



## SAFETY DATA SHEET

(REACH regulation (EC) n° 1907/2006 - n° 2015/830)

### SECTION 1 : IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

#### 1.1. Product identifier

Product name : STERANIOS 2%  
Product code : 382000.

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

Disinfection of medical devices  
For further information on product indication, please see the label.

#### 1.3. Details of the supplier of the safety data sheet

Registered company name : Laboratoires ANIOS.  
Address : PAVE DU MOULIN .59260.LILLE - HELLEMES.FRANCE.  
Telephone : + 33 (0)3 20 67 67 67. Fax : + 33 (0)3 20 67 67 68.  
e:mail : fds@anios.com  
www.anios.com

#### 1.4. Emergency telephone number : + 33(0)1 45 42 59 59.

Association/Organisation : INRS.

### SECTION 2 : HAZARDS IDENTIFICATION

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

##### In compliance with EC regulation No. 1272/2008 and its amendments.

Skin irritation, Category 2 (Skin Irrit. 2, H315).  
Eye irritation, Category 2 (Eye Irrit. 2, H319).  
Respiratory sensitisation, Category 1 (Resp. Sens. 1, H334).  
Skin sensitisation, Category 1A (Skin Sens. 1A, H317).  
Specific target organ toxicity (single exposure), Category 3 (STOT SE 3, H335).  
This mixture does not present a physical hazard. Refer to the recommendations regarding the other products present on the site.  
This mixture does not present an environmental hazard. No known or foreseeable environmental damage under standard conditions of use.

#### 2.2. Label elements

##### In compliance with EC regulation No. 1272/2008 and its amendments.

Hazard pictograms :



GHS07

GHS08

Signal Word :

DANGER

Product identifiers :

EC 203-856-5                      GLUTARALDEHYDE

Hazard statements :

H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H319	Causes serious eye irritation.
H334	May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H335	May cause respiratory irritation.

Precautionary statements - General :

P102                      Keep out of reach of children.

## Precautionary statements - Prevention :

P260 Do not breathe vapours.  
 P280 Wear protective gloves.  
 P284 In case of inadequate ventilation wear respiratory protection.

## Precautionary statements - Response :

P302 + P352 IF ON SKIN: Wash with plenty of water.  
 P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.  
 P333 + P313 If skin irritation or rash occurs: Get medical advice/attention.  
 P342 + P311 If experiencing respiratory symptoms: Call a POISON CENTER or doctor/physician.

## Precautionary statements - Storage :

P403 Store in a well-ventilated place.

## Precautionary statements - Disposal :

P501 Dispose of unused product and its container as hazardous waste.

**2.3. Other hazards**

The mixture does not contain substances classified as 'Substances of Very High Concern' (SVHC)  $\geq 0.1\%$  published by the European Chemicals Agency (ECHA) under article 57 of REACH: <http://echa.europa.eu/fr/candidate-list-table>  
 No other hazard identified in the current state of knowledge.

**SECTION 3 : COMPOSITION/INFORMATION ON INGREDIENTS**

Title for H and EUH statements: see § 16.

**3.2. Mixtures****Composition :**

Identification	(EC) 1272/2008	Note	%
CAS: 111-30-8 EC: 203-856-5 REACH: 01-2119455549-26  GLUTARALDEHYDE	GHS06, GHS05, GHS09, GHS08 Dgr Acute Tox. 3, H301 Skin Corr. 1B, H314 Skin Sens. 1A, H317 Acute Tox. 2, H330 Resp. Sens. 1, H334 Aquatic Chronic 2, H411 Aquatic Acute 1, H400 M Acute = 1 EUH:071	[1]	0 $\leq$ x % < 2.5

**Information on ingredients :**

[1] Substance for which maximum workplace exposure limits are available.

**SECTION 4 : FIRST AID MEASURES**

As a general rule, in case of doubt or if symptoms persist, always call a doctor.  
 NEVER induce swallowing by an unconscious person.  
 Reminder: any unconscious person must be placed in the lateral recovery position.

**4.1. Description of first aid measures****In the event of exposure by inhalation :**

Move the person away from the place of exposure and take him/her outside.  
 In the event of respiratory problems (e.g. heavy coughing):  
 Put the person in a half-seated position, with the torso raised ; keep the person warm and calm.  
 Call a doctor immediately.

**In the event of splashes or contact with eyes :**

If applicable, remove contact lenses.  
 Wash thoroughly with soft clean water for 15 minutes, holding the eyelids open.  
 If there is any redness, pain or visual impairment, consult an ophthalmologist.

**In the event of splashes or contact with skin :**

Remove all contaminated or stained clothing immediately. Do not use them again until they have been decontaminated.  
 Rinse immediately and thoroughly with water.  
 In the event of skin irritation, seek medical advice. Show this container or label.

**In the event of swallowing :**

Rinse out the mouth, do not allow to drink, do not induce vomiting. Calm the person down and transfer immediately to hospital or doctor. Show the

label to the doctor.

#### 4.2. Most important symptoms and effects, both acute and delayed

Cf. § 11

#### 4.3. Indication of any immediate medical attention and special treatment needed

Refer to the recommendation of the doctor.

## SECTION 5 : FIREFIGHTING MEASURES

### 5.1. Extinguishing media

#### Suitable methods of extinction

Any extinguishing agents are authorized: foam, sand, carbon dioxide, water, powder.

### 5.2. Special hazards arising from the substance or mixture

A fire will often produce a thick black smoke. Exposure to decomposition products may be hazardous to health.

In the event of a fire, the following may be formed :

- carbon dioxide (CO<sub>2</sub>)

### 5.3. Advice for firefighters

Due to the toxicity of the gas emitted on thermal decomposition of the products, fire-fighting personnel are to be equipped with autonomous insulating breathing apparatus.

Full protective suit.

## SECTION 6 : ACCIDENTAL RELEASE MEASURES

### 6.1. Personal precautions, protective equipment and emergency procedures

Consult the safety measures listed under headings 7 and 8.

Keep away any unprotected person.

Avoid inhaling the fumes.

Avoid all contact with skin or eyes.

### 6.2. Environmental precautions

Contain and control the leaks or spills with non-combustible absorbent materials such as sand, earth, vermiculite, diatomaceous earth in drums for waste disposal.

Do not get rid in natural spaces (waterways, ground and vegetations...)

### 6.3. Methods and material for containment and cleaning up

Absorb any spilled product with absorbent non-combustible materials, and sweep away or remove with a shovel. Put any waste in drums for disposal. Do not mix with any other waste. Wash the contaminated surface thoroughly with water.

Do not collect the product for re-use.

### 6.4. Reference to other sections

Disposal considerations: see section 13.

## SECTION 7 : HANDLING AND STORAGE

### 7.1. Precautions for safe handling

Product for external use - do not swallow.

Avoid all contact with skin, eyes and clothes.

Handle in accordance with user instructions on label

#### Fire prevention :

Handle in well-ventilated areas.

Prevent access by unauthorised personnel.

#### Recommended equipment and procedures :

For personal protection, see section 8.

Observe precautions stated on label and also industrial safety regulations.

Avoid skin and eye contact with this mixture.

Water source nearby.

Change any contaminated or wet work clothes immediately.

Ensure room is well ventilated.

#### Prohibited equipment and procedures :

No smoking, eating or drinking in areas where the mixture is used.

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

Keep the container tightly closed

Store ONLY in the original package.

Store between + 5 °C and + 35 °C in a dry, well ventilated place

Do not use after the expiry date mentioned on the packaging.

Keep out of the reach of children

Store away from incompatible materials (see section 10)

### 7.3. Specific end use(s)

For professional use only

Refer to paragraph 1 for product indication

## SECTION 8 : EXPOSURE CONTROLS/PERSONAL PROTECTION

The information in this chapter refers to the product specifically described in this document. If the product is handled and/or exposed simultaneously with other chemical agents, these must be taken into consideration when choosing personal safety equipment.

The Exposure Threshold Limit Value and the Average Exposure Value given below are quoted by the CAS number of the substance. Paragraph 3 details the chemical name corresponding to the CAS number.

Individuals should not be exposed to this product if they have already experienced skin irritation or asthma caused by :

- glutaraldehyde

### 8.1. Control parameters

#### Occupational exposure limits :

- Germany - AGW (BAuA - TRGS 900, 21/06/2010) :

CAS	VME :	VME :	Excess	Notes
111-30-8		0,05 ppm 0,2 mg/m3		2(l)

- Belgium (Order of 19/05/2009, 2010) :

CAS	TWA :	STEL :	Ceiling :	Definition :	Criteria :
111-30-8		0,05 ppm 0,21 mg/m3		M	

- France (INRS - ED984 :2012) :

CAS	VME-ppm :	VME-mg/m3 :	VLE-ppm :	VLE-mg/m3 :	Notes :	TMP No :
111-30-8	0.1	0.4	0.2	0.8	-	65.66

- Spain (Instituto Nacional de Seguridad e Higiene en el Trabajo (INSHT), Mayo 2010) :

CAS	TWA :	STEL :	Ceiling :	Definition :	Criteria :
111-30-8		0,05 ppm 0,2 mg/m3		Sen	

- Poland (2014) :

CAS	TWA :	STEL :	Ceiling :	Definition :	Criteria :
111-30-8	0,4 mg/m3	0,6 mg/m3			

- Czech Republic (Regulation No. 361/2007) :

CAS	TWA :	STEL :	Ceiling :	Definition :	Criteria :
111-30-8	0,2 mg/m3	0,4 mg/m3		I, S	

- Slovakia (Regulation No. 300/2007) :

CAS	TWA :	STEL :	Ceiling :	Definition :	Criteria :
111-30-8	0,05 ppm 0,21 mg/m3	0,42 mg/m3		S	

- Switzerland (SUVA 2015) :

CAS	VME	VLE	Valeur plafond	Notations
111-30-8	0,05 ppm 0,21 mg/m3	0,1 ppm 0,42 mg/m3		S SSC

- UK / WEL (Workplace exposure limits, EH40/2005, 2007) :

CAS	TWA :	STEL :	Ceiling :	Definition :	Criteria :
111-30-8	0,05 ppm 0,2 mg/m3	0,05 ppm 0,2 mg/m3		Sen	

### 8.2. Exposure controls

#### Appropriate engineering controls

Ensure the rooms are well-ventilated. Atmospheric concentrations at the workplace must not exceed the limit values given for normal conditions of use.

#### Personal protection measures, such as personal protective equipment

Use personal protective equipment that is clean and has been properly maintained.

Store personal protective equipment in a clean place, away from the work area.

Never eat, drink or smoke during use. Remove and wash contaminated clothing before re-using. Ensure that there is adequate ventilation, especially in confined areas.

#### - Eye / face protection

Avoid contact with eyes.

Prescription glasses are not considered as protection.

Water source nearby.

#### - Hand protection

Use suitable protective gloves that are resistant to chemical agents in accordance with standard EN374.

Gloves must be selected according to the application and duration of use at the workstation.

Protective gloves need to be selected according to their suitability for the workstation in question : other chemical products that may be handled, necessary physical protections (cutting, pricking, heat protection), level of dexterity required.

Butyl or nitrile gloves are recommended.

Gloves must be replaced immediately if they show signs of wear and tear.

#### - Body protection

Avoid skin contact.

Work clothing worn by personnel shall be laundered regularly.

After contact with the product, all parts of the body that have been soiled must be washed.

Change wet and dirty work clothes immediately.

#### - Respiratory protection

In case of insufficient ventilation, with the risk of exceeding the TLVs (Treshold Limit Values)/TWA, wear suitable breathing apparatus.

Use Type A1P1 or A2P2 filters.

## SECTION 9 : PHYSICAL AND CHEMICAL PROPERTIES

### 9.1. Information on basic physical and chemical properties

#### General information :

Physical state :	Fluid liquid.
Odour:	typical
Colour:	green

#### Important health, safety and environmental information

pH :	Not stated.
	Neutral.
Boiling point/boiling range :	Not specified.
Flash point interval :	Not relevant.
Vapour pressure (50°C) :	Not relevant.
Density :	+/- 1.0
Water solubility :	Soluble.
Melting point/melting range :	Not specified.
Self-ignition temperature :	Not specified.
Decomposition point/decomposition range :	Not specified.

### 9.2. Other information

pH pure product:	5.5 - 6.5
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## SECTION 10 : STABILITY AND REACTIVITY

### 10.1. Reactivity

No hazardous reaction if the instructions/indications for storage and handling are respected.

### 10.2. Chemical stability

This mixture is stable under the recommended handling and storage conditions in section 7.

### 10.3. Possibility of hazardous reactions

Cf. § 10.1 and 10.2

### 10.4. Conditions to avoid

Avoid :

- frost

Do not mix with other products.

### 10.5. Incompatible materials

Latex

Refer to the scientific folder\*: product/material compatibility table

\* available on request

### 10.6. Hazardous decomposition products

At high temperatures, dangerous decomposition products may be produced, such as fumes, carbon dioxide and carbon monoxide, nitrogen oxide.

## SECTION 11 : TOXICOLOGICAL INFORMATION

### 11.1. Information on toxicological effects

#### 11.1.1. Substances

Not specified

#### 11.1.2. Mixture

The toxicological data of the mixture (resulting from studies or in accordance with conventional methods) are outlined below.

#### Acute toxicity :

Acute toxicity estimate (ATE)\* :

Oral ATE : > 2000 mg/kg

\* according to the method of calculation describe in the CLP regulation (Classification, Labelling, Packaging) Part 3 Chapter 3.1 based on the data of the different components present in the product.

Inhalation may lead to irritation of the respiratory tracts.

Sore throat, coughing, shortness of breath, respiratory failure

If swallowed: burns to upper digestive and respiratory tract, abdominal pain, vomiting blood, serious lesions to mucous membranes and risk of perforation.

#### Skin corrosion/skin irritation :

Skin irritation: itching, light to moderate local redness, burning sensation...

#### Serious damage to eyes/eye irritation :

Ocular irritation: notably redness of the conjunctiva and lacrimation.

#### Respiratory or skin sensitisation :

May cause allergy or asthma symptoms or breathing difficulties if inhaled.

#### Germ cell mutagenicity :

Product not classified in this hazard category.

#### Carcinogenicity :

Product not classified in this hazard category.

#### Reproductive toxicant :

Product not classified in this hazard category.

#### Specific target organ systemic toxicity - single exposure :

May cause respiratory irritation.

#### Specific target organ systemic toxicity - repeated exposure :

Product not classified in this hazard category.

#### Aspiration hazard :

Product not classified in this hazard category.

#### Other information

Repeated or prolonged exposure may lead to sensitization by inhalation (risk of asthma) and by skin contact (risk of eczema).

## SECTION 12 : ECOLOGICAL INFORMATION

### 12.1. Toxicity

#### 12.1.1. Substances

Not specified

#### 12.1.2. Mixtures

The mixture has not been classified as an environmental hazard, in compliance with EC regulation 1272/2008.

### 12.2. Persistence and degradability

No data available.

### 12.3. Bioaccumulative potential

No data available.

### 12.4. Mobility in soil

No data available.

### 12.5. Results of PBT and vPvB assessment

No data available.

### 12.6. Other adverse effects

No data available.

## SECTION 13 : DISPOSAL CONSIDERATIONS

Proper waste management of the mixture and/or its container must be determined in accordance with Directive 2008/98/EC.

The packages must not be reused.

Do not pour into waterways.

### 13.1. Waste treatment methods

**Waste :**

Waste management is carried out without endangering human health, without harming the environment and, in particular without risk to water, air, soil, plants or animals.

Recycle or dispose of waste in compliance with current legislation, preferably via a certified collector or company.

**Soiled packaging :**

Empty container completely. Keep label(s) on container.

Give to a certified disposal contractor.

**Codes of wastes (Decision 2001/573/EC, Directive 2006/12/EEC, Directive 94/31/EEC on hazardous waste) :**

18 01 06 \* chemicals consisting of or containing dangerous substances

For information :

The waste code is given for indicative purposes.

The waste code must be determined by the user, according to the application of the product.

18 = Wastes from human or animal health care and/or related research (except kitchen and restaurant wastes not arising from immediate health care)

**SECTION 14 : TRANSPORT INFORMATION**

Exempt from transport classification and labelling.

**14.1. UN number**

-

**14.2. UN proper shipping name**

-

**14.3. Transport hazard class(es)**

-

**14.4. Packing group**

-

**14.5. Environmental hazards**

-

**14.6. Special precautions for user**

-

**SECTION 15 : REGULATORY INFORMATION**

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

**- Classification and labelling information included in section 2:**

The following regulations have been used:

Regulation (EC) No. 1272/2008 and its amendments.

**- Container information:**

No data available.

**15.2. Chemical safety assessment**

Information from the chemical safety assessment of substances present in the product is included in the appropriate sections of this safety data sheet, whenever necessary.

**SECTION 16 : OTHER INFORMATION**

Since the user's working conditions are not known by us, the information supplied on this safety data sheet is based on our current level of knowledge and on national and community regulations.

It is at all times the responsibility of the user to take all necessary measures to comply with legal requirements and local regulations.

The information in this safety data sheet must be regarded as a description of the safety requirements relating to the mixture.

It is recommended that the information contained in this safety data sheet is provided to the users, if necessary in an appropriate form.

This information relates to the specifically designated product and may not be valid in combination with any another product. The product must not be used for applications other than those specified in heading 1 without having first obtained written handling instructions.

UPDATES SINCE PREVIOUS VERSION

- § 2
- § 4
- § 7
- § 8
- § 9
- § 11

**Wording of the phrases mentioned in section 3 :**

H301	Toxic if swallowed.
H314	Causes severe skin burns and eye damage.
H317	May cause an allergic skin reaction.
H330	Fatal if inhaled.
H334	May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H400	Very toxic to aquatic life.
H411	Toxic to aquatic life with long lasting effects.
EUH071	Corrosive to the respiratory tract.

**Abbreviations :**

ADR : European agreement concerning the international carriage of dangerous goods by Road.

IMDG : International Maritime Dangerous Goods.

IATA : International Air Transport Association.

ICAO : International Civil Aviation Organisation

RID : Regulations concerning the International carriage of Dangerous goods by rail.

GHS07 : Exclamation mark

GHS08 : Health hazard

PBT: Persistent, bioaccumulable and toxic.

vPvB : Very persistent, very bioaccumulable.

SVHC : Substances of very high concern.