically and place in suitable containers for disposal.

SECTION 7: Handling and storage

7.1. Protective measures for safe handling

Notes on safe handling

Do not eat, drink or smoke while working. Wash hands thoroughly after use.

Notes on general hygiene measures at the workplace

Avoid contact with skin, eyes and clothing. Create and observe skin protection

plan!7.2. Conditions for safe storage, including any incompatibilities

Requirements forstorage rooms and containers

Store only in the original container in a cool, well-ventilated place. Do not store at temperatures above 28 °C. Protect from exposure to light.

Combined storage instructions

Do not store together with: Food Keep away from combustible materials.

SECTION 8: Exposure controls/personal protection

8.1. Control Parameters

8.2. Exposure controls

Individual protective measures, for example personal protective equipment

Protection and hygiene measures

Avoid contact with skin, eyes and clothing. Create and observe skin protection plan!

Eye/face protection

Tight fitting safety goggles

Hand protection

Wear protective gloves.

Body protection

Wear suitable protective clothing when working.

Respiratory protection

none

Environmental exposure controls and monitoring

Do not allow to enter drains or water courses.

SECTION 9: Physical and chemical properties

9.1. Information on the basic physical and chemical properties

State of aggregation:

Color:

Odor:

pH (at 20 °C):

Water solubility:

Gel

colorless

mint

5 - 6

miscible



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SECTION 10: Stability and reactivity

10.2. Chemical stability

The product is stable when stored at normal ambient temperatures.

10.3. Possibility of hazardous reactions

Exothermic reaction with:

Oxidizing agents, acids, alkalis (lyes)

Reducing agents, alcohols, amines

10.4. Conditions to avoid

Protect from heat.

10.6 Hazardous decomposition products

No hazardous decomposition products are known.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity

Based on available data, the classification criteria are not met.

CAS No.	Designation				
	Exposure routes	Method	Dose	Species	Source
7722-84-1	Hydrogen peroxide in solution %				
	Oral	LD50	1193 - 1270 mg/kg	Rat	IUCLID
	Dermal	LD50	> 2000 mg/kg	Rabbit	
	Inhalative (4 h) vapor	LC50	(0.17) mg/l	Rat	
	Inhalative aerosol	ATE	1,5 mg/l		

Irritant and corrosive effect

Causes serious eye damage.

Sensitizing effects

Based on available data, the classification criteria are not met.

Carcinogenic, mutagenic and toxic for reproduction effects

Based on available data, the classification criteria are not met.

Specific target organ toxicity at single exposure

Based on available data, the classification criteria are not met.

Specific target organ toxicity in case of repeated exposure

Based on available data, the classification criteria are not met.

Aspiration hazard

Based on available data, the classification criteria are not met.

11.2. Information on other hazards

General remarks

The product has not been tested. The statement is derived from the properties of the individual components.

SECTION 12: Ecological information

12.1. Toxicity

CAS No.	Designation					
	Aquatic toxicity	Method	Dose	[h] [d]	Species	Source
7722-84-1	Hydrogen peroxide solution %					
	Acute fish toxicity	LC50	16,4 mg/l	96 h	Pimephales promelas	IUCLID
	Acute algal toxicity	ErC50	2.5 mg/l	72 h	Chlorella vulgaris	



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12.5 Results of PBT and vPvB assessment

The substances in the mixture do not meet the PBT/vPvB criteria according to REACH, Annex XIII.

12.6 Endocrine disrupting properties

This product does not contain any substance that exhibits endocrine disrupting properties towards non-target organisms as no ingredient meets the criteria.

More hints

Do not allow to enter drains or water courses.

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Recommendations for disposal

Do not allow to enter drains or water courses. Dispose of in accordance with official regulations.

Waste code - unused product

 $160903 ABSTACLES \ NOT \ OTHERWISE \ LISTED \ IN \ THE \ LIST; \ Oxidizing \ Substances;$

Peroxides, e.g. hydrogen peroxide; hazardous waste

Waste code - spent product

160903ABSTACLES NOT OTHERWISE LISTED IN THE LIST; Oxidizing Substances;

Peroxides, e.g. hydrogen peroxide; hazardous waste

Waste code - uncleaned packaging

160903ABSTACLES NOT OTHERWISE LISTED IN THE LIST; Oxidizing Substances;

Peroxides, e.g. hydrogen peroxide; hazardous waste

Disposal of uncleaned packaging and recommended cleaning agents

This product and its container must be disposed of as hazardous waste. Contaminated packaging must be treated in the same way as the substance.

SECTION 14: Transport information

Land transport (ADR/RID)

14.1. UN number or ID number: 14.2. UN proper shipping name: Not a hazardous material as defined by these transport regulations.

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14.3. Transport hazard class(es):

14.4. Packing group:

Hazard label:

Classification code:

Limited Quantity (LQ):

Exempted quantity:

Transport category:

Hazard number:

Tunnel restriction code:

Other relevant information on land transport

Quantity exempted: E2

Inland waterway transport (ADN)



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14.1. UN number or ID number:

Not a hazardous material as defined by these transport regulations.

14.2. UN proper shipping name:

14.3. Transport hazard class(es):

14.4. Packing group:

Hazard label:

Classification code:

Limited Quantity (LQ):

Exempted Quantity:

Other relevant information on inland waterway transport

Quantity exempted: E2

Sea transport (IMDG)

14.1. UN number or ID number: Not a hazardous material as defined by these transport regulations.

14.2. UN proper shipping name:

14.3. Transport hazard class(es):

14.4. Packing group:

Hazard label:

Special provisions:

Limited Quantity (LQ):

EmS:

Other relevant information on maritime transport

Air transport (ICAO-TI/IATA-DGR)

14.1. UN number or ID number: Not a hazardous material as defined by these transport regulations.

14.2. UN proper shipping name:

14.3. Transport hazard class(es):

14.4. Packing group:

Hazard label:

Limited Quantity (LQ):

Passenger LQ:

Excepted Quantity:

IATA Packing Instructions - Passenger:

IATA Maximum Quantity - Passenger:

IATA- Packing Instruction - Cargo:

IATA- Maximum Quantity - Cargo:

Other relevant information on air transport

14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC code

inapplicable

SECTION 15: Regulatory information

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

EU regulations

Restrictions on use (REACH, Annex XVII):

Entry 3

National regulations

Water hazard class: 1 - slightly hazardous to water

Status: Mixing rule according to VwVwS Annex 4, No. 3

Additional notes

The national legal regulations must also be observed!

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SECTION 16: Other information

Changes

This data sheet contains changes to the previous version in the section(s): 2,3,10,11,14.

Abbreviations and acronyms

Ox. Liq: Oxidizing liquids Flam. Liq: Flammable liquids Acute Tox: Acute toxicity Skin Corr: Skin corrosivity Eye Dam: Serious eye damage Skin Sens: Skin sensitization

Classification of mixtures and assessment method used according to Regulation (EC) No 1272/2008 [CLP].

Classification	Classification procedure
Acute Tox. 4; H302	
Acute Tox. 4; H332	Calculation method
Eye Dam. 1; H318	Calculation method

Wording of H- and EUH-phrases (number and full text)

H271	May cause fire or explosion; strong oxidizer.
H302	Harmful if swallowed.
H304	May be fatal if swallowed and enters airways.
H314	Causes severe skin burns and eye damage.
H315	Causes skin irritation.
H317	May cause allergic skin reactions. Causes
H319	severe eye irritation.
H332	Harmful by inhalation.
H411	Toxic to aquatic organisms, with long lasting effects. Harmful to
H412	aguatic life, with long lasting effects.

More details

The information in this safety data sheet is based on our best knowledge at the time of printing. The information is intended to provide guidance on the safe handling of the product specified in this safety data sheet during storage, processing, transportation and disposal. The information is not transferable to other products. Insofar as the product is mixed, blended or processed with other materials or subjected to treatment, the information in this safety data sheet cannot be transferred to the new material thus produced, unless expressly stated otherwise.

(The data of the hazardous ingredients were taken from the latest safety data sheet of the supplier).

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