

Surface disinfection

PHAGO'SEPT QUICK & CLEAN

Ready to use, alcoholic solution for surface disinfection

Product description

PHAGO'SEPT QUICK & CLEAN is a ready to use, alcoholic solution for surface disinfection. The product must not be diluted by the user. It contains quarternary ammonium compounds and is free of aldehydes and phenols. After the contact time has elapsed, treated surfaces dry quickly. PHAGO'SEPT QUICK & CLEAN can be applied for wipe as well as spray disinfection.

Areas of application

PHAGO'SEPT QUICK & CLEAN is suitable for rapid disinfection of alcohol-resistant surfaces of non-invasive, non-critical medical devices, medical equipment as well as all kinds of wipeable surfaces.

Suitable for:

- Surfaces close to patients, dental chairs, examination couches, operating tables
- Areas in medical and dental practices which are used for medical purposes
- Rapid disinfection between surgeries and procedures
- Clothes like OR shoes, OR aprons, X-ray aprons
- Alcohol-resistant surfaces of medical equipment
- Materials according to material compatibility (see page 2)

Not tested for food and veterinary areas. Not suitable for disinfection of skin and hands. Not suitable for disinfection of invasive medical devices. Do not use for disinfection of semi-critical and critical medical devices.

Further information on cleaning and disinfection of surfaces and medical devices:

Recommendation of the Commission for Hospital Hygiene and Infection Prevention at the Robert-Koch Institute (RKI) entitled „Hygiene Requirements for Cleaning and Disinfecting Surfaces“. Available online.

Personal protection

Put on protective gloves, face mask and safety glasses prior to each disinfection. Provide adequate ventilation. Keep away from unprotected individuals. Avoid contact with eyes. Avoid breathing vapours. Keep away from sources of ignition.

Application

In case the surfaces are contaminated with organic material (e.g. blood, secretions etc.): Remove the visible contamination with a disposable cloth soaked with disinfectant and discard it. Subsequently, disinfect surface. Please note that the disinfection does not substitute cleaning of the surface.

Wipe disinfection: Apply the ready to use solution to a clean, dry single use cloth or directly onto the surface. Wipe the surface applying mild pressure (wet wiping) and keep the surface completely moist during contact time.

Spray disinfection: Spray disinfection may only be applied for inaccessible, twisted surfaces. For spray disinfection, apply the product undiluted directly onto the surface. Ensure that the surface is completely moist and keep moist during contact time.

After the contact time has elapsed: Remove residues with a clean, dry, undyed disposable cloth or allow to dry.

Special advice

Read safety datasheet and technical datasheet before use.

Do not dilute the product. Do not mix with additives or other products.

For professional use only.

Do not use after expiry date.

Electronic devices must be disconnected from their power supply before disinfection. Ensure that the disinfectant does not seep into electronic devices.



Manufacturer: PLIWA Hygiene GmbH

Pliwastraße 2
34323 Malsfeld, Germany
www.pliwa.de - info@pliwa.de
Tel.: 0049 5661 / 7317 0

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Efficacy spectrum

Efficacy (ready to use product, at room temperature)	Standard	Contact time
Bacteria		
<i>S. aureus</i> , <i>E. hirae</i> , <i>P. aeruginosa</i> , <i>E. coli</i> , MRSA (dirty conditions)	EN 13727	30 s
<i>S. aureus</i> , <i>E. hirae</i> , <i>P. aeruginosa</i> , <i>E. coli</i> (dirty conditions*)	EN 13697	5 min
<i>S. aureus</i> , <i>E. hirae</i> , <i>P. aeruginosa</i> (dirty conditions)	EN 16615	1 min
<i>S. aureus</i> , <i>E. hirae</i> , <i>P. aeruginosa</i> (dirty conditions)	Standard methods VAH*2	5 min
Mycobacteria/TB		
<i>M. terrae</i> , <i>M. avium</i> (dirty conditions)	EN 14348	1 min
Yeasts		
<i>C. albicans</i> (dirty conditions)	EN 13624	30 sec
<i>C. albicans</i> (dirty conditions)	EN 16615	1 min
<i>C. albicans</i> (dirty conditions*)	EN 13697	5 min
<i>C. albicans</i> (dirty conditions)	Standard methods VAH*2	5 min
Viruses		
Enveloped viruses		
MVA Modified Vacciniavirus Ankara (dirty conditions)	EN 14476	30 sec
BVDV (dirty conditions)		
Non-enveloped viruses		
Adenovirus Typ 5 (dirty conditions)	EN 14476	5 min
Humaner Rotavirus (clean conditions)		5 min
MNV murine Norovirus (dirty conditions)		5 min
MNV murines Norovirus (dirty conditions)	EN 16777	5 min
Adenovirus Typ 5 (dirty conditions)		5 min

*dirty conditions according to EN 13697:2015-06 Quantitative non-porous surface test for the evaluation of bactericidal and/or fungicidal activity of chemical disinfectants used in food, industrial, domestic and institutional areas.

*2 standard methods of the VAH (Association of Applied Hygiene) for surface disinfection by wiping (quantitative carrier test with mechanical action, practical conditions)

Material compatibility

Metal	Aluminium, stainless steel, copper, brass
Plastics	PSU, PVC, silicone
Rubber	EPDM, natural rubber
Advice	Upon compliance to the intended use and the indicated contact time, no material damage is to be expected with the above mentioned materials. Avoid contact of longer than 48 hours with linoleum flooring. Avoid contact with acrylates. May cause stress corrosion of acrylic glass. Test material compatibility for polyacrylates, polycarbonates as well as not mentioned materials in an inconspicuous place before use.

Composition

100 g ready to use solution contain:

33.66 g ethanol, 15.84 g 2-propanol, 0.05 g didecyldimethylammonium chloride 70%, parfum*3

Chemical/physical parameters

appearance:	clear and colourless
pH value:	5.0 – 6.0
density (20°C):	0.900 – 0.920
flash point (EN 22719)	22.75 + 0.5 °C

Storage conditions

Keep container tightly closed and in a well-ventilated place. Keep cool. Protect from sunlight. Keep away from sources of ignition. No smoking. Take precautionary measures against static discharge. Store in original container. Store in an upright position.

See safety datasheet for further advice.

Labelling according to Regulation (EC) No 1272/2008 (CLP)

For information on labeling according to Regulation (EC) No 1272/2008 (CLP) see safety datasheet and label.



UN 1987

Identification, certificates

Medical device class II a / MD 0108



Expert opinions and further information

The efficacy of the chemical composition of PHAGO'SEPT QUICK & CLEAN has been assessed by independent laboratories.

To exclude adverse effects on the skin upon unintentional contact with the product, a dermatologically survey was carried out by the company Dermatest.

For further details concerning expert opinions, informations on products and answers to specific questions contact us by e-mail (info@pliwa.de) or telephone (0049 5661 73170).

The manufacturer has a manufacturing authorisation as per §13 German medicines act as well as a GMP- and an EN ISO 13485 certificate.

Please report serious incidents related to this product to the manufacturer and the respective authorities.

*3 Please note that parfum may cause allergies. Only applicable for PHAGO'SEPT QUICK & CLEAN LF.



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Informations for order

Single package	Item No.
1 L (cone bottle with spray head)	12-411 (PHAGO'SEPT QUICK & CLEAN LF), 12-511 (PHAGO'SEPT QUICK & CLEAN)
1 L (cylinder bottle with spout* ⁴)	12-411-1 (PHAGO'SEPT QUICK & CLEAN LF), 12-511-1 (PHAGO'SEPT QUICK & CLEAN)
5 L (canister)	12-412 (PHAGO'SEPT QUICK & CLEAN LF), 12-512 (PHAGO'SEPT QUICK & CLEAN)

*⁴ The spout facilitates a more precise pouring of the product.



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Version number: 1.0

First version: 2021-04-30

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

1.1 Product identifier

Trade name	<u>PHAGO'SEPT QUICK & CLEAN</u>
Registration number (REACH)	Not relevant (mixture).
CAS number	not relevant (mixture)

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

Relevant identified uses	Surface disinfectant
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1.3 Details of the supplier of the safety data sheet

PLIWA Hygiene GmbH Pliwa-Straße 2 34323 Malsfeld-Ostheim Germany	Telephone: +49 5661 73170 Telefax: +49 5661 731710 e-mail: info@pliwa.de Website: www.pliwa.de
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e-mail (competent person)	sdb@csb-online.de
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Please do not use this e-mail address to ask for the latest safety data sheet. For this purpose contact PLIWA Hygiene GmbH

1.4 Emergency telephone number

Emergency information service	PLIWA Hygiene GmbH. +49 5661 73170 Monday-Friday 07:00 - 16:00.
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As above or nearest toxicological information centre.

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification according to Regulation (EC) No 1272/2008 (CLP)

Classification				
Section	Hazard class	Category	Hazard class and category	Hazard statement
2.6	flammable liquid	3	Flam. Liq. 3	H226
3.3	serious eye damage/eye irritation	2	Eye Irrit. 2	H319

For full text of abbreviations: see SECTION 16

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The most important adverse physicochemical, human health and environmental effects

The product is combustible and can be ignited by potential ignition sources.

2.2 Label elements

Labelling according to Regulation (EC) No 1272/2008 (CLP)

Signal word warning

Pictograms

GHS02, GHS07



Hazard statements

H226 Flammable liquid and vapour.

H319 Causes serious eye irritation.

Precautionary statements

P102 Keep out of reach of children.

P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.

P261 Avoid breathing vapours.

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.

P403+P233 Store in a well-ventilated place. Keep container tightly closed.

P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

2.3 Other hazards

Results of PBT and vPvB assessment

This mixture does not contain any substances that are assessed to be a PBT or a vPvB.

SECTION 3: Composition/information on ingredients

3.1 Substances









Not relevant (mixture).

3.2 Mixtures

Description of the mixture

Alcoholic solution.

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Hazardous ingredients					
Name of substance	Identifier	Wt%	Classification acc. to GHS	Pictograms	Notes
ethanol	CAS No 64-17-5 ECNo 200-578-6 Index No 603-002-00-5	25 – <50	Flam. Liq. 2 / H225 Eye Irrit. 2 / H319	 	GHS-HC
propan-2-ol	CAS No 67-63-0 ECNo 200-661-7 Index No 603-117-00-0	10 – <20	Flam. Liq. 2 / H225 Eye Irrit. 2 / H319 STOT SE 3 / H336	 	GHS-HC
Didecyldimethylammonium chloride	CAS No 7173-51-5 ECNo 230-525-2	0.01 – <0.1	Acute Tox. 3 / H301 Skin Corr. 1B / H314 Eye Dam. 1 / H318 Aquatic Acute 1 / H400 Aquatic Chronic 2 / H411	   	GHS-HC

Notes

GHS- Harmonised classification (the classification of the substance corresponds to the entry in the list according to
 HC: 1272/2008/EC, Annex VI)

Name of substance	Specific Conc. Limits	M-Factors	ATE	Exposure route
ethanol	Eye Irrit. 2; H319: C ≥ 50 %	-	-	-
propan-2-ol	-	-	-	inhalation: vapour
Didecyldimethylammonium chloride	-	M-factor (acute) = 10.0	238 mg/kg	oral

SECTION 4: First aid measures

4.1 Description of first aid measures

General notes

Take off immediately all contaminated clothing.

In all cases of doubt, or when symptoms persist, seek medical advice.

Following inhalation

Provide fresh air.

If breathing is irregular or stopped, immediately seek medical assistance and start first aid actions.

Following skin contact

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Rinse skin with water/shower.

Following eye contact

Rinse cautiously with water for several minutes.

Remove contact lenses, if present and easy to do. Continue rinsing.

If eye irritation persists: Get medical advice/attention.

Following ingestion

Rinse mouth. Do not induce vomiting.

Get medical advice/attention if you feel unwell.

Notes for the doctor

None.

4.2 Most important symptoms and effects, both acute and delayed

Following inhalation: Dizziness. May cause respiratory irritation.

Following skin contact: Has degreasing effect on the skin. Repeated exposure may cause skin dryness or cracking.

Following eye contact: Causes serious eye irritation.

4.3 Indication of any immediate medical attention and special treatment needed

None.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media

water spray, alcohol resistant foam, fire extinguishing powder, carbon dioxide (CO₂)

Unsuitable extinguishing media

water jet

5.2 Special hazards arising from the substance or mixture

Hazardous decomposition products: Section 10.

In case of insufficient ventilation and/or in use, may form flammable/explosive vapour-air mixture.

Solvent vapours are heavier than air and may spread along floors.

Places which are not ventilated, e.g. unventilated below ground level areas such as trenches, conduits and shafts, are particularly prone to the presence of flammable substances or mixtures.

Hazardous combustion products

nitrogen oxides (NO_x), carbon monoxide (CO), carbon dioxide (CO₂)

5.3 Advice for firefighters

In case of fire and/or explosion do not breathe fumes.

Co-ordinate firefighting measures to the fire surroundings.

Do not allow firefighting water to enter drains or water courses.

Collect contaminated firefighting water separately.

Fight fire with normal precautions from a reasonable distance.

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Special protective equipment for firefighters

self-contained breathing apparatus (EN 133)

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel

Remove persons to safety.

Ventilate affected area.

Do not breathe vapour/spray.

Avoid contact with skin and eyes.

Wearing of suitable protective equipment (including personal protective equipment referred to under Section 8 of the safety data sheet) to prevent any contamination of skin, eyes and personal clothing.

For emergency responders

Wear breathing apparatus if exposed to vapours/dust/spray/gases.

6.2 Environmental precautions

Keep away from drains, surface and ground water.

Retain contaminated washing water and dispose of it.

If substance has entered a water course or sewer, inform the responsible authority.

6.3 Methods and material for containment and cleaning up

Advice on how to clean up a spill

Collect spillage.

Absorbent material (e.g. sand, diatomaceous earth, acid binder, universal binder, sawdust, etc.).

Appropriate containment techniques

Use of adsorbent materials.

Other information relating to spills and releases

Place in appropriate containers for disposal.

Ventilate affected area.

6.4 Reference to other sections

Hazardous combustion products: see section 5.

Personal protective equipment: see section 8.

Incompatible materials: see section 10.

Disposal considerations: see section 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Measures to prevent fire as well as aerosol and dust generation

Use local and general ventilation.

Keep away from sources of ignition - No smoking.

Take precautionary measures against static discharge.

Use explosion-proof electrical/ventilating/lighting/equipment.

Use only non-sparking tools.

Specific notes/details

Places which are not ventilated, e.g. unventilated below ground level areas such as trenches, conduits and shafts, are particularly prone to the presence of flammable substances or mixtures.

Vapours are heavier than air, spread along floors and form explosive mixtures with air.

Vapours may form explosive mixtures with air.

Measures to protect the environment

Avoid release to the environment.

Advice on general occupational hygiene

Do not eat, drink and smoke in work areas.

Wash hands after use.

Preventive skin protection (barrier creams/ointments) is recommended.

Remove contaminated clothing and protective equipment before entering eating areas.

7.2 Conditions for safe storage, including any incompatibilities

Explosive atmospheres

Keep container tightly closed and in a well-ventilated place.

Use local and general ventilation.

Keep cool.

Protect from sunlight.

Flammability hazards

Keep away from sources of ignition - No smoking.

Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.

Take precautionary measures against static discharge.

Protect from sunlight.

Incompatible substances or mixtures

Incompatible materials: see section 10.

Protect against external exposure, such as

high temperatures

Consideration of other advice

Keep away from food, drink and animal feeding stuffs.

Store in a well-ventilated place. Keep container tightly closed.

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Ventilation requirements

Provision of sufficient ventilation.

Packaging compatibilities

Only packagings which are approved (e.g. acc. to ADR) may be used.

7.3 Specific end use(s)

No information available.

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational exposure limit values (Workplace Exposure Limits)									
Country	Name of agent	CAS No	Identifier	TWA [ppm]	TWA [mg/m ³]	STEL [ppm]	STEL [mg/m ³]	Notation	Source
GB	ethanol	64-17-5	WEL	1,000	1,920	-	-	-	EH40/2005
GB	propan-2-ol	67-63-0	WEL	400	999	500	1,250	-	EH40/2005

Notation

STEL short-term exposure limit: a limit value above which exposure should not occur and which is related to a 15-minute period (unless otherwise specified)

TWA time-weighted average (long-term exposure limit): measured or calculated in relation to a reference period of 8 hours time-weighted average (unless otherwise specified)

Relevant DNELs of components of the mixture						
Name of substance	CAS No	Endpoint	Threshold level	Protection goal, route of exposure	Used in	Exposure time
ethanol	64-17-5	DNEL	950 mg/m ³	human, inhalatory	worker (industry)	chronic - systemic effects
ethanol	64-17-5	DNEL	343 mg/kg bw/day	human, dermal	worker (industry)	chronic - systemic effects
propan-2-ol	67-63-0	DNEL	500 mg/m ³	human, inhalatory	worker (industry)	chronic - systemic effects
propan-2-ol	67-63-0	DNEL	888 mg/kg bw/day	human, dermal	worker (industry)	chronic - systemic effects
Didecyldimethylammonium chloride	7173-51-5	DNEL	8.6 mg/kg bw/day	human, dermal	worker (industry)	chronic - systemic effects
Didecyldimethylammonium chloride	7173-51-5	DNEL	18.2 mg/m ³	human, inhalatory	worker (industry)	chronic - systemic effects

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Relevant PNECs of components of the mixture				
Name of substance	CAS No	Endpoint	Threshold level	Environmental compartment
ethanol	64-17-5	PNEC	0.96 mg/l	freshwater
ethanol	64-17-5	PNEC	580 mg/l	sewage treatment plant (STP)
ethanol	64-17-5	PNEC	3.6 mg/kg	freshwater sediment
ethanol	64-17-5	PNEC	0.63 mg/kg	soil
ethanol	64-17-5	PNEC	2.9 mg/kg	marine sediment
propan-2-ol	67-63-0	PNEC	140.9 mg/l	water
propan-2-ol	67-63-0	PNEC	140.9 mg/l	marine water
propan-2-ol	67-63-0	PNEC	2,251 mg/l	sewage treatment plant (STP)
propan-2-ol	67-63-0	PNEC	552 mg/kg	freshwater sediment
propan-2-ol	67-63-0	PNEC	552 mg/kg	marine sediment
propan-2-ol	67-63-0	PNEC	140.9 mg/l	freshwater
propan-2-ol	67-63-0	PNEC	28 mg/kg	soil
Didecyldimethylammonium chloride	7173-51-5	PNEC	2 µg/l	freshwater
Didecyldimethylammonium chloride	7173-51-5	PNEC	0.2 µg/l	marine water
Didecyldimethylammonium chloride	7173-51-5	PNEC	0.595 mg/l	sewage treatment plant (STP)
Didecyldimethylammonium chloride	7173-51-5	PNEC	2.82 mg/kg	freshwater sediment
Didecyldimethylammonium chloride	7173-51-5	PNEC	0.28 mg/kg	marine sediment
Didecyldimethylammonium chloride	7173-51-5	PNEC	1.4 mg/kg	soil
ethanol: PNEC Oral - Predators - Secondary poisoning - 0,38 g/kg				
propan-2-ol: PNEC Oral - Predators - Secondary poisoning - 160 mg/kg				

8.2 Exposure controls

Appropriate engineering controls

General ventilation.

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Individual protection measures (personal protective equipment)

Eye/face protection

Wear eye/face protection.

Hand protection

Protective gloves		
Material	Material thickness	Breakthrough times of the glove material
FKM: fluoro-elastomer	≥ 0,4 mm	>60 minutes (permeation: level 3)
IIR: isobutene-isoprene (butyl) rubber	≥ 0,5 mm	>60 minutes (permeation: level 3)
CR: chloroprene (chlorobutadiene) rubber	≥ 0,5 mm	>60 minutes (permeation: level 3)
NBR: acrylonitrile-butadiene rubber	≥ 0,11 mm	>10 minutes (permeation: level 1)

Wear suitable gloves.

Chemical protection gloves are suitable, which are tested according to EN 374.

Check leak-tightness/impermeability prior to use.

For special purposes, it is recommended to check the resistance to chemicals of the protective gloves mentioned above together with the supplier of these gloves.

Respiratory protection

In case of inadequate ventilation wear respiratory protection.

Type: A (against organic gases and vapours with a boiling point of > 65 °C , colour code: Brown).

Environmental exposure controls

Use appropriate container to avoid environmental contamination.

Keep away from drains, surface and ground water.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Physical state	liquid
Colour	clear - colourless
Odour	like alcohol
Melting point/freezing point	<0 °C
Boiling point or initial boiling point and boiling range	~78 °C
Flammability	flammable liquid in accordance with GHS criteria
Lower and upper explosion limit	50 g/m ³ - 335 g/m ³ / 2 vol% - 15 vol%
Flash point	>21 – <24 °C
Auto-ignition temperature	>360 °C

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Decomposition temperature	not relevant
pH (value)	5–6 (20 °C)
Kinematic viscosity	not determined
Dynamic viscosity	not determined
Solubility(ies)	
Water solubility	miscible in any proportion
Partition coefficient n-octanol/water (log value)	not determined
Vapour pressure	~60 hPa at 20 °C
Density and/or relative density	
Density	0.9 – 0.92 g/cm ³ at 20 °C
Relative vapour density	information on this property is not available
Particle characteristics	not relevant (liquid)

9.2 Other information

Information with regard to physical hazard classes	there is no additional information
Other safety characteristics	
Temperature class (EU, acc. to ATEX)	T2 (maximum permissible surface temperature on the equipment: 300°C)

SECTION 10: Stability and reactivity

10.1 Reactivity

Risk of ignition.

10.2 Chemical stability

See below "Conditions to avoid".

10.3 Possibility of hazardous reactions

In case of insufficient ventilation and/or in use, may form flammable/explosive vapour-air mixture.

10.4 Conditions to avoid

Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
Take precautionary measures against static discharge.

Use explosion-proof electrical/ventilating/lighting/equipment.

Use only non-sparking tools.

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10.5 Incompatible materials

oxidisers

10.6 Hazardous decomposition products

Reasonably anticipated hazardous decomposition products produced as a result of use, storage, spill and heating are not known.

Hazardous combustion products: see section 5.

SECTION 11: Toxicological information

11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

Classification procedure

If not otherwise specified the classification is based on:

Ingredients of the mixture (additivity formula).

Classification according to GHS (1272/2008/EC, CLP)

Acute toxicity

Shall not be classified as acutely toxic.

Name of substance	CAS No	Exposure route	End-point	Value	Species	Method	Source
ethanol	64-17-5	inhalation: vapour	LC50	124.7 mg/l/4h	rat	OECD Guideline 403	ECHA
ethanol	64-17-5	oral	LD50	10,470 mg/kg	rat	OECD Guideline 401	ECHA
propan-2-ol	67-63-0	oral	LD50	5,840 mg/kg	rat	OECD Guideline 401	ECHA
propan-2-ol	67-63-0	dermal	LD50	13,100 mg/kg	rabbit	OECD Guideline 402	ECHA
Didecyldimethylammonium chloride	7173-51-5	oral	LD50	329 mg/kg	rat	OECD Guideline 401	ECHA
Didecyldimethylammonium chloride	7173-51-5	dermal	LD50	>1,000 mg/kg	rat	OECD Guideline 402	ECHA

Skin corrosion/irritation

Shall not be classified as corrosive/irritant to skin.

Serious eye damage/eye irritation

Causes serious eye irritation.

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Respiratory or skin sensitisation

Skin sensitisation

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

Respiratory sensitisation

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

Germ cell mutagenicity

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

Carcinogenicity

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

Reproductive toxicity

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

Specific target organ toxicity - single exposure

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

Specific target organ toxicity - repeated exposure

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

Aspiration hazard

Shall not be classified as presenting an aspiration hazard.

11.2 Information on other hazards

There is no additional information.

Endocrine disrupting properties

None of the ingredients are listed.

SECTION 12: Ecological information

12.1 Toxicity

Aquatic toxicity (acute)

Test data are not available for the complete mixture.

Aquatic toxicity (acute) of components of the mixture

Name of substance	CAS No	Endpoint	Value	Species	Exposure time	Method	Source
ethanol	64-17-5	LC50	5,012 mg/l	Ceriodaphnia dubia (water flea)	48 h	ASTM E729-80	ECHA
ethanol	64-17-5	LC50	14.2 g/l	fathead minnow (Pimephales promelas)	96 h	USEPA method E03-05	ECHA

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Name of substance	CAS No	Endpoint	Value	Species	Exposure time	Method	Source
ethanol	64-17-5	EC50	>10,000 mg/l	Ceriodaphnia dubia (water flea)	48 h	DIN 38412 Teil 11	ECHA
ethanol	64-17-5	EC50	12.9 ^g /l	fathead minnow (Pimephales promelas)	96 h	USEPA method E03-05	ECHA
ethanol	64-17-5	ErC50	275 mg/l	algae (Chlorella vulgaris)	72 h	OECD Guideline 201	ECHA
propan-2-ol	67-63-0	LC50	9,640 mg/l	fathead minnow (Pimephales promelas)	96 h	OECD Guideline 203	ECHA
propan-2-ol	67-63-0	LC50	>10,000 mg/l	daphnia magna	24 h	OECD Guideline 202	ECHA
Didecyl-dimethylammonium chloride	7173-51-5	EC50	0.029 mg/l	daphnia magna	48 h	OECD Guideline 202	ECHA
Didecyl-dimethylammonium chloride	7173-51-5	LC50	0.49 mg/l	zebra fish (Danio rerio)	96 h	OECD Guideline 203	ECHA
Didecyl-dimethylammonium chloride	7173-51-5	ErC50	0.062 mg/l	algae (pseudokirchneriella subcapitata)	72 h	OECD Guideline 201	ECHA

Aquatic toxicity (chronic)

Test data are not available for the complete mixture.

Aquatic toxicity (chronic) of components of the mixture

Name of substance	CAS No	Endpoint	Value	Species	Exposure time	Method	Source
ethanol	64-17-5	LC50	454 mg/l	daphnia magna	9 d	-	ECHA
ethanol	64-17-5	LC50	1,806 mg/l	Ceriodaphnia dubia (water flea)	10 d	-	ECHA
ethanol	64-17-5	NOEC	2 mg/l	Ceriodaphnia dubia (water flea)	10 d	-	ECHA

PHAGO'SEPT QUICK & CLEAN

Name of substance	CAS No	Endpoint	Value	Species	Exposure time	Method	Source
ethanol	64-17-5	NOEC	250 mg/l	zebra fish (Danio rerio)	120 h	OECD Guideline 212	ECHA
ethanol	64-17-5	growth rate (ErCx) 10%	11.5 mg/l	algae (Chlorella vulgaris)	3 d	OECD Guideline 201	ECHA
ethanol	64-17-5	growth rate (ErCx) 10%	86 mg/l	algae (Chlorella vulgaris)	4 d	OECD Guideline 201	ECHA
Didecyl-dimethylammonium chloride	7173-51-5	EC50	0.031 mg/l	daphniamagna	21 d	OECD Guideline 211	ECHA
Didecyl-dimethylammonium chloride	7173-51-5	NOEC	0.013 mg/l	algae (pseudokirchneriella subcapitata)	72 h	OECD Guideline 201	ECHA
Didecyl-dimethylammonium chloride	7173-51-5	NOEC	0.021 mg/l	daphniamagna	21 d	OECD Guideline 211	ECHA
Didecyl-dimethylammonium chloride	7173-51-5	LOEC	0.047 mg/l	daphniamagna	21 d	OECD Guideline 211	ECHA

12.2 Persistence and degradability

Degradability of components of the mixture

Name of substance	CAS No	Process	Degradation rate	Time	Method	Source
ethanol	64-17-5	oxygen depletion	~84 %	20 d	-	ECHA
propan-2-ol	67-63-0	oxygen depletion	53 %	5 d	EU method C.5	ECHA
Didecyl-dimethylammonium chloride	7173-51-5	oxygen depletion	69 %	28 d	OECD301D	ECHA

Biodegradation

The relevant substances of the mixture are readily biodegradable.

PHAGO'SEPT QUICK & CLEAN

Persistence

No data available.

12.3 Bioaccumulative potential

Test data are not available for the complete mixture.

Bioaccumulative potential of components of the mixture

Name of substance	CAS No	BCF	Log KOW
ethanol	64-17-5	-	-0.35 (pH value: 7.4, 24 °C)
Didecyldimethylammonium chloride	7173-51-5	-	2.59 (pH value: 7, 20 °C)

12.4 Mobility in soil

No data available.

12.5 Results of PBT and vPvB assessment

This mixture does not contain any substances that are assessed to be a PBT or a vPvB.

12.6 Endocrine disrupting properties

None of the ingredients are listed.

12.7 Other adverse effects

Data are not available.

Remarks

Wassergefährdungsklasse, WGK (water hazard class): 2

SECTION 13: Disposal considerations

13.1 Waste treatment methods

This material and its container must be disposed of as hazardous waste.

Sewage disposal-relevant information

Do not empty into drains.

Waste treatment of containers/packages

Completely emptied packages can be recycled.


Handle contaminated packages in the same way as the substance itself.

Remarks

Please consider the relevant national or regional provisions.

PHAGO'SEPT QUICK & CLEAN

SECTION 14: Transport information

14.1	UN number or ID number	
	ADR/RID/ADN	UN1987
	IMDG-Code	UN1987
	ICAO-TI	UN1987
14.2	UN proper shipping name	
	ADR/RID/ADN	ALCOHOLS, N.O.S.
	IMDG-Code	ALCOHOLS, N.O.S.
	ICAO-TI	Alcohols, n.o.s.
	Technical name (hazardous ingredients)	ethanol, isopropanol
14.3	Transport hazard class(es)	
	ADR/RID/ADN	3
	IMDG-Code	3
	ICAO-TI	3
14.4	Packing group	
	ADR/RID/ADN	III
	IMDG-Code	III
	ICAO-TI	III
14.5	Environmental hazards	-
14.6	Special precautions for user	-
14.7	Maritime transport in bulk according to IMO - instruments	
14.8	<u>Information for each of the UN Model Regulations</u>	
	Transport of dangerous goods by road, rail and inland waterway (ADR/RID/ADN)	
	Additional information	
	Particulars in the transport document	UN1987, ALCOHOLS, N.O.S., (ethanol, isopropanol, solution), 3, III, (D/E)
	Classification code	F1
	Danger label(s)	3
		
	Special provisions (SP)	274, 601

PHAGO'SEPT QUICK & CLEAN

Excepted quantities (EQ)	E1
Limited quantities (LQ)	5 L
Transport category (TC)	3
Tunnel restriction code (TRC)	D/E
Hazard identification No	30
Emergency Action Code	3Y

International Maritime Dangerous Goods Code (IMDG) Additional information

Marine pollutant	-
Danger label(s)	3



Special provisions (SP)	223, 274
Excepted quantities (EQ)	E1
Limited quantities (LQ)	5 L
EmS	F-E, S-D
Stowage category	A

International Civil Aviation Organization (ICAO-IATA/DGR) Additional information

Danger label(s)	3
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Special provisions (SP)	A3, A180
Excepted quantities (EQ)	E1
Limited quantities (LQ)	10 L

SECTION 15: Regulatory information

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

Relevant provisions of the European Union (EU)

Restrictions according to REACH, Annex XVII

Name	Name acc. to inventory	CAS No	Restriction
PHAGO'SEPT QUICK & CLEAN	this product meets the criteria for classification in accordance with Regulation No 1272/2008/EC	-	R3
ethanol	flammable / pyrophoric	-	R40

PHAGO'SEPT QUICK & CLEAN

Name	Name acc. to inventory	CASNo	Restriction
propan-2-ol	flammable / pyrophoric	-	R40

Legend

- R3**
1. 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,
 2. Articles not complying with paragraph 1 shall not be placed on the market.
 3. Shall not be placed on the market if they contain a colouring agent, unless required for fiscal reasons, or perfume, or both, if they:
 - can be used as fuel in decorative oil lamps for supply to the general public, and
 - present an aspiration hazard and are labelled with H304.
 4. Decorative oil lamps for supply to the general public shall not be placed on the market unless they conform to the European Standard on Decorative oil lamps (EN 14059) adopted by the European Committee for Standardisation (CEN).
 5. Without prejudice to the implementation of other Union provisions relating to the classification, labelling and packaging of substances and mixtures, suppliers shall ensure, before the placing on the market, that the following requirements are met:
 - (a) lamp oils, labelled with H304, intended for supply to the general public are visibly, legibly and indelibly marked as follows: "Keep lamps filled with this liquid out of the reach of children"; and, by 1 December 2010, "Just a sip of lamp oil – or even sucking the wick of lamps – may lead to life-threatening lung damage";
 - (b) grill lighter fluids, labelled with H304, intended for supply to the general public are legibly and indelibly marked by 1 December 2010 as follows: 'Just a sip of grill lighter fluid may lead to life threatening lung damage';
 - (c) lamps oils and grill lighters, labelled with H304, intended for supply to the general public are packaged in black opaque containers not exceeding 1 litre by 1 December 2010.;
- R40**
1. Shall not be used, as substance or as mixtures in aerosol dispensers where these aerosol dispensers are intended for supply to the general public for entertainment and decorative purposes such as the following:
 - metallic glitter intended mainly for decoration,
 - artificial snow and frost,
 - 'whoopee' cushions,
 - silly string aerosols,
 - imitation excrement,
 - horns for parties,
 - decorative flakes and foams,
 - artificial cobwebs,
 - stink bombs.
 2. Without prejudice to the application of other Community provisions on the classification, packaging and labelling of substances, suppliers shall ensure before the placing on the market that the packaging of aerosol dispensers referred to above is marked visibly, legibly and indelibly with: 'For professional users only'.
 3. By way of derogation, paragraphs 1 and 2 shall not apply to the aerosol dispensers referred to Article 8 (1a) of Council Directive 75/324/EEC (2).
 4. The aerosol dispensers referred to in paragraphs 1 and 2 shall not be placed on the market unless they conform to the requirements indicated.

List of substances subject to authorisation (REACH, Annex XIV) / SVHC - candidate list

None of the ingredients are listed.

PHAGO'SEPT QUICK & CLEAN

Seveso Directive

2012/18/EU (Seveso III)				
No	Dangerous substance/hazard categories	Qualifying quantity (tonnes) for the application of lower and upper-tier requirements		Notes
P5c	flammable liquids (cat. 2, 3)	5,000	50,000	51)

Notation

51) flammable liquids, categories 2 or 3 not covered by P5a and P5b

Regulation (EU) 2019/1148 of the European Parliament and of the Council of 20 June 2019 on the marketing and use of explosives precursors, amending Regulation (EC) No 1907/2006 and repealing Regulation (EU) No 98/2013

None of the ingredients are listed.

Regulation on substances that deplete the ozone layer (ODS)

None of the ingredients are listed.

Regulation concerning the export and import of hazardous chemicals (PIC)

Not all ingredients are listed.

Regulation on persistent organic pollutants (POP)

None of the ingredients are listed.

15.2 Chemical Safety Assessment

No Chemical Safety Assessment has been carried out for this mixture by the supplier.

Chemical safety assessments for substances in this mixture were not carried out.

SECTION 16: Other information

Abbreviations and acronyms

Abbr.	Descriptions of used abbreviations
Acute Tox.	Acute toxicity
ADN	Accord européen relatif au transport international des marchandises dangereuses par voies de navigation intérieures (European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways)
ADR	Accord européen relatif au transport international des marchandises dangereuses par route (European Agreement concerning the International Carriage of Dangerous Goods by Road)
ADR/RID/ADN	European Agreements concerning the International Carriage of Dangerous Goods by Road/Rail/Inland Waterways (ADR/RID/ADN)
Aquatic Acute	Hazardous to the aquatic environment - acute hazard
Aquatic Chronic	Hazardous to the aquatic environment - chronic hazard

PHAGO'SEPT QUICK & CLEAN

Abbr.	Descriptions of used abbreviations
ATE	Acute Toxicity Estimate
BCF	Bioconcentration factor
CAS	Chemical Abstracts Service (service that maintains the most comprehensive list of chemical substances)
CLP	Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures
DGR	Dangerous Goods Regulations (see IATA/DGR)
DNEL	Derived No-Effect Level
EC50	Effective Concentration 50 %. The EC50 corresponds to the concentration of a tested substance causing 50 % changes in response (e.g. on growth) during a specified time interval
ECNo	The EC Inventory (EINECS, ELINCS and the NLP-list) is the source for the seven-digit EC number, an identifier of substances commercially available within the EU (European Union)
EH40/2005	EH40/2005 Workplace exposure limits (http://www.nationalarchives.gov.uk/doc/open-government-licence/)
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINCS	European List of Notified Chemical Substances
EmS	Emergency Schedule
ErC50	≡ EC50: in this method, that concentration of test substance which results in a 50 % reduction in either growth (EbC50) or growth rate (ErC50) relative to the control
Eye Dam.	Seriously damaging to the eye
Eye Irrit.	Irritant to the eye
Flam. Liq.	Flammable liquid
GHS	"Globally Harmonized System of Classification and Labelling of Chemicals" developed by the United Nations
IATA	International Air Transport Association
IATA/DGR	Dangerous Goods Regulations (DGR) for the air transport (IATA)
ICAO	International Civil Aviation Organization
ICAO-TI	Technical instructions for the safe transport of dangerous goods by air
IMDG	International Maritime Dangerous Goods Code
IMDG-Code	International Maritime Dangerous Goods Code
index No	The Index number is the identification code given to the substance in Part 3 of Annex VI to Regulation (EC) No 1272/2008
LC50	Lethal Concentration 50%: the LC50 corresponds to the concentration of a tested substance causing 50 % lethality during a specified time interval
LD50	Lethal Dose 50 %: the LD50 corresponds to the dose of a tested substance causing 50 % lethality during a specified time interval
LOEC	Lowest Observed Effect Concentration

PHAGO'SEPT QUICK & CLEAN

Abbr.	Descriptions of used abbreviations
log KOW	n-Octanol/water
M-factor	Means a multiplying factor. It is applied to the concentration of a substance classified as hazardous to the aquatic environment acute category 1 or chronic category 1, and is used to derive by the summation method the classification of a mixture in which the substance is present
NLP	No-Longer Polymer
NOEC	No Observed Effect Concentration
PBT	Persistent, Bioaccumulative and Toxic
PNEC	Predicted No-Effect Concentration
ppm	Parts per million
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
RID	Règlement concernant le transport International ferroviaire des marchandises Dangereuses (Regulations concerning the International carriage of Dangerous goods by Rail)
Skin Corr.	Corrosive to skin
Skin Irrit.	Irritant to skin
STEL	Short-term exposure limit
STOT SE	Specific target organ toxicity - single exposure
SVHC	Substance of Very High Concern
TWA	Time-weighted average
vPvB	Very Persistent and very Bioaccumulative
WEL	Workplace exposure limit

Key literature references and sources for data

Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures.
Regulation (EC) No. 1907/2006 (REACH).

Transport of dangerous goods by road, rail and inland waterway (ADR/RID/ADN).

International Maritime Dangerous Goods Code (IMDG).

Dangerous Goods Regulations (DGR) for the air transport (IATA).

Classification procedure

Physical and chemical properties.

Health hazards.

Environmental hazards.

The method for classification of the mixture is based on ingredients of the mixture (additivity formula).

PHAGO'SEPT QUICK & CLEAN

List of relevant phrases (code and full text as stated in chapter 2 and 3)

Code	Text
H225	Highly flammable liquid and vapour.
H226	Flammable liquid and vapour.
H301	Toxic if swallowed.
H314	Causes severe skin burns and eye damage.
H318	Causes serious eye damage.
H319	Causes serious eye irritation.
H336	May cause drowsiness or dizziness.
H400	Very toxic to aquatic life.
H411	Toxic to aquatic life with long lasting effects.

Responsible for the safety data sheet

C.S.B. GmbH
Düsseldorfer Str. 113
47809 Krefeld, Germany

Telephone: +49 (0) 2151 - 652086 - 0
Telefax: +49 (0) 2151 - 652086 - 9
e-Mail: info@csb-online.de
Website: www.csb-online.de

Disclaimer

This information is based upon the present state of our knowledge.
This SDS has been compiled and is solely intended for this product.



**Auszug aus der EG-Konformitätserklärung
für Medizinprodukte der Klasse IIa**

*Extract of the EC-Declaration of Conformity
for Class IIa Medical Devices*

Extract of
AN 42009
Rev. 03
Stand: 2021-05
(Phago')

(nach Anhang II ohne Abschnitt (4) der EG-Richtlinie 93/42/EWG über Medizinprodukte)
(in accordance with annex II without section (4) of the Council Directive for Medical Devices 93/42/EEC)

Name des Herstellers /
Name of manufacturer
Adresse /
Address

PLIWA Hygiene GmbH
Pliwastraße 2
D-34323 Malsfeld

Hiermit erklärt der Hersteller PLIWA Hygiene GmbH in alleiniger Verantwortung, dass die folgenden Medizinprodukte allen anwendbaren Anforderungen der Richtlinie 93/42/EWG entsprechen.

The manufacturer PLIWA Hygiene GmbH hereby declares in sole responsibility, that the following medical devices correspond to all requirements of Medical Device Directive 93/42/EEC.

PLIWA® Lemon Fresh AF
PLIWA® Lemon Fresh AF ohne Parfüm

Quick & Clean S-Wipes Lemon Fresh
Quick & Clean S-Wipes ohne Parfüm

Mikroclean Plus D

Trioton rapid AF

Produktvarianten und Handelsnamen finden sich auf den folgenden Seiten dieses Dokuments.
Product variants and trade names can be found on the following pages of this document.

Klassifizierung nach Anhang IX, Regel 15: / *Classification according to annex IX, rule 15:*
Klasse IIa / *Class IIa*

MD 0108_1

Desinfektionsmittel für nicht-invasive Medizinprodukte / *Disinfectant for non-invasive medical devices*

Benannte Stelle: / *Notified Body:*

TÜV-Süd Product Service, Certification Body, Ridlerstraße 65, 80339 München

Kennnummer: / *Identification number:* 0123

EG Zertifikat gemäß Richtlinie 93/42/EWG Anhang II ohne Abschnitt (4)

EC Certificate according to Directive 93/42/EEC Annex II excluding (4)

Zertifikat-Nr. G1 003919 0002 Rev. 01, gültig vom 26.03.2020 bis 17.09.2023

Certificate No. G1 003919 0002 Rev. 01, valid from 26.03.2020 until 17.09.2023

Diese Erklärung ist gültig vom 25.05.2021 bis zum 17.09.2023 oder bis zur Ausstellung einer revidierten Konformitätserklärung nach Änderung der Produkte oder des Konformitätsbewertungsverfahrens.

This declaration is valid from 25.05.2021 until 17.09.2023 or until issuance of a revised declaration of conformity due to changes of the products or the conformity assessment procedure.

Malsfeld-Ostheim, 25.05.2021

Olivera Mautner

Verantwortliche Person nach Art. 15 MDR
*Person Responsible for Regulatory
Compliance*



Dr. Nico Funk

Qualitätsmanagementbeauftragter /
Quality Management Representative



**Auszug aus der EG-Konformitätserklärung
für Medizinprodukte der Klasse IIa**
*Extract of the EC-Declaration of Conformity
for Class IIa Medical Devices*

Extract of
AN 42009
Rev. 03
Stand: 2021-05
(Phago')

Produktvarianten und Handelsnamen: / Product variants and trade names:

Produkt / Product	Artikelnr. / Ref. no.	Gebinde / Pack size
PLIWA® Lemon Fresh AF	10-410	250 ml
	10-407	500 ml
	10-411	1 Liter
	10-411-1	1 Liter
	10-411-2	1 Liter
	10-412	5 Liter
	10-413	10 Liter
	10-419	30 Liter
	10-416	1000 Liter
Handelsnamen:		
PHAGO'SEPT QUICK & CLEAN LF	12-411	1 Liter
	12-411-1	1 Liter
	12-412	5 Liter
PHAGO'SEPT QUICK & CLEAN LF (englisches Etikett)	12-411-E	1 Liter
	12-411-1-E	1 Liter
	12-412-E	5 Liter
<hr/>		
PLIWA® Lemon Fresh AF ohne Parfüm	10-510	250 ml
	10-511	1 Liter
	10-511-1	1 Liter
	10-512	5 Liter
	10-513	10 Liter
Handelsnamen:		
PHAGO'SEPT QUICK & CLEAN	12-511	1 Liter
	12-511-1	1 Liter
	12-512	5 Liter
PHAGO'SEPT QUICK & CLEAN (englisches Etikett)	12-511-E	1 Liter
	12-511-1-E	1 Liter
	12-512-E	5 Liter
<hr/>		
Quick & Clean S-Wipes Lemon Fresh	10-452	1,5 L Nfb. + 70er Vliesrolle
	10-453	2,0 L Nfb. + 90er Vliesrolle
Handelsnamen:		
PHAGO'SEPT QUICK & CLEAN WIPES LF	12-453	2,0 L Nfb. + 90er Vliesrolle
PHAGO'SEPT QUICK & CLEAN WIPES LF (englisches Etikett)	12-453-E	2,0 L Nfb. + 90er Vliesrolle



**Auszug aus der EG-Konformitätserklärung
für Medizinprodukte der Klasse IIa**

*Extract of the EC-Declaration of Conformity
for Class IIa Medical Devices*

Extract of
AN 42009

Rev. 03
Stand: 2021-05

(Phago')

Produkt / Product	Artikelnr. / Ref. no.	Gebinde / Pack size
Quick & Clean S-Wipes ohne Parfüm	10-552	1,5 L Nfb. + 70er Vliesrolle
	10-553	2,0 L Nfb. + 90er Vliesrolle
Handelsnamen:		
PHAGO'SEPT QUICK & CLEAN WIPES	12-553	2,0 L Nfb. + 90er Vliesrolle
PHAGO'SEPT QUICK & CLEAN WIPES (englisches Etikett)	12-553-E	2,0 L Nfb. + 90er Vliesrolle
<hr/>		
Mikroclean Plus D	10-0011	1 Liter
	10-0012	2 Liter
	10-0013	5 Liter
	10-0014	10 Liter
Handelsnamen:		
PHAGO'DENT ASPI	12-011	1 Liter
	12-011-1	1 Liter
	12-013	5 Liter
PHAGO'DENT ASPI (englisches Etikett)	12-011-E	1 Liter
	12-011-1-E	1 Liter
	12-013-E	5 Liter
<hr/>		
Trioton rapid AF	10-0071	1 Liter
	10-0071-1	1 Liter
	10-0072	2 Liter
	10-0074	5 Liter
	10-0075	10 Liter
	10-0076	30 Liter
Handelsnamen:		
PHAGO'SURF AF	12-0071	1 Liter
	12-0071-1	1 Liter
	12-0074	5 Liter
PHAGO'SURF AF (englisches Etikett)	12-0071-E	1 Liter
	12-0071-1-E	1 Liter
	12-0074-E	5 Liter



Zertifikat

Nr. Q5 003919 0004 Rev. 00

Zertifikatsinhaber: **PLIWA Hygiene GmbH**
Pliwa-Straße 2
34323 Malsfeld-Ostheim
DEUTSCHLAND

Betriebsstätte(n): PLIWA Hygiene GmbH
Pliwa-Straße 2, 34323 Malsfeld-Ostheim, DEUTSCHLAND

**Zertifizierungs-
zeichen:**



Geltungsbereich: **Design und Entwicklung, Produktion und Vertrieb
von Desinfektionsmitteln für Medizinprodukte**

**Angewandte
Norm(en):** EN ISO 13485:2016
Medizinprodukte - Qualitätsmanagementsysteme -
Anforderungen für regulatorische Zwecke
(ISO 13485:2016)
DIN EN ISO 13485:2016

Die Zertifizierstelle von TÜV SÜD Product Service GmbH bescheinigt, dass das oben genannte Unternehmen ein Qualitätsmanagementsystem eingeführt hat und anwendet, das den Anforderungen der genannten Norm(en) entspricht. Umseitige Hinweise sind zu beachten.

Bericht Nr.: 713158898

Gültig ab: 2020-03-26

Gültig bis: 2023-03-25

Datum, 2020-03-26

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD
ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ CERTIFICADO ◆ CERTIFIKAT ◆ CERTIFICADO ◆ CERTIFICAT



Certificate

No. Q5 003919 0004 Rev. 00

Holder of Certificate: **PLIWA Hygiene GmbH**
Pliwa-Straße 2
34323 Malsfeld-Ostheim
GERMANY

Facility(ies): PLIWA Hygiene GmbH
Pliwa-Straße 2, 34323 Malsfeld-Ostheim, GERMANY

Certification Mark:



Scope of Certificate: **Design and Development, Production and Distribution of Disinfectants for Medical Devices**

Applied Standard(s): EN ISO 13485:2016
Medical devices - Quality management systems -
Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: 713158898

Valid from: 2020-03-26

Valid until: 2023-03-25

Date, 2020-03-26

Christoph Dicks
Head of Certification/Notified Body



REGISTRUL DE STAT AL DISPOZITIVELOR MEDICALE

Tip	Denumire	Введите текст для поиска...									
Nr	Denumire	Den.comerc.	Model	Nr. catalog	Tara	Producatorul	Reprezentant	Ordin	Data	Cod vamal	
I.2. Declarația de conformitate CE	Declarație de conformitate CE						pliwa				
I.3. Certificatul CE	Certificat CE										
DM000323750	DEZINFECTANT PENTRU SUPRAFEȚE ȘI DISPOZITIVE MEDICALE	PLIWA® LEMON FRESH AF	PHAGO` SEPT QUICK & CLEAN, 1 L	12-511-1	Germania	PLIWA HYGIENE GMBH	SOFRAGRUP S.R.L.	Rg04-000285	22-11-2021		
DM000323751	DEZINFECTANT PENTRU SUPRAFEȚE ȘI DISPOZITIVE MEDICALE	PLIWA® LEMON FRESH AF	PHAGO` SEPT QUICK & CLEAN, 5 L	12-512	Germania	PLIWA HYGIENE GMBH	SOFRAGRUP S.R.L.	Rg04-000285	22-11-2021		
DM000323749	DEZINFECTANT PENTRU SUPRAFEȚE ȘI DISPOZITIVE MEDICALE	PLIWA® LEMON FRESH AF	PHAGO` SEPT QUICK & CLEAN, 1 L	12-511	Germania	PLIWA HYGIENE GMBH	SOFRAGRUP S.R.L.	Rg04-000285	22-11-2021		

[Содержит\(\[Producatorul\]\), "pliwa"\).](#)
[Очистить](#)