

# 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 : Saniswiss biosanitizer A  
Product code : 132020, 132021, 132039

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

Cleaning and disinfection of suction circuits and medical devices in dental sector.  
For further information on product indication, please see the label.

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

Registered company name : Saniswiss SA  
Address : ch. des tulpiers 19. 1208 Geneva - Switzerland.  
t +41 22 718 75 75 – f +41 22 718 75 76 (during business hours Monday – Friday)  
[info@saniswiss.com](mailto:info@saniswiss.com)

### 1.4. Emergency telephone number : 145 ou +41 1 251 51 51.

Association/Organisation : CSIT (Tox) / STIZ (Tox-Zentrum) / STIC (The Tox).

## SECTION 2 : HAZARDS IDENTIFICATION

### 2.1. Classification of the substance or mixture

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

Substance that is corrosive to metals, Category 1 (Met. Corr. 1, H290).  
Skin irritation, Category 2 (Skin Irrit. 2, H315).  
Serious eye damage, Category 1 (Eye Dam. 1, H318).  
Hazardous to the aquatic environment - Chronic hazard, Category 2 (Aquatic Chronic 2, H411).

### 2.2. Label elements

Detergent mixture (see section 15).

This mixture being intended for professional use only, the labelling for contents under detergent regulation does not appear on the label but is resumed in section 15

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

Hazard pictograms :



GHS05



GHS09

Signal Word :

DANGER

Product identifiers :

EC 270-331-5

N-DECYL-N-ISONONYL-N,N-DIMETHYLAMMONIUM CHLORIDE

Hazard statements :

H290 May be corrosive to metals.  
H315 Causes skin irritation.  
H318 Causes serious eye damage.  
H411 Toxic to aquatic life with long lasting effects.

Precautionary statements - General :

P102 Keep out of reach of children.

Precautionary statements - Prevention :

P273 Avoid release to the environment.  
P280 Wear protective gloves and eye protection/face 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.  
P310 Immediately call a POISON CENTER or doctor/physician.

Saniswiss biosanitizer A - 2179000

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: 138698-36-9 EC: 270-331-5  N-DECYL-N-ISONONYL-N,N-DIMETHYL AMMONIUM CHLORIDE	GHS07, GHS05, GHS09 Dgr Acute Tox. 4, H302 Skin Corr. 1B, H314 Aquatic Acute 1, H400 M Acute = 1 Aquatic Chronic 1, H410 M Chronic = 1		2.5 $\leq$ x % < 10
CAS: 37971-36-1 EC: 253-733-5 REACH: 01-2119436643-39  2- PHOSPHONOBUTANE-1,2,4- TRICARBOXYLIC ACID	GHS05 Wng Met. Corr. 1, H290 Eye Irrit. 2, H319		0 $\leq$ x % < 2.5

**Information on ingredients :**

CAS: 64-17-5 REACH: 01-2119457610-43 : GHS02 GHS07 Dgr Flam. Liq. 2: H225 ; Eye Irrit. 2: H319 [1]

x % < 1

CAS: 27083-27-8 POLYHEXAMETHYLENE BIGUANIDE HYDROCHLORIDE GHS06, GHS05, GHS09, GHS08 Dgr Acute Tox. 4 : H302 ; Skin Sens. 1 : H317 ; Eye Dam. 1 : H318 ; Acute Tox. 2 : H330 ; Carc. 2 : H351 ; STOT RE 1 : H372 ; Aquatic Acute 1 H400 M Acute = 10 ; Aquatic Chronic 1 : H410 M Chronic = 10 [2] 0  $\leq$  x % < 2.5

[1] Substance for which there are exposure limits in the workplace.

[2] Carcinogenic, mutagenic or reprotoxic (CMR) substance.

CAS: 64-17-5 EC: 200-578-6	ETHYL ALCOHOL
-------------------------------	---------------

**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.

**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 splashes or contact with eyes :**

If applicable, remove contact lenses.

Wash thoroughly with soft clean water for 15 minutes, holding the eyelids open.

Take care not to introduce rinsing water in the undamaged eye.

Additional treatment to be provided immediately in an eye clinic or by an ophthalmologist. Show this container or label.

Continue rinsing until medical advice is obtained.

**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.

Do not breathe in smoke.

### 5.3. Advice for firefighters

Use autonomous insulating breathing apparatus and a 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.

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.

Use drums to dispose of collected waste in compliance with current regulations (see section 13).

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.

Do not get rid in natural spaces.

### 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

#### Recommended equipment and procedures :

For personal protection, see section 8.

Observe precautions stated on label and also industrial safety regulations.

Avoid eye contact with this mixture at all times.

Eye bath and water point nearby.

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)

Splash pan for high quantities' storage

### 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.

**8.1. Control parameters****Occupational exposure limits :**

- Switzerland (SUVA 2009) :

CAS	VME-mg/m3 :	VME-ppm :	VLE-mg/m3 :	VLE-ppm :	Temps :	RSB :
64-17-5	960	500	1920	1000	4x15	-

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

CAS	VME :	VME :	Excess	Notes
64-17-5	500 ml/m3	960 mg/m3	2(II)	DFG. Y

Slovakia (Regulation No. 300/2007) :

CAS	TWA :	STEL :	Ceiling :	Definition :	Criteria :
64-17-5	500 ppm	960 mg/m3	II..1		

Czech Republic (Regulation No. 361/2007) :

CAS	TWA :	STEL :	Ceiling :	Definition :	Criteria :
64-17-5	1000 mg/m3	3000 mg/m3	-	-	-

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

CAS	TWA :	STEL :	Ceiling :	Definition :	Criteria :
64-17-5	1000 ppm	-	-	-	-

- Poland (2009) :

CAS	TWA :	STEL :	Ceiling :	Definition :	Criteria :
64-17-5	1900 mg/m3	-	-	-	-

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

CAS	TWA :	STEL :	Ceiling :	Definition :	Criteria :
64-17-5	1000 ppm	-	-	-	-

- France (INRS - ED984 :2008) :

CAS	VME-ppm :	VME-mg/m3 :	VLE-ppm :	VLE-mg/m3 :	Notes :	TMP No :
64-17-5	1000	1900	5000	9500	-	84

**8.2. Exposure controls****Suitable technical inspections**

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.

Before handling, wear safety goggles with protective sides accordance with standard EN166.

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.

Nitrile, latex or vinyl gloves.

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.

**- Respiratory protection**

In case of insufficient ventilation, with the risk of exceeding the TLVs (Threshold Limit values)/TWA, wear suitable breathing apparatus (mask which filters organic vapours - type A protection)

**SECTION 9 : PHYSICAL AND CHEMICAL PROPERTIES****9.1. Information on basic physical and chemical properties****General information :**

Physical state :	Fluid liquid.
Odour:	Weak
Colour:	yellow

**Important health, safety and environmental information**

pH :	Not stated.
	Strongly acidic.
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: < 2.

The strong acid property is linked to the formulation natural pH - it does not correspond to the presence of strong acid compound in the preparation.

**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**

The risk of corrosion to metals concerns the concentrated product when put in contact with crude steel or an aluminium-based alloy.

At the application rate, the product is compatible with the materials encountered for the recommended uses.

**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****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.

Ingestion may lead to irritation of the digestive system, abdominal pain, headaches and nausea.

**Skin corrosion/skin irritation :**

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

Dermal irritation/corrosion test in the rabbit (OECD 404) - similar preparation:

The preparation, tested as such, appears to be irritating to skin.

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

Serious eyes damage.

Burns, characterized by discomfort or pain, excessive blinking, lacrimation and redness, swelling of the conjunctiva.

**Respiratory or skin sensitisation :**

Skin sensitisation in the guinea-pig - maximisation test (OECD 406):

The preparation is not classified among the chemicals which may cause sensitisation by skin contact.

**SECTION 12 : ECOLOGICAL INFORMATION**

Following information is based on data from the compounds.

Avoid any product release into waterways.

**12.1. Toxicity****12.1.1. Substances**

Not specified

**12.1.2. Mixtures**

Chronic toxicity:

Toxic to aquatic life with long lasting effects.

**12.2. Persistence and degradability**

The surfactant(s) contained in this preparation complies(comply) with the biodegradability criteria as laid down in Regulation (EC) No.648/2004 on detergents.

Data to support this assertion are held at the disposal of the competent authorities of the Member States and will be made available to them, at their direct request or at the request of a detergent manufacturer.

**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 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**

Transport product in compliance with provisions of the ADR for road, RID for rail, IMDG for sea and ICAO/IATA for air transport (ADR 2015 - IMDG 2014 - ICAO/IATA 2015).

**14.1. UN number**

3082

**14.2. UN proper shipping name**

UN3082=ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.

N.O.S. : (POLYHEXAMETHYLENE BIGUANIDE HYDROCHLORIDE)

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

- Classification :



9

**14.4. Packing group**

III

**14.5. Environmental hazards**

- Environmentally hazardous material :

**14.6. Special precautions for user**

ADR/RID	Class	Code	Pack gr.	Label	Ident.	LQ	Provis.	EQ	Cat.	Tunnel
	9	M6	III	9	90	5 L	274 335 375 601	E1	3	E

\*Not subject to this regulation if Q &lt;= 5 l / 5 kg (ADR 3.3.1 - DS 375)

IMDG	Class	2°Label	Pack gr.	LQ	EMS	Provis.	EQ
	9	-	III	5 L	F-A,S-F	274 335 969	E1

\*Not subject to this regulation if Q &lt;= 5 l / 5 kg (IMDG 3.3.1 - 2.10.2.7)

IATA	Class	2°Label	Pack gr.	Passager	Passager	Cargo	Cargo	note	EQ
	9	-	III	964	450 L	964	450 L	A97 A158 A197	E1
	9	-	III	Y964	30 kg G	-	-	A97 A158 A197	E1

\*Not subject to this regulation if Q &lt;= 5 l / 5 kg (IATA 4.4.4 - DS A197)

For limited quantities, see part 2.7 of the OACI/IATA and chapter 3.4 of the ADR and IMDG.

For excepted quantities, see part 2.6 of the OACI/IATA and chapter 3.5 of the ADR and IMDG.

**14.7. Transport in bulk according to Annex II of Marpol and the IBC Code**

Not applicable

**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.

**- Particular provisions :**

No data available.

**- Labelling for detergents (EC Regulation No. 648/2004,907/2006) :**

- less than 5 % : phosphonates
- less than 5 % : nonionic surfactants
- disinfectants

**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**

- Implementation of classification and labelling in compliance with EC regulation 1272/2008.

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

H290	May be corrosive to metals.
H302	Harmful if swallowed.
H314	Causes severe skin burns and eye damage.
H319	Causes serious eye irritation.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.

H225 Highly flammable liquid and vapour.

H317 May cause an allergic skin reaction.

H318 Causes serious eye damage.

H351 Suspected of causing cancer.

H372 Causes damage to organs through prolonged or repeated exposure.

**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.

GHS05 : Corrosion

GHS09 : Environment

PBT: Persistent, bioaccumulable and toxic.

vPvB : Very persistent, very bioaccumulable.

SVHC : Substances of very high concern.