SANIBIOS 6% free

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

1.1. Product identifier

Mixture identification:

Trade name: SANIBIOS 6% free

Trade code: 2010.31 – 2020.31 – 2030.31

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

Recommended use: Aerial disinfectant for non-invasive medical devices and surfaces such as equipments, operating tables and medical units. Professional use only.

Uses advised against: all except those recommended.

1.3. Details of the supplier of the safety data sheet

Company:

AMIL CARE ITALIA Srl

Via Garibaldi, 15/17

22070 Carbonate (CO)

Tel./Fax. 0331 026338

Sito web: www.amil-care.com

E-mail: info@amilcareitalia.com

C.F. E P.IVA: 03514310121

Competent person responsible for the safety data sheet: info@amilcareitalia.com

1.4. Emergency telephone number

CAV "Osp. Pediatrico Bambino Gesù", Roma, 06 68593726

Az. Osp. Univ. Foggia, Foggia, 800183459

Az. Osp. "A. Cardarelli", Napoli, 081 7472901

CAV Policlinico "Umberto I", Roma, 06-49978000

CAV Policlinico "A. Gemelli", Roma, 06-3054343

Az. Osp. "Careggi", Firenze, 055-7947819

CAV Centro Nazionale di Informazione Tossicologica, Pavia, 0382-24444

Osp. Niguarda Ca' Granda, Milano, 02-66101029

Azienda Ospedaliera Papa Giovanni XXII, Bergamo, 800883300

Azienda Ospedaliera Integrata Verona, 800011858

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

REGULATION (EC) No 1272/2008 (CLP):

Classification of this product has been carried out in accordance with CLP Regulation (EC) No 1272/2008.

Eye Irrit. 2: Eye irritation, Category 2, H319

2.2. Label elements

REGULATION (EC) No 1272/2008 (CLP):

Warning

Hazard statements:

Eye Irrit. 2: H319 Causes serious eye irritation.

Precautionary statements:

P264 Wash hands thoroughly after handling.

P280 Wear protective gloves/protective clothing/eye protection/face protection.

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.

UFI: KM00-G0GH-100Q-9EUF

2.3. Other hazards

Product fails to meet PBT/vPvB criteria

SECTION 3: Composition/information on ingredients

3.1. Substances

Non-applicable

3.2. Mixtures

Chemical description: Aqueous mixture composed of hydrogen peroxide

Components:

In accordance with Annex II of Regulation (EC) nº1907/2006 (point 3), the product contains:

Identification	Chemical name/Classification		Conc.
CAS: 7722-84-1 EC: 231-765-0 Index: 008-003-00-9 REACH: 01-2119485845-22-XXXX	**hydrogen peroxide solution**(1)	ATP CLP00	6%
	Regulation (EC) No 1272/2008	Acute Tox. 4: H302+H332; Ox. Liq. 1: H271; Skin Corr. 1A: H314 - Danger	

(1) Substances presenting a health or environmental hazard which meet criteria laid down in Regulation (EU) No. 2020/878

To obtain more information on the hazards of the substances consult sections 11, 12 and 16.

Other information:

Identification	Specific concentration limit
hydrogen peroxide solution CAS: 7722-84-1 EC: 231-765-0	% (p/p) >=70: Ox. Liq. 1 - H271 50<= % (p/p) <70: Ox. Liq. 2 - H272 % (p/p) >=70: Skin Corr. 1A - H314 50<= % (p/p) <70: Skin Corr. 1B - H314 35<= % (p/p) <50: Skin Irrit. 2 - H315 % (p/p) >=8: Eye Dam. 1 - H318 5<= % (p/p) <8: Eye Irrit. 2 - H319 % (p/p) >=35: STOT SE 3 - H335

SECTION 4: First aid measures

4.1. Description of first aid measures

The symptoms resulting from intoxication can appear after exposure, therefore, in case of doubt, seek medical attention for direct exposure to the chemical product or persistent discomfort, showing the SDS of this product.

By inhalation:

This product is not classified as hazardous through inhalation, however, it is recommended in case of intoxication symptoms to remove the person affected from the area of exposure, provide clean air and keep at rest. Request medical attention if symptoms persist.

By skin contact:

This product is not classified as hazardous when in contact with the skin. However, in case of skin contact it is recommended to remove
contaminated clothes and shoes, rinse the skin or shower the person affected if necessary thoroughly with cold water and neutral soap. In case of serious reaction consult a doctor.

By eye contact:

Rinse eyes thoroughly with water for at least 15 minutes. Do not let the person involved rub or close their eyes. If the injured person uses contact lenses, these should be removed unless they are stuck to the eyes, as this could cause further damage. In all cases, after cleaning, a doctor should be consulted as quickly as possible with the SDS of the product.

By ingestion/aspiration:

Do not induce vomiting, but if it does happen keep the head down to avoid aspiration. Keep the person affected at rest. Rinse out the mouth and throat, as they may have been affected during ingestion.

4.2. Most important symptoms/effects, acute and delayed

Acute and delayed effects are indicated in sections 2 and 11.

4.3. Indication of immediate medical attention and special treatment needed, if necessary

Not applicable

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media:

Product is non-flammable under normal conditions of storage, handling and use. Preferably use water.

Unsuitable extinguishing media:

Chemical or foam extinguishers

5.2. Special hazards arising from the substance or mixture:

As a result of combustion or thermal decomposition reactive sub-products are created that can become highly toxic and, consequently, can present a serious health risk.

5.3. Advice for firefighters

Depending on the magnitude of the fire it may be necessary to use full protective clothing and individual respiratory equipment. Minimum emergency facilities and equipment should be available (fire blankets, portable first aid kit,...) in compliance with Directive 89/654 / EC.

Additional provisions:

Act in accordance with the Internal Emergency Plan and the Information Sheets on actions to take after an accident or other emergencies. Destroy any source of ignition. In case of fire, refrigerate the storage containers and tanks for products susceptible to inflammation, explosion or BLEVE as a result of high temperatures. Avoid spillage of the products used to extinguish the fire into an aqueous medium.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Isolate leaks provided that there is no additional risk for the people performing this task. Personal protection equipment must be used against potential contact with the spilt product (See section 8). Evacuate the area and keep out those who do not have protection.

6.2. Environmental precautions

This product is not classified as hazardous to the environment. Keep product away from drains, surface and underground water.

6.3. Methods and material for containment and cleaning up

It is recommended:

Absorb the spillage using sand or inert absorbent and move it to a safe place. Do not absorb in sawdust or other combustible absorbents. For any concern related to disposal consult section 13

6.4. Reference to other sections

See also section 8 and 13

SECTION 7: Handling and storage

7.1. Precautions for safe handling

A- Precautions for safe manipulation

Comply with the current legislation concerning the prevention of industrial risks. Keep containers hermetically sealed. Control spills and residues, destroying them with safe methods (section 6). Avoid leakages from the container. Maintain order and cleanliness where dangerous products are used.

B- Technical recommendations for the prevention of fires and explosions

it is recommended to transfer at slow speeds to avoid the generation of electrostatic charges that can affect flammable products. Consult section 10 for information on conditions and materials that should be avoided.

C- Technical recommendations to prevent ergonomic and toxicological risks.

Do not eat or drink during the process, washing hands afterwards with suitable cleaning products.

D.- Technical recommendations to prevent environmental risks

It is recommended to have absorbent material available at close proximity to the product (See subsection 6.3).

7.2. Conditions for safe storage, including any incompatibilities:

A.- Technical measures for storage

Store in a cool, dry, well-ventilated location.

B.- General conditions for storage

Avoid sources of heat, radiation, static electricity and contact with food. For additional information see subsection 10.5.

7.3. Specific end use(s):

Except for the instructions already specified it is not necessary to provide any special recommendation regarding the uses of this product

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Substances whose occupational exposure limits have to be monitored in the workplace:

DNEL (Workers):

Identification		Short exposure		Long exposure	
		Systemic	Local	Systemic	Local
hydrogen peroxide solution	Oral	Non-applicable	Non-applicable	Non-applicable	Non-applicable
CAS: 7722-84-1	Dermal	Non-applicable	Non-applicable	Non-applicable	Non-applicable
EC: 231-765-0	Inhalation	Non-applicable	3 mg/m³	Non-applicable	1,4 mg/m³

DNEL (Population):

Identification		Short exposure		Long exposure	
		Systemic	Local	Systemic	Local
hydrogen peroxide solution	Oral	Non-applicable	Non-applicable	Non-applicable	Non-applicable
CAS: 7722-84-1	Dermal	Non-applicable	Non-applicable	Non-applicable	Non-applicable
EC: 231-765-0	Inhalation	Non-applicable	1,93 mg/m³	Non-applicable	0,21 mg/m³

PNEC:

Identification				
hydrogen peroxide solution	STP	4,66 mg/L	Fresh water	0,013 mg/L
CAS: 7722-84-1	Soil	0,002 mg/kg	Marine water	0,013 mg/L
EC: 231-765-0	Intermittent	0,014 mg/L	Sediment (Fresh water)	0,047 mg/kg
	Oral	Non-applicable	Sediment (Marine water)	0,047 mg/kg

8.2. Exposure controls

A.- General security and hygiene measures in the work place

As a preventative measure it is recommended to use basic Personal Protection Equipment, with the corresponding "CE marking". For more information on Personal Protection Equipment (storage, use, cleaning, maintenance, class of protection,…) consult the information leaflet provided by the manufacturer. The indications contained in this point refer to the pure product. The protective measures for the diluted product may vary depending on its degree of dilution, use, method of application, etc. To determine the obligation to install emergency showers and / or eye drops in warehouses, the legislation relating to the storage of chemical products applicable to each case will be taken into consideration. For more information see subsection 7.1 and 7.2

B.- Respiratory protection

The use of protection equipment will be necessary if a mist forms or if the occupational exposure limits are exceeded.

C.- Specific protection for the hands

Non-applicable

D.- Ocular and facial protection

Pictogram	PPE	Labelling	CEN Standard	Remarks
Mandatory face protection	Face shiel	CE CAT II	EN 166:2002 EN 167:2002 EN 168:2002 EN ISO 4007:2018	Clean daily and disinfect periodically according to the manufacturer´s instructions.

E.- Bodily protection

Pictogram	PPE	Labelling	CEN Standard	Remarks
	Work clothing	CE CAT I		Replace at any sign of deterioration. For periods of prolonged exposure to the product for professional/industrial users CE III is recommended, in accordance with the regulations in EN ISO 6529: 2013, EN ISO 6530: 2005, EN ISO 13688: 2013, EN 464: 1994
	Anti-slip work shoes	CE CAT II	EN ISO 20347:2012	Replace at any sign of deterioration. For periods of prolonged exposure to the product for professional/industrial users CE III is recommended, in accordance with the regulations in EN ISO 20345:2012 and EN 13832-1:2007

F.- Additional emergency measures

Emergency measure	Standards	Emergency measure	Standards
Emergency shower	ANSI Z358-1 ISO 3864-1:2011, ISO 3864-4:2011	Eyewash stations	DIN 12 899 ISO 3864-1:2011, ISO 3864-4:2011

Environmental exposure controls:

In accordance with the community legislation for the protection of the environment it is recommended to avoid environmental spillage of both the product and its container. For additional information see subsection 7.1.D

Volatil organic compounds:

With regard to Directive 2010/75/EU , this product has the following characteristics:

V.O.C. (Supply):	6 % weight
V.O.C. density at 20 ºC:	61,14 kg/m³ (61,14 g/L)
Average carbon numbe:	Non-applicable
Average molecular weight:	34,01 g/mol

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties:

Apperance:	
Physical state at 20 °C:	Liquid
Apperance:	Not available
Color:	Colorless
Odor:	Odorless
Odour threshold:	Non-applicable *
Volatility:	
Boiling point at atmospheric pressure:	102 °C
Vapour pressure at 20 °C:	2279 Pa
Vapour pressure at 50 °C:	12019,73 Pa (12,02 kPa)
Evaporation rate at 20 °C:	Non-applicable *
Product description:	
Density at 20 °C:	1019 kg/m³
Relative density at 20 °C:	1,02
Dynamic viscosity at 20 °C:	1,02 cP
Kinematic viscosity at 20 °C:	0,98 cSt
Kinematic viscosity at 40 °C:	Non-applicable *
Concentration:	Non-applicable *
pH:	3,9 - 4,9
Vapour density at 20 °C:	Non-applicable *
Partition coefficient n-octanol/water 20 °C:	Non-applicable *
Solubility in water at 20 °C:	
Solubility properties:	Soluble in water
Decomposition temperature:	Non-applicable *
Melting point/freezing point:	Non-applicable *
Explosive properties:	Non-applicable *
Oxidising properties:	Non-applicable *
Flammability:	
Flash Point:	Non Flammable (>60 °C)
Heat of combustion:	Non-applicable *
Flammability (solid, gas):	Non-applicable *
Autoignition temperature:	Non-applicable *
Lower flammability limit:	Non-applicable *
Upper flammability limit:	Non-applicable *
Explosive:	
Lower explosive limit	Non-applicable *
Upper explosive limit:	Non-applicable *

9.2. Other information

Surface tension at 20 °C:	Non-applicable *
Refraction index:	Non-applicable *

*Not relevant due to the nature of the product, not providing information property of its hazards.

SECTION 10: Stability and reactivity

10.1. Reactivity

No hazardous reactions are expected if the following technical instructions storage of chemicals. See section 7.

10.2. Chemical stability

Chemically stable under the conditions of storage, handling and use.

10.3. Possibility of hazardous reactions

Under the conditions no hazardous reactions are expected to produce a pressure or excessive temperatures

10.4. Conditions to avoid

Applicable for handling and storage at room temperature:

Shock and friction	Contact with air	Increase in temperature	Sunlight	Humidity
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable

10.5. Incompatible materials

Acids	Water	Oxidising materials	Combustible materials	Others
Avoid strong acids	Not applicable	Precaution	Precaution	Avoid alkalis or strong bases

10.6. Hazardous decomposition products

See subsection 10.3, 10.4 and 10.5 to find out the specific decomposition products. Depending on the decomposition conditions, complex mixtures of chemical substances can be released: carbon dioxide (CO2), carbon monoxide and other organic compounds

SECTION 11: Toxicological information

11.1. Information on toxicological effects

The experimental information related to the toxicological properties of the product itself is not available

Dangerous health implications:

In case of exposure that is repetitive, prolonged or at concentrations higher than recommended by the occupational exposure limits, it may result in adverse effects on health depending on the means of exposure:

A- Ingestion (acute effect):

- Acute toxicity : Based on available data, the classification criteria are not met, however, it contains substances classified as dangerous for consumption. For more information see section 3
-Corrosivity/Irritability: Based on available data, the classification criteria are not met. However, it does contain substances classified as dangerous for this effect. For more information see section 3.

B- Inhalation (acute effect):

- Acute toxicity : Based on available data, the classification criteria are not met. However, it contains substances classified as dangerous for inhalation. For more information see section 3.
- Corrosivity/Irritability: Based on available data, the classification criteria are not met. However, it does contain substances classified as dangerous for this effect. For more information see section 3

C- Contact with the skin and the eyes (acute effect):

- Contact with the skin: Based on available data, the classification criteria are not met. However, it contains substances classified as dangerous for skin contact. For more information see section 3.
- Contact with the eyes: Produces eye damage after contact.

D- CMR effects (carcinogenicity, mutagenicity and toxicity to reproduction):

- Carcinogenicity: Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous for the effects mentioned. For more information see section 3..
IARC: hydrogen peroxide solution (3)
- Mutagenicity: Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous for this effect. For more information see section 3.
- Reproductive toxicity: Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous for this effect. For more information see section 3.

E- Sensitizing effects:

- Respiratory: Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous with sensitising effects. For more information see section 3.
- Cutaneous: Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous for this effect. For more information see section 3.

F- Specific target organ toxicity (STOT) - single exposure:

Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous for this effect. For more information see section 3.

G- Specific target organ toxicity (STOT)-repeated exposure:

- Specific target organ toxicity (STOT)-repeated exposure: Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous for this effect. For more information see section 3. - Skin: Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous for this effect. For more information see section 3.

H- Aspiration hazard:

Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous for this effect. For more information see section 3.

Other information:

Non-applicable

Specific toxicology information on the substances:

Identification	Acute toxicity		Genus
hydrogen peroxide solution	DL50 oral	500 mg/kg (ATEi)	
CAS: 7722-84-1	DL50 dermal	Non-applicable	
EC: 231-765-0	CL50 inhalation	11 mg/L (4 h) (ATEi)	

Acute Toxicity Estimate **(ATE mix):**

ATE mix		Ingredient(s) of unknown toxicity
Oral	8333,33 mg/kg (Calculation method)	0 %
Dermal	>2000 mg/kg (Calculation method)	Non-applicable
Inhalation	183,33 mg/L (4 h) (Calculation method)	0 %

SECTION 12: Ecological information

12.1. Toxicity

Identification	Acute toxicity		Species	Genus
hydrogen peroxide solution	CL50	16,4 mg/L (96 h)	Pimephales promelas	Fish
CAS: 7722-84-1	EC50	7,7 mg/L (24 h)	Daphnia magna	Crustacean
EC: 231-765-0	EC50	2,5 mg/L (72 h)	Chlorella vulgaris	Alga

12.2. Persistence and degradability

Not available

12.3. Bioaccumulative potential

Not available

12.4. Mobility in soil

Not available

12.5. Results of PBT and vPvB assessment

Product fails to meet PBT/vPvB criteria

12.6. Other adverse effects

Not described

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Type of waste (Regulation (EU) No 1357/2014):

HP8 Corrosive

Waste management (disposal and evaluation):

Consult the authorized waste service manager on the assessment and disposal operations in accordance with Annex 1 and Annex 2 (Directive 2008/98/EC, Legislative Decree 205/2010). As under 15 01 (2014/955/EC) of the code and in case the container has been in direct contact with the product, it will be processed the same way as the actual product. Otherwise, it will be processed as non-dangerous residue. We do not recommended disposal down the drain. See paragraph 6.2.

Regulations related to waste management:

In accordance with Annex II of Regulation (EC) nº1907/2006 (REACH) the community or state provisions related to waste management are stated

Community legislation: Directive 2008/98/EC, 2014/955/UE, Regulation (EC) nº. 1357/2014

National legislation: Legislative Decree 205/2010

SECTION 14: Transport information

This product is not regulated for transport (ADR/RID,IMDG,IATA)

SECTION 15: Regulatory information

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

Composition of the active ingredients (REGULATION (EU) n. 528/2012): hydrogen peroxide solution (6%)

Candidate substances for authorisation under the Regulation (EC) 1907/2006 (REACH Non-applicable

Substances included in Annex XIV of REACH ("Authorisation List") and sunset date: Non-applicable

Regulation (EC) 1005/2009, about substances that deplete the ozone layer: Non-applicable

Article 95, REGULATION (EU) No 528/2012: hydrogen peroxide solution (Product type 1, 2, 3, 4, 5, 6, 11, 12)

REGULATION (EU) No 649/2012, in relation to the import and export of hazardous chemical products: Non-applicable

Substances in nanoform: Non-applicable

Seveso III: Non-applicable

Limitations to commercialisation and the use of certain dangerous substances and mixtures (Annex XVII, REACH, etc...):

Shall not be used in:

- ornamental articles intended to produce light or colour effects by means of different phases, for example in ornamental lamps and ashtrays,

- tricks and jokes,
- games for one or more participants, or any article intended to be used as such, even with ornamental aspects.
Regulation (EC) 2019/1148 on the marketing and use of explosives precursors: Contains hydrogen peroxide solution. Product in accordance with article 9.

Specific provisions in terms of protecting people or the environment:
It is recommended to use the information included in this safety data sheet as data used in a risk evaluation of the local circumstances in order to establish the necessary risk prevention measures for the manipulation, use, storage and disposal of this product.

Other legislation:
Legislative Decree No 205/2010: laying down provisions for the implementation of Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste and repealing certain Directives.
Legislative Decree 126/1998: Regulation containing rules for the implementation of directive 94/9 / EC on equipment and protection systems intended for use in potentially explosive atmospheres
Legislative Decree 233/2003: Implementation of Directive 1999/92 / EC concerning the minimum requirements for improving the protection of the safety and health of workers exposed to the risk of explosive atmospheres
Legislative Decree 186/2011: Sanctioning discipline for the violation of the provisions of Regulation (EC) no. 1272/2008
Official Gazette 14 March 2016 n. 61 - Legislative Decree 15 February 2016, n. 39
Consolidated Act on Health and Safety at Work - Rev. June 2016
Regulation (EU) n. 528/2012 of the European Parliament and of the Council, of 22 May 2012, relating to the making available on the market and use of biocidal products

15.2. Chemical safety assessment
The supplier has not carried out evaluation of chemical safety.

SECTION 16: Other information

Legislation related to safety data sheets:
This safety data sheet has been designed in accordance with ANNEX II-Guide to the compilation of safety data sheets of Regulation (EC) Nº 1907/2006 (Regulation (EU) Nº 2020/878)

Modifications related to the previous security card which concerns the ways of managing risk:
General revision of the sections of the SDS, update to Regulation no. 2020/878.

Texts of the legislative phrases mentioned in section 2:
H319: Causes serious eye irritation

Texts of the legislative phrases mentioned in section 3:
The phrases indicated do not refer to the product itself; they are present merely for informative purposes and refer to the individual components which appear in section 3

CLP Regulation (EC) No 1272/2008:
Acute Tox. 4: H302+H332 - Harmful if swallowed or if inhaled.
Eye Dam. 1: H318 - causes serious eye damage.
Ox. Liq. 1: H271 - May cause fire or explosion, strong oxidizer.
Skin Corr. 1A: H314 - Causes severe skin burns and eye damage.

Classification procedure:
Eye Irrit. 2: Calculation method

Advice related to training:
Minimal training is recommended in order to prevent industrial risks for staff using this product and to facilitate their comprehension and interpretation of this safety data sheet, as well as the label on the product.

Principal bibliographical sources:
http://echa.europa.eu
http://eur-lex.europa.eu

Abbreviations and acronyms:
ADR: European agreement concerning the international carriage of dangerous goods by road
IMDG: International maritime dangerous goods code
IATA: International Air Transport Association
ICAO: International Civil Aviation Organisation
COD: Chemical Oxygen Demand
BOD5: 5-day biochemical oxygen demand
BCF: Bioconcentration factor
LD50: Lethal Dose 50
LC50: Lethal Concentration 50

EC50: Effective concentration 50
Log-POW: Octanol-water partition coefficient
Koc: Partition coefficient of organic carbon

The information contained in this safety data sheet is based on sources, technical knowledge and current legislation at European and state level, without being able to guarantee its accuracy. This information cannot be considered a guarantee of the properties of the product, it is simply a description of the security requirements. The occupational methodology and conditions for users of this product are not within our awareness or control, and it is ultimately the responsibility of the user to take the necessary measures to obtain the legal requirements concerning the manipulation, storage, use and disposal of chemical products. The information on this safety data sheet only refers to this product, which should not be used for needs other than those specified