

SOLUSCOPE NW

INDICATIONS : nettoyage des endoscopes. À utiliser exclusivement la *Soluscope Serie 1*. **COMPOSITION :** tensioactifs non ionique et anionique, agent séquestrant, excipients. **MODE D'EMPLOI :** solution concentrée

MADE IN FRANCE
FABRIQUÉ EN FRANCE

EMB 59298D



LOT



Ouvert le / Open on :

FG24820005LEWV - 150302

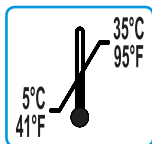
Labd-HW5-ENFR2-D0870A

**Soluscope
SAS**

100, rue du Fauge - ZI Les Paluds
13400 Aubagne - FRANCE

+ 33 (0)4 91 83 21 22

www.soluscope.com



SOLUSCOPE GTA

(EN) HIGH LEVEL DISINFECTANT FOR AUTOMATIC ENDOSCOPE REPROCESSOR (AER)

INDICATIONS: High level disinfectant for endoscopes. To be used exclusively with *Soluscope Serie 1*. **COMPOSITION:**

Concentrated solution of glutaraldehyde, sequestering agent, colouring and excipients. **MICROBIOLOGICAL PROPERTIES:** Bactericide in 10 min, 0.5%, 40°C (EN 13727, EN 14561). Mycobactericide in 10 min, 1%, 40°C (EN 14348, EN 14563). Fungicide in 10 min, 1%, 40°C (EN 13624, EN 14562). Virucide in 10 min, 0.5%, 40°C (EN 14476+A1).

INSTRUCTIONS FOR USE: Concentrated solution for professional use. Insert the container. Screw the white cap connected to your *Soluscope Serie 1* onto the container (refer to user manual of the AER). Make sure that the vent hole is not blocked. Automated dilution = 1% (10mL/L), 40°C, 10min. Use within 2 months of the date of connection to the machine (note the opening date on the label in the location provided for this purpose). Shelf-life: see date on the container. At the dilution of use, the product doesn't show incompatibility with commonly found materials.

PRECAUTIONS FOR USE: DANGER. Contains glutaraldehyde. Harmful if swallowed or if inhaled. Causes severe skin burns and eye damage. May cause an allergic skin reaction. May cause allergy or asthma symptoms or breathing difficulties if inhaled. May cause respiratory irritation. Harmful to aquatic life with long lasting effects. May be corrosive to metals. Use in well-ventilated areas. Do not breathe vapours. Wear protective gloves, protective clothing, eyes/face protection. In case of inadequate ventilation wear respiratory protection. IF INHALED: Remove person to fresh air and keep comfortable for breathing. IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. IF SWALLOWED: rinse mouth. Do NOT induce vomiting. Immediately call a POISON CENTER or doctor/physician. Keep out of reach of children. Keep only in original container. Do not reuse the packaging. Avoid release to the environment. Dispose of unused product and its container as hazardous waste.

(FR) DÉSINFECTANT DE HAUT NIVEAU POUR LAVEUR-DÉSINFECTEUR D'ENDOSCOPES (LDE)

INDICATIONS : désinfection de haut niveau des endoscopes. À utiliser exclusivement avec la *Soluscope Serie 1*.

COMPOSITION : solution concentrée de glutaraldéhyde, agent séquestrant, colorant et excipients. **PROPRIÉTÉS MICROBIOLOGIQUES :** bactéricide en 10 min, 0,5%, 40°C (EN 13727, EN 14561). Mycobactéricide en 10 min, 1%, 40°C (EN 14348, EN 14563). Fongicide en 10 min, 1%, 40°C (EN 13624, EN 14562). Virucide en 10 min, 0,5%, 40°C (EN 14476+A1).

MODE D'EMPLOI : solution concentrée pour usage professionnel. Mettre le bidon en place. Visser, sur le bidon, le bouchon blanc raccordé à votre *Soluscope Serie 1* (se référer au mode d'emploi du LDE). S'assurer que l'évent n'est pas bouché. Dilution automatique = 1% (10mL/L), 40°C, 10min. À utiliser dans les 2 mois après la date de connexion à la machine (inscrire la date d'ouverture sur l'étiquette dans l'emplacement prévu à cet effet). Date limite d'utilisation : voir date sur le bidon. À la dilution d'emploi, le produit ne présente pas d'incompatibilité avec les matériaux couramment rencontrés. **PRÉCAUTIONS D'EMPLOI :** DANGER. Contient du glutaraldéhyde. Nocif en cas d'ingestion ou d'inhalation. Provoque des brûlures de la peau et des lésions oculaires graves. Peut provoquer une allergie cutanée. Peut provoquer des symptômes allergiques ou d'asthme ou des difficultés respiratoires par inhalation. Peut irriter les voies respiratoires. Nocif pour les organismes aquatiques, entraîne des effets néfastes à long terme. Peut être corrosif pour les métaux. Utiliser dans des zones bien ventilées. Ne pas respirer les vapeurs. Porter des gants de protection, des vêtements de protection et un équipement de protection des yeux/du visage. Lorsque la ventilation du local est insuffisante, porter un équipement de protection respiratoire. EN CAS D'INHALATION : transporter la personne à l'extérieur et la maintenir au repos dans une position où elle peut confortablement respirer. EN CAS DE CONTACT AVEC LA PEAU (ou les cheveux) : enlever immédiatement tous les vêtements contaminés. Rincer la peau à l'eau/se doucher. EN CAS DE CONTACT AVEC LES YEUX : rincer avec précaution à l'eau pendant plusieurs minutes. Enlever les lentilles de contact si la victime en porte et si elles peuvent être facilement enlevées. Continuer à rincer. EN CAS D'INGESTION : rincer la bouche. NE PAS faire vomir. Appeler immédiatement un CENTRE ANTIPOISON ou un médecin. Tenir hors de portée des enfants. Conserver uniquement dans le récipient d'origine. Ne pas réutiliser l'emballage. Éviter le rejet dans l'environnement. Éliminer le produit non utilisé et son récipient comme un déchet dangereux.



MADE IN FRANCE
FABRIQUÉ EN FRANCE

EMB 59298D

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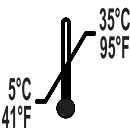


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LabB-GTAS-ENFR2-D0873A

SAFETY DATA SHEET

(REACH regulation (EC) n° 1907/2006 - n° 453/2010)

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

1.1. Product identifier

Product name : SOLUSCOPE GTA

Product code : 2484000_

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 : 1 SOLUSCOPE.

Address : 100 rue du Fauge, ZI Les Paluds.13400.AUBAGNE.FRANCE.

Telephone : +33 (0)4 91 83 21 22. Fax : +33 (0)4 91 83 21 10.

e-mail : fds@anios.com

Registered company name 2: Laboratoires Anios - 59260 Lille-Hellemmes - France - www.anios.com

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

Association/Organisation : INRS / ORFILA <http://www.centres-antipoison.net>.

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).

Acute oral toxicity, Category 4 (Acute Tox. 4, H302).

Acute inhalation toxicity, Category 4 (Acute Tox. 4, H332).

Skin corrosion, Category 1B (Skin Corr. 1B, H314).

Respiratory sensitisation, Category 1 (Resp. Sens. 1, H334).

Skin sensitisation, Category 1 (Skin Sens. 1, H317).

Specific target organ toxicity (single exposure), Category 3 (STOT SE 3, H335).

Hazardous to the aquatic environment - Chronic hazard, Category 3 (Aquatic Chronic 3, H412).

In compliance with directives 67/548/EEC, 1999/45/EC and their amendments.

Acute oral toxicity: harmful (Xn, R 22).

Acute inhalation toxicity: harmful (Xn, R 20).

Corrosive (C, R 34).

Respiratory sensitisation (Xi, R 42).

Skin sensitisation (Xi, R 43).

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.

Irritant for the respiratory tract (Xi, R 37).

2.2. Label elements

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

Hazard pictograms :



GHS07



GHS05



GHS08

Signal Word :

DANGER

Product identifiers :

EC 203-856-5

GLUTARALDEHYDE

Hazard statements :

H290

May be corrosive to metals.

H302 + H332

Harmful if swallowed or if inhaled.

H314

Causes severe skin burns and eye damage.

H317

May cause an allergic skin reaction.

H334	May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H335	May cause respiratory irritation.
H412	Harmful to aquatic life with long lasting effects.
Precautionary statements - General :	
P102	Keep out of reach of children.
Precautionary statements - Prevention :	
P234	Keep only in original container.
P260	Do not breathe vapours.
P273	Avoid release to the environment.
P280	Wear protective gloves/protective clothing/eye protection/face protection.
P284	In case of inadequate ventilation wear respiratory protection.
Precautionary statements - Response :	
P301 + P330 + P331	IF SWALLOWED: rinse mouth. Do NOT induce vomiting.
P303 + P361 + P353	IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower.
P304 + P340	IF INHALED: Remove person to fresh air and keep comfortable for breathing.
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.
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, EUH and R indications: see § 16.

3.2. Mixtures

Composition :

Identification	(EC) 1272/2008	67/548/EEC	Note	%
CAS: 111-30-8 EC: 203-856-5 REACH: 01-2119455549-26 GLUTARALDEHYDE	GHS06, GHS05, GHS09, GHS08 Dgr Met. Corr. 1, H290 Acute Tox. 3, H301 Skin Corr. 1B, H314 Skin Sens. 1, H317 Acute Tox. 3, H331 Resp. Sens. 1, H334 STOT SE 3, H335 Aquatic Chronic 2, H411 Aquatic Acute 1, H400 M Acute = 1	T,N T;R23/25 C;R34 Xn;R42/43 N;R50	[1]	10 $\leq$ x % < 25

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.
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 :

If possible, wear rubber gloves when giving first aid.
Remove all contaminated or stained clothing immediately. Do not use them again until they have been decontaminated.
Rinse thoroughly with water during 15 minutes.
If the contaminated area is widespread and/or there is damage to the skin, a doctor must be consulted or the patient transferred to hospital.

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.

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

- nitrogen oxide (NO)
- carbon monoxide (CO)
- carbon dioxide (CO₂)

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.

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.

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

Fire prevention :

SAFETY DATA SHEET (REGULATION (EC) n° 1907/2006 - REACH)
SOLUSCOPE GTA - 2484000

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.
 Do not inhale vapours.
 Provide vapor extraction at the emission source and also general ventilation of the premises.
 Safety shower, eye bath and water point 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 :

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

CAS	TWA :	STEL :	Ceiling :	Definition :	Criteria :
111-30-8	0.2 ppm	-	-	-	-

- France (INRS - ED984 :2008) :

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	-	0.5 ppm	-	-	-

- Poland (2009) :

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	-	0.8 mg/m3	-	-	-

Slovakia (Regulation No. 300/2007) :

CAS	TWA :	STEL :	Ceiling :	Definition :	Criteria :
111-30-8	0.1 ppm	0.42 mg/m3	l.	-	-

- Switzerland (SUVA 2009) :

CAS	VME-mg/m3 :	VME-ppm :	VLE-mg/m3 :	VLE-ppm :	Temps :	RSB :
111-30-8	0,21	0,05	0,42	0,1	4x15	S

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

CAS	TWA :	STEL :	Ceiling :	Definition :	Criteria :
111-30-8	0.05 ppm	0.05 ppm	-	-	-

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.

Provide eye washes in workshops.

If necessary, the nearest water supply

- 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 (Threshold 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:	spicy
Colour:	green

Important health, safety and environmental information

pH :	4.00 .
	Slightly acidic.
Boiling point/boiling range :	Not specified.
Flash point interval :	Not relevant.
Vapour pressure (50°C) :	Not relevant.
Density :	+/- 1.1
Water solubility :	Soluble.
Melting point/melting range :	Not specified.
Self-ignition temperature :	Not specified.
Decomposition point/decomposition range :	Not specified.

9.2. Other information

No data available.

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

Keep away from :

- amines

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

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 :]300-2000] mg/kg

ATE Inhalation (Dusts and mists):] 1.0 – 5.0] mg/l

* 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 :

Severe skin irritation, burns, redness, dermatitis, necrosis of tissue.

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 :

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

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:

Harmful to aquatic life with long lasting effects.

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

Transport product in compliance with provisions of the ADR for road, RID for rail, IMDG for sea and ICAO/IATA for air transport (ADR 2013 - IMDG 2012 - ICAO/IATA 2014).

14.1. UN number

1903

14.2. UN proper shipping name

UN1903=DISINFECTANT, LIQUID, CORROSIVE, N.O.S.

(glutaraldehyde)

14.3. Transport hazard class(es)

- Classification :



8

14.4. Packing group

III

14.5. Environmental hazards**14.6. Special precautions for user**

ADR/RID	Class	Code	Pack gr.	Label	Ident.	LQ	Provis.	EQ	Cat.	Tunnel
	8	C9	III	8	80	5 L	274	E1	3	E
IMDG	Class	2°Label	Pack gr.	LQ	EMS	Provis.	EQ			
	8	-	III	5 L	F-A,S-B	223 274	E1			
IATA	Class	2°Label	Pack gr.	Passager	Passager	Cargo	Cargo	note	EQ	
	8	-	III	852	5 L	856	60 L	A3 A803	E1	
	8	-	III	Y841	1 L	-	-	A3 A803	E1	

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 MARPOL73/78 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.

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.

SOLUSCOPE NW

Instructiuni de utilizare.

RO. Detergent pentru reprocesor automat al endoscoapelor.

Indicatii: Curatarea endoscoapelor. Ase utiliza exclusiv cu reprocesorul SOLUSCOPE seria 1.

COMPOZITIE: Surfactanti non ionici si anionici, agent de sechestrare, coloranti si excipienți.

INSTRUCIUNI DE UTILIZARE: Solutie concentrata pentru uz profesional. Însurubati capacul alb al Soluscope 1 in canistra. Verificati ca filetul nu este blocat. Dilutia are loc automat =0,5 % (5 ml/litru). A se utiliza nu mai mult de 2 luni din momentul montarii canistrei. Durata pastrarii indicata pe ambalaj.

Precautiuni: Periculos. Contine sodium etasulfat, amestec de 5- clor-2-metil-4-isotiazolin-3-unu si 2-metil-2H*isotiazol3-3unu (3:1).

Poate cauza reactii alergice si afectiuni severe a ochilor, utilizati manusi si ochelari de protectie. La contact cu ochii spalati sub jet continuu citeva minute, contactati centrele de toxicologie sau un medic. Pastrati in canistre originale, nu lasati la indemina copiilor. Nu reutilizati vasul. Evitati eliberarea in mediul inconjurator. Aruncati produsele neutilizate ca produse periculoase.

Producator Soluscope SAS, Franta.

Data ultimei reviziuni a textului: 12 09 2016

Reprezentant autorizat in Rep. Moldova : ERICON SRL.or. Durl esti. Srt.V. Lupu 6.

Nr. de Inregistrare:



SAFETY DATA SHEET

(REACH regulation (EC) n° 1907/2006 - n° 453/2010)

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

1.1. Product identifier

Product name : SOLUSCOPE NW

Product code : 2482000_.

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

Liquid detergent for machine washing

For further information on product indication, please see the label.

1.3. Details of the supplier of the safety data sheet

Registered company name : 1 SOLUSCOPE.

Address : 100 rue du Fauge, ZI Les Paluds.13400.AUBAGNE.FRANCE.

Telephone : +33 (0)4 91 83 21 22. Fax : +33 (0)4 91 83 21 10.

Registered company name 2: Laboratoires Anios - 59260 Lille-Hellemmes - France - www.anios.com

e-mail : fds@anios.com

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

Association/Organisation : INRS / ORFILA <http://www.centres-antipoison.net>.

SECTION 2 : HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture

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

Serious eye damage, Category 1 (Eye Dam. 1, H318).

May produce an allergic reaction (EUH208).

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.

In compliance with directives 67/548/EEC, 1999/45/EC and their amendments.

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 a health hazard with the exception of possible occupational exposure thresholds (see paragraphs 3 and 8).

This mixture does not present an environmental hazard. No known or foreseeable environmental damage under standard conditions of use.

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

Signal Word :

DANGER

Product identifiers :

EC 204-812-8

SODIUM 2-ETHYLHEXYL SULFATE

Additional labeling :

EUH208

Contains REACTION MASS OF: 5-CHLORO-2-METHYL-4-ISOTHIAZOLIN-3-ONE [EC NO. 247-500-7] AND 2-METHYL-2H-ISOTHIAZOL-3-ONE [EC NO. 220-239-6] (3:1). May produce an allergic reaction.

Hazard statements :

H318

Causes serious eye damage.

Precautionary statements - General :

P102

Keep out of reach of children.

Precautionary statements - Prevention :

P280

Wear protective gloves and eye protection/face protection.

Precautionary statements - 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.
P310 Immediately call a POISON CENTER or doctor/physician.
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) >= 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, EUH and R indications: see § 16.

3.2. Mixtures

Composition :

Identification	(EC) 1272/2008	67/548/EEC	Note	%
CAS: 126-92-1 EC: 204-812-8 SODIUM 2-ETHYLHEXYL SULFATE CAS: 55965-84-9	GHS05 Dgr Skin Irrit. 2, H315 Eye Dam. 1, H318	Xi Xi;R38-R41		2.5 <= x % < 10
REACTION MASS OF: 5-CHLORO-2-METHYL-4- ISOTHIAZOLIN-3-ONE [EC NO. 247-500-7] AND 2-METHYL-2H -ISOTHIAZOL-3-ONE [EC NO. 220-239-6] (3:1)	GHS06, GHS05, GHS09 Dgr Acute Tox. 3, H301 Acute Tox. 3, H311 Skin Corr. 1B, H314 Skin Sens. 1, H317 Acute Tox. 3, H331 Aquatic Acute 1, H400 M Acute = 10 Aquatic Chronic 1, H410 M Chronic = 1	T,N T;R23/24/25 C;R34 Xi;R43 N;R50/53		0 <= x % < 2.5

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.

Take care not to skid.

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 put any spilt product back into its original container with the intention of 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 or eyes.

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.

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

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.

8.1. Control parameters

Not applicable

8.2. Exposure controls

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.

Provide eye washes in workshops.

If necessary, the nearest water supply

- 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

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

Not applicable in normal conditions of use.

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

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

Important health, safety and environmental information

pH :	7.00 .
	Neutral.
Boiling point/boiling range :	Not specified.
Flash point interval :	Not relevant.
Vapour pressure (50°C) :	Not relevant.
Density :	+/- 1.1
Water solubility :	Soluble.
Melting point/melting range :	Not specified.
Self-ignition temperature :	Not specified.
Decomposition point/decomposition range :	Not specified.

9.2. Other information

No data available.

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

10.5. Incompatible materials

Do not mix with other products.

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 :

Possibility of itching with light to moderate local redness.

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 :

Contains at least one sensitising substance. May cause an allergic reaction.

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

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 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.

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.

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

- less than 5 % : phosphonates
- less than 5 % : anionic surfactants
- 5 % or over but less than 15 % : nonionic surfactants
- Methylchloroisothiazolinone, Methylisothiazolinone

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.

Title for H, EUH and R indications mentioned in section 3 :

H301	Toxic if swallowed.
H311	Toxic in contact with skin.
H314	Causes severe skin burns and eye damage.
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H318	Causes serious eye damage.
H331	Toxic if inhaled.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.
R 23/24/25	Toxic by inhalation, in contact with skin and if swallowed.
R 34	Causes burns.
R 38	Irritating to skin.
R 41	Risk of serious damage to eyes.
R 43	May cause sensitisation by skin contact.
R 50/53	Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

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



CERTIFICATE

EC Certificate No. 1434-MDD-420/2021

Full Quality Assurance System

Directive 93/42/EEC concerning medical devices

Polish Centre for Testing and Certification certifies
that the quality assurance system in the organization:

Soluscope SAS

100 rue du Fauge

ZI Les Paluds

Aubagne 13400 FRANCE

for the design, manufacture and final inspection of
medical devices, class IIb

**Washer-disinfectors for endoscopes or TEE probes and disinfectant
solutions**

The list of medical devices covered by this certificate is provided in the annex 1

complies with requirements
of Annex II (excluding Section 4) to Directive 93/42/EEC (as amended)
implemented into Polish law,
as evidenced by the audit conducted by the PCBC

Validity of the Certificate: **from 25.05.2021 to 26.05.2024**

The date of issue of the Certificate: **25.05.2021**

The date of the first issue of the Certificate: **26.04.2019**



Issued under the Contract No. MD-15/2020, MD-33/2021

Application No: 642/2020, 520/2021

Certificate bears the authorized person signature.

Warsaw, 25/05/2021

Module **H2/3/4/5**

FBM-26-E_9


Vice-President

REGISTRUL DE STAT AL DISPOZITIVELOR MEDICALE

Введите текст для поиска...											
Nr	▼	▼	▼	▼	▼	▼	▼	▼	▼	▼	▼
	▼	▼	▼	▼	▼	▼	▼	▼	▼	▼	▼
DM000017265			DETERGENT PENTRU REPROCESOR AUTOMAT AL ENDOSCOAPELOR			SOLUSCOPE INW	5 L				
DM000017267			DEZINFECTANT DE NIVEL ÎNALT PENTRU REPROCESOR AUTOMAT AL ENDOSCOAPELOR			SOLUSCOPE GTA	5 L				
DM000017266			REPROCESOR AUTOMAT PENTRU DEZINFECTAREA ENDOSCOAPELOR, VERSIONE SOFTWARE SL- V1 V 4.0.0.			SOLUSCOPE	SERIE 1, SL-V1-GTA				
Conexiuni(Producatorul) „solusc”											
✓											



REGISTRUL DE STAT AL DISPOZITIVELOR MEDICALE

Введите текст для поиска...

Nr	Denumire	Den.comerc.	Model	Nr. catalog	Tara	Producatorul	Reprezentant	Ordin	Data
						solus			
DM000380771	DEZINFECTANT PENTRU DISPOZITIVELE MEDICALE INVAZIVE		SOLUSCOPE PA		Franta	SOLUSCOPE SAS	ERICON S.R.L.	Rg04-000247	25-10-2022
DM000380750	DETERGENT ENZIMATIC PENTRU INSTRUMENTAR		SOLUSCOPE EZ	2483444BR	Franta	SOLUSCOPE SAS	ERICON S.R.L.	Rg04-000247	25-10-2022
DM000380757	MAȘINĂ PENTRU STERILIZAREA ENDOSCOAPELOR	SOLUSCOPE	SERIE 1	SL-V1-PA	Franta	SOLUSCOPE SAS	ERICON S.R.L.	Rg04-000247	25-10-2022
DM000380753	DETERGENT ENZIMATIC PENTRU INSTRUMENTAR		SOLUSCOPE EZ	2483444UP	Franta	SOLUSCOPE SAS	ERICON S.R.L.	Rg04-000247	25-10-2022
DM000380758	MAȘINĂ PENTRU STERILIZAREA ENDOSCOAPELOR	SOLUSCOPE	SERIE 1	SL-V1-GTA	Franta	SOLUSCOPE SAS	ERICON S.R.L.	Rg04-000247	25-10-2022
DM000380751	DETERGENT ENZIMATIC PENTRU INSTRUMENTAR		SOLUSCOPE EZ	2483444FG	Franta	SOLUSCOPE SAS	ERICON S.R.L.	Rg04-000247	25-10-2022
DM000380748	DETERGENT ENZIMATIC PENTRU INSTRUMENTAR		SOLUSCOPE EZ	248344444	Franta	SOLUSCOPE SAS	ERICON S.R.L.	Rg04-000247	25-10-2022
DM000380752	DETERGENT ENZIMATIC PENTRU INSTRUMENTAR		SOLUSCOPE EZ	2483444GZ	Franta	SOLUSCOPE SAS	ERICON S.R.L.	Rg04-000247	25-10-2022
DM000380760	MAȘINĂ PENTRU STERILIZAREA ENDOSCOAPELOR	SOLUSCOPE	SERIE 1	SL-V1-AL-GTA	Franta	SOLUSCOPE SAS	ERICON S.R.L.	Rg04-000247	25-10-2022
DM000380759	MAȘINĂ PENTRU STERILIZAREA ENDOSCOAPELOR	SOLUSCOPE	SERIE 1	SL-V1-AL-PA	Franta	SOLUSCOPE SAS	ERICON S.R.L.	Rg04-000247	25-10-2022

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☒ Содержит(['Producatorul'], 'solus').



REGISTRUL DE STAT AL DISPOZITIVELOR MEDICALE

Nr	Denumire	Den.comerc.	Model	Nr. catalog	Tara	Producatorul	Reprezentant	Ordin	Data
						solus			
DM000380749	DETERGENT ENZIMATIC PENTRU INSTRUMENTAR		SOLUSCOPE EZ	24834447Q	Franta	SOLUSCOPE SAS	ERICON S.R.L.	Rg04-000247	25-10-2022
DM000380754	DETERGENT ENZIMATIC PENTRU INSTRUMENTAR		SOLUSCOPE EZ	2483444ZH	Franta	SOLUSCOPE SAS	ERICON S.R.L.	Rg04-000247	25-10-2022

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