

THICK WIPES IMPREGNATED WITH A CLEANING AND DISINFECTING LOTION



PHAGO'WIPES MD



- Medical device
- Large wipes
- Great anti microbial spectrum of activity

USE

PHAGO'WIPES MD is a medical device.
Those wipes are designed to clean and disinfect non-invasive and non-submersible medical devices (small medical and dental equipment).

COMPOSITION

Active disinfectant:
Ethanol (N° CAS : 64-17-5)
Alkyldimethylbenzylammonium chloride (n° CAS 68424-85-1)
Propan-2-ol (n° CAS 67-63-0)

CHARACTERISTICS

Nonwoven wipes
Wipes color: white
Fragrance: eucalyptus

INSTRUCTIONS OF USE

Single use wipes; ready to use.

- When using for the first time: open the flap, remove the tamper-evident seal, thread the first wipe through the hole, then close the flap.
- Clean the equipment with the wipe.
- Contact time between 30 seconds to 15 minutes depending on the requested antimicrobial activity.
- Allow the surface to dry.
- Do not rinse.
- Close the flap after each use to prevent the wipes from drying out.

COMPATIBILITY

Always test on a small surface before using it.

PRESERVATION

Shelf life : 30 months after production.
we advice to use it within 3 months after the opening of the flow pack. Keep the product according to the producer recommendations.

MICROBIOLOGICAL ACTIVITIES

SPECTRUM OF ACTIVITY		CONTACT TIME
Bactericidal	EN 13727* - EN 14561* EN 14561 : MRSA	5 minutes
Fungicidal	EN 14562 : <i>Aspergillus fumigatus</i>	5 minutes
Yeasticidal	EN 13624 - EN 14562 : <i>Candida albicans</i>	5 minutes
Tuberculocidal	EN 14348 - EN 14563 : <i>Mycobacterium terrae</i>	15 minutes
Virucidal	EN 14476* : HBV - HCV - Adenovirus - Coronavirus - Norovirus - VRS - H1N1 - HSV1 EN 14476 : Polyomavirus EN 14476 : Rotavirus	1 minute 15 minutes pour le Rotavirus
ADDITIONNAL TESTS		
Bactericidal	EN 1276 EN 13697	30 secondes 5 minutes
Yeasticidal	EN 16650* - EN 13697 : <i>Candida albicans</i>	5 minutes

*In dirty conditions

PRECAUTIONS FOR USE

Product for professional use.
safety data sheet is available on www.quickfds.com
Dangerous.

Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

REFERENCE

P60013 Flowpack of 100 white wipes (dim: 13cm x 20cm)
Palet of 50 box of 12 flowpacks

PHAGO'WIPES MD

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830

Issue date: 09/03/2016

Revision date: 25/11/2020

Supersedes version of: 09/11/2018

Version: 2.2

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

1.1. Product identifier

Product form : Mixture
Product name : PHAGO'WIPES MD
Product code : Formula 998871
Type of product : Detergent, Medical devices

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

1.2.1. Relevant identified uses

Use of the substance/mixture : Disinfection and cleaning of non- invasive medical devices. For more information, see the label.

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

LABORATOIRES SARBEC
10 rue du Vertuquet
59960 NEUVILLE-EN-FERRAIN - FRANCE
T 03.20.69.26.26 - F 03.20.69.26.69
msds@sarbec.com - www.felt.com

1.4. Emergency telephone number

Country	Organisation/Company	Address	Emergency number	Comment
France	ORFILA		+33 1 45 42 59 59	

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

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

Hazardous to the aquatic environment — H412
Chronic Hazard, Category 3

Full text of H statements : see section 16

Adverse physicochemical, human health and environmental effects

Harmful to aquatic life with long lasting effects.

2.2. Label elements

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

Signal word (CLP) : -
Hazard statements (CLP) : H412 - Harmful to aquatic life with long lasting effects.
Precautionary statements (CLP) : P273 - Avoid release to the environment.
P501 - Dispose of contents/container to an approved waste disposal plant.
P102 - Keep out of reach of children.
P280 - Wear protective gloves.
P305 - IF IN EYES:
P351 - Rinse cautiously with water for several minutes.

2.3. Other hazards

No additional information available

SECTION 3: Composition/information on ingredients

3.1. Substances

Not applicable

3.2. Mixtures

PHAGO'WIPES DM

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
ethanol; ethyl alcohol	(CAS-No.) 64-17-5 (EC-No.) 200-578-6 (EC Index-No.) 603-002-00-5 (REACH-no) 01-2119457610-43	2.5 - 5	Flam. Liq. 2, H225 Eye Irrit. 2, H319
Quaternary ammonium compounds, benzyl-C12-16-alkyldimethyl, chlorides	(CAS-No.) 68424-85-1 (EC-No.) 270-325-2 (REACH-no) 01-2119970550-39	0,1 – 1	Acute Tox. 4 (Oral), H302 Skin Corr. 1B, H314 Eye Dam. 1, H318 Aquatic Acute 1, H400 Aquatic Chronic 1, H410
propan-2-ol; isopropyl alcohol; isopropanol	(CAS-No.) 67-63-0 (EC-No.) 200-661-7 (EC Index-No.) 603-117-00-0 (REACH-no) 01-2119457558-25	0,1 – 1	Flam. Liq. 2, H225 Eye Irrit. 2, H319 STOT SE 3, H336

Full text of H-statements: see section 16

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures after eye contact : Rinse eyes with water as a precaution.
First-aid measures after ingestion : Call a poison center or a doctor if you feel unwell.

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

No additional information available

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

Treat symptomatically.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media : Water spray. Dry powder. Foam. Carbon dioxide.

5.2. Special hazards arising from the substance or mixture

Hazardous decomposition products in case of fire : Toxic fumes may be released.

5.3. Advice for firefighters

Protection during firefighting : Do not attempt to take action without suitable protective equipment. Self-contained breathing apparatus. Complete protective clothing.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

Emergency procedures : Ventilate spillage area.

6.1.2. For emergency responders

Protective equipment : Do not attempt to take action without suitable protective equipment. For further information refer to section 8: "Exposure controls/personal protection".

6.2. Environmental precautions

Avoid release to the environment.

6.3. Methods and material for containment and cleaning up

Other information : Dispose of materials or solid residues at an authorized site.

6.4. Reference to other sections

For further information refer to section 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : Ensure good ventilation of the work station. Wear gloves.
Hygiene measures : Do not eat, drink or smoke when using this product.

7.2. Conditions for safe storage, including any incompatibilities

Storage temperature : 5 – 35 °C
Special rules on packaging : Package of wipes.

PHAGO'WIPES DM

Safety Data Sheet

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7.3. Specific end use(s)

No additional information available

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

ethanol; ethyl alcohol (64-17-5)		
France	Local name	Alcool éthylique
France	VME (mg/m ³)	1900 mg/m ³
France	VME (ppm)	1000 ppm
France	VLE (mg/m ³)	9500 mg/m ³
France	VLE (ppm)	5000 ppm
France	Note (FR)	Valeurs recommandées/admises
United Kingdom	Local name	Ethanol
United Kingdom	WEL TWA (mg/m ³)	1920 mg/m ³
United Kingdom	WEL TWA (ppm)	1000 ppm

propan-2-ol; isopropyl alcohol; isopropanol (67-63-0)		
France	Local name	Alcool isopropylique
France	VLE (mg/m ³)	980 mg/m ³
France	VLE (ppm)	400 ppm
France	Note (FR)	Valeurs recommandées/admises
United Kingdom	Local name	Propan-2-ol
United Kingdom	WEL TWA (mg/m ³)	999 mg/m ³
United Kingdom	WEL TWA (ppm)	400 ppm
United Kingdom	WEL STEL (mg/m ³)	1250 mg/m ³
United Kingdom	WEL STEL (ppm)	500 ppm

8.2. Exposure controls

Appropriate engineering controls:

Ensure good ventilation of the work station.

Hand protection:

Protective gloves

Environmental exposure controls:

Avoid release to the environment.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Liquid
Appearance	: White wipes. Impregnated wipes.
Colour	: Colourless liquid.
Odour	: characteristic.
Odour threshold	: No data available
pH	: 5 – 7
Relative evaporation rate (butylacetate=1)	: No data available
Melting point	: Not applicable
Freezing point	: No data available
Boiling point	: No data available
Flash point	: > 60 °C
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
Flammability (solid, gas)	: Not applicable
Vapour pressure	: No data available
Relative vapour density at 20 °C	: No data available
Relative density	: No data available
Solubility	: dilutable in water.
Partition coefficient n-octanol/water (Log Pow)	: No data available

PHAGO'WIPES DM

Safety Data Sheet

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Viscosity, kinematic	: No data available
Viscosity, dynamic	: No data available
Explosive properties	: No data available
Oxidising properties	: No data available
Explosive limits	: No data available

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

The product is non-reactive under normal conditions of use, storage and transport.

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use.

10.4. Conditions to avoid

None under recommended storage and handling conditions (see section 7).

10.5. Incompatible materials

No additional information available

10.6. Hazardous decomposition products

Under normal conditions of storage and use, hazardous decomposition products should not be produced.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity (oral)	: Not classified
Acute toxicity (dermal)	: Not classified
Acute toxicity (inhalation)	: Not classified
Skin corrosion/irritation	: Not classified pH: 5 – 7
Serious eye damage/irritation	: Not classified pH: 5 – 7
Respiratory or skin sensitisation	: Not classified
Germ cell mutagenicity	: Not classified
Carcinogenicity	: Not classified
Reproductive toxicity	: Not classified
STOT-single exposure	: Not classified
STOT-repeated exposure	: Not classified
Aspiration hazard	: Not classified

SECTION 12: Ecological information

12.1. Toxicity

Ecology - general	: Harmful to aquatic life with long lasting effects.
Hazardous to the aquatic environment, short-term (acute)	: Not classified
Hazardous to the aquatic environment, long-term (chronic)	: Harmful to aquatic life with long lasting effects.

12.2. Persistence and degradability

No additional information available

12.3. Bioaccumulative potential

No additional information available

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Safety Data Sheet

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12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

No additional information available

12.6. Other adverse effects

No additional information available

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste treatment methods : Dispose of contents/container in accordance with licensed collector's sorting instructions.

SECTION 14: Transport information

In accordance with ADR / RID / IMDG / IATA / ADN

ADR	IMDG	IATA	ADN	RID
14.1. UN number				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
14.2. UN proper shipping name				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
14.3. Transport hazard class(es)				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
14.4. Packing group				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
14.5. Environmental hazards				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
No supplementary information available				

14.6. Special precautions for user

- Overland transport

Not applicable

- Transport by sea

Not applicable

- Air transport

Not applicable

- Inland waterway transport

Not applicable

- Rail transport

Not applicable

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

Not applicable

SECTION 15: Regulatory information

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

15.1.1. EU-Regulations

Contains no REACH substances with Annex XVII restrictions

Contains no substance on the REACH candidate list

Contains no REACH Annex XIV substances

Detergent Regulation: Labelling of contents:

Component	%
non-ionic surfactants	<5%
disinfectants	
perfumes	

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15.1.2. National regulations

No additional information available

15.2. Chemical safety assessment

No chemical safety assessment has been carried out

SECTION 16: Other information

Indication of changes:

Section	Changed item	Change	Comments
	SDS Ref.	Modified	
1.1	Name	Modified	
1.1	Product code	Modified	
3	Composition/information on ingredients	Modified	
9.1	Flash point	Added	

Full text of H- and EUH-statements:

Acute Tox. 4 (Oral)	Acute toxicity (oral), Category 4
Aquatic Acute 1	Hazardous to the aquatic environment — Acute Hazard, Category 1
Aquatic Chronic 1	Hazardous to the aquatic environment — Chronic Hazard, Category 1
Aquatic Chronic 3	Hazardous to the aquatic environment — Chronic Hazard, Category 3
Eye Dam. 1	Serious eye damage/eye irritation, Category 1
Eye Irrit. 2	Serious eye damage/eye irritation, Category 2
Flam. Liq. 2	Flammable liquids, Category 2
Skin Corr. 1B	Skin corrosion/irritation, Category 1, Sub-Category 1B
STOT SE 3	Specific target organ toxicity — Single exposure, Category 3, Narcosis
H225	Highly flammable liquid and vapour.
H302	Harmful 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.
H410	Very toxic to aquatic life with long lasting effects.
H412	Harmful to aquatic life with long lasting effects.

FDS UE (Annexe II REACH) - Cerello

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ATTESTATION CE / EC CERTIFICATE

Approbation du Système Complet d'assurance Qualité / Approval of full Quality Assurance System

ANNEXE II excluant le point 4 Directive 93/42/CEE relative aux dispositifs médicaux

ANNEX II excluding section 4 Directive 93/42/EEC concerning medical devices

Pour les dispositifs de classe III, un certificat CE de conception est requis

For class III devices, a EC design certificate is required

Fabricant / Manufacturer

CHRISTEYNS FRANCE

31 Rue de la Maladrie PI de la Vertonne

44120 VERTOU FRANCE

Catégorie du(des) dispositif(s) / Device(s) category

Produits désinfectants de dispositifs médicaux invasifs.

Disinfectants products for invasive medical devices.

Voir détails sur addendum / See attachment for additional information

GMED atteste qu'à l'examen des résultats figurant dans le rapport référencé P600289, le système d'assurance qualité - pour la conception, la production et le contrôle final - des dispositifs médicaux énumérés ci-dessus est conforme aux exigences de l'annexe II excluant le point 4 de la Directive 93/42/CEE.

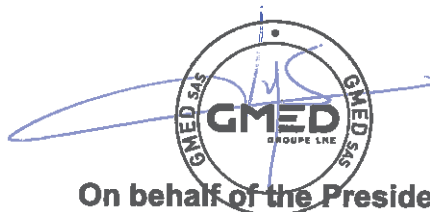
GMED certifies that, on the basis of the results contained in the file referenced P600289, the quality system - for design, manufacturing, and final inspection - of medical devices listed here above complies with the requirements of the Directive 93/42/EEC, annex II excluding section 4

La validité du présent certificat est soumise à une vérification périodique ou imprévue

The validity of the certificate is subject to periodic or unexpected verification

Début de validité / Effective date : January 23rd, 2020 (included)

Valable jusqu'au / Expiry date : July 24th, 2022 (included)



On behalf of the President

Béatrice LYS

Technical Director

GMED certifie que le système de management de la qualité développé par
GMED certifies that the quality management system developed by

CHRISTEYNS FRANCE
31 Rue de la Maladrie Pl de la Vertonne
44120 VERTOU FRANCE

pour les activités
for the activities

Conception, production, vente et distribution de désinfectants de dispositifs médicaux invasifs.
Vente et distribution de système de filtration de l'eau pour le rinçage final des endoscopes.

Conception, production, sale and distribution of disinfectants for invasive medical devices.
Sale and distribution of water filtration system for final rinsing of endoscopes.

réalisées sur le(s) site(s) de
performed on the location(s) of

CHRISTEYNS FRANCE
31 rue de la Maladrie Pl de la Vertonne 44120 Vertou FRA
CHRISTEYNS FOOD HYGIENE
24580 Rouffignac Saint-Cernin-de-Reilhac FRA

est conforme aux exigences des normes internationales
complies with the requirements of the international standards

ISO 13485 : 2016 - NF EN ISO 13485 : 2016

Début de validité / Effective date : January 23rd, 2020 (included)

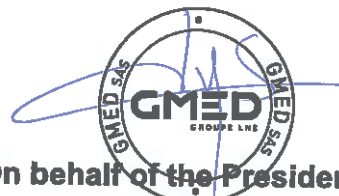
Valable jusqu'au / Expiry date : July 24th, 2022 (included)

Etabli le / Issued on : January 23rd, 2020



**CERTIFICATION
DE SYSTEMES
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On behalf of the President
Béatrice LYS
Technical Director

GMED N° 36451-0

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