



Phago'wash LD

**Detergent liquide alcalin pour machines automatées
de désinfection d'instruments médicaux et
endoscopes**



Propriétés

- ✓ Detergent n'espumant
- ✓ action puissante sur la saleté organique
- ✓ Sans NTA, EDTA, et phosphates
- ✓ Contient des agents de séquestration biodégradables

Packaging

Presentation	Code	Number of units/pack
5L canister	70443	2 units
10L canister	70444	-
20L canister	70445	-
200L drum	70447	-





Phago'wash LD

Domeniul de utilizare

- ✓ Phago'wash LD este un detergent lichid pentru curățarea manuală a instrumentelor, endoscoapelor și echipamentelor de laborator.
- ✓ Phago'wash LD este utilizat cu dezinfectoare automate.
- ✓ Phago'wash LD este un detergent care poate fi folosit, după clătire cu apă de calitate, pe suprafețele care vin în contact cu produsele alimentare.

Componenta

- ✓ Non-ionic surfactanti.
- ✓ Agenti surfactanti . Detergent alcalin:
- ✓ triethanolamine. Fara, NTA, EDTA, or
- ✓ fosfati.

Proprietati organoleptice-

Aspect : lichid galben.

- ✓ pH (pur) : 10,0 – 11,0.
- ✓ Densitate(20°C) (g/ml) : 1,057 +/- 0,005.

Instructiuni

- ✓ Dilutie : de la 2 la 8 mL la 10 litri de apa. se
- ✓ utilizeaza in asociere cu **PHAGO'WASH RINSE** –neutralizator.
- ✓ Se clateste cu apa in abundenta.

Recomandari

- ✓ Nu se amesteca cu alte produse
- ✓ Compatibil cu suprafețele sensibile la mediul bazic

Precautiuni

- ✓ Fisa de securitate accesibila : www.quickfds.com





PHAGO'WASH RINSE

Lichid de clătire (neutralizant)
pentru dispozitive medicale
și echipamente de laborator



Beneficii

- ✓ Îmbunătățește performanța de uscare și nu lasă urme
- ✓ Reduce sau elimină necesitatea lubrifierii
- ✓ Nespumant

Packaging

Presentation	Code No.	Number of units/pack
5-litre jerry can	70033	2 units
10-litre jerry can	70034	1 unit





PHAGO'WASH RINSE

Aplicarea

- ✓ PHAGO'WASH RINSE este un lichid acid de clătire pentru curățarea instrumentelor de laborator și a altor echipamente dintr-o mașină de dezinfectare a instrumentelor.

Contine

- ✓ Non-ionic surfactant
- ✓ Organic acid.

Proprietati Fizico-chimici

- ✓ Aspect: lichid transparent
- ✓ Incolor
- ✓ Miros caracteristic
- ✓ pH (nediluat) at 20°C: 2.10 to 2.60
- ✓ Densitatea at 20°C (g/ml): 1.025 ± 0.005

Utilizarea

- ✓ Diluare automată într-o mașină de dezinfectat instrument: 0,3 până la 1 mL / litru ca clătire finală (etapa de dezinfecție termică).

Recomandari

- ✓ Se folosește împreună cu PHAGO'WASH LD
- ✓ Nu se amesteca cu alte substanțe.
- ✓ Nu utilizați pentru a curăța instrumentele care conțin anumite materiale sintetice de tip polietersulfonă (tip PES)
- ✓ Citiți manualul de instrucțiuni pentru echipamentul tratat, pentru a verifica ce spune despre compatibilitate.
- ✓ Efectuați un test anterior înainte de a trata dispozitivele medicale sensibile cu acizi organici.

Precauțiuni

- ✓ Fisa de securitate accesibilă pe:
www.quickfds.com



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

1.1. Product identifier

Product form : Mixture
Product name : PHAGO'WASH LD
Product code : PHA065_F170
Type of product : Detergent
Product group : Mixture

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

1.2.1. Relevant identified uses

Main use category : Professional use
Description/Application : Liquid detergent for manual use, use in ultrasonic washers and washers disinfectors for endoscopes and other instruments.

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

CHRISTEYNS France - Division Santé
31. rue de la Maladrie
44120 VERTOU - FRANCE
T 02 40 80 27 27 - F 02 40 03 09 73
health-security@christeyns.fr - www.phagogene.fr

1.4. Emergency telephone number

Country	Organisation/Company	Address	Emergency number	Comment
France	INRS		+33 1 45 42 59 59	
United Kingdom	National Poisons Information Service Medical Toxicology Unit		0870 243 2241	

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

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

Corrosive to metals, Category 1 H290
Serious eye damage/eye irritation, Category 1 H318

Full text of hazard classes and H-statements : see section 16

Adverse physicochemical, human health and environmental effects

No additional information available

2.2. Label elements

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

Hazard pictograms (CLP) :



GHS05

CLP Signal word : Danger
Hazardous ingredients : (L+)Lactic acid; 2-ethylhexanol ethoxylated; D-Glucopyranose, oligomeric, decyl octyl glycosides
Hazard statements (CLP) : H290 - May be corrosive to metals
H318 - Causes serious eye damage
Precautionary statements (CLP) : P234 - Keep only in original container
P280 - Wear eye protection
P305+P351+P338+P310 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a doctor

2.3. Other hazards

No additional information available

PHAGO'WASH LD

Safety Data Sheet

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

SECTION 3: Composition/information on ingredients

3.1. Substances

Not applicable

3.2. Mixtures

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Sodium cumenesulfonate	(CAS-no) 15763-76-5 (Einecs nr) 239-854-6 (REACH-no) 01-2119489411-37	< 5	Eye Irrit. 2, H319
(L+)Lactic acid	(CAS-no) 79-33-4 (Einecs nr) 201-196-2 (REACH-no) 01-2119474164-39	< 3	Skin Irrit. 2, H315 Eye Dam. 1, H318
2-ethylhexanol ethoxylated	(CAS-no) 26468-86-0	< 3	Acute Tox. 4 (Oral), H302 Skin Irrit. 2, H315 Eye Dam. 1, H318
D-Glucopyranose, oligomeric, decyl octyl glycosides	(CAS-no) 54549-24-5 (Einecs nr) / (EG annex nr) / (REACH-no) 01-2119492545-29	< 3	Eye Dam. 1, H318

Full text of H-statements: see section 16

SECTION 4: First aid measures

4.1. Description of first aid measures

General advice : In case of doubt or persistent symptoms, consult always a physician. For symptom description, see item 11.

Inhalation : In case of malaise, seek medical advice.

Skin contact : Take off immediately all contaminated clothing. Wash off immediately with plenty of water.

Eye contact : Rinse immediately and plentifully with water and take medical advice.

Ingestion : If swallowed, seek medical advice immediately and show this container or label.

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

Acute effects inhalation : No data available.

Acute effects skin : No data available.

Acute effects eyes : Causes serious eye damage.

Acute effects oral route : No data available.

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

No additional information available

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media : The product itself does not burn. Foam, powder, carbon dioxide (CO₂), water spray.

5.2. Special hazards arising from the substance or mixture

No additional information available

5.3. Advice for firefighters

Protection during firefighting : Use a self-contained breathing apparatus and also a protective suit.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

Protective equipment : Concerning personal protective equipment to use, see section 8.

6.1.2. For emergency responders

No additional information available

6.2. Environmental precautions

Prevent liquid from entering sewers, watercourses, underground or low areas.

6.3. Methods and material for containment and cleaning up

Methods for cleaning up : Rinse with water.

6.4. Reference to other sections

PHAGO'WASH LD

Safety Data Sheet

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

No additional information available

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : Avoid contact with the skin and the eyes. Shower, eyes shower and water point in proximity.
Hygiene measures : Always wash hands after handling the product.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Store in original container.
Storage temperature : 5 - 40 °C
Material(s) to avoid : Not determined.

7.3. Specific end use(s)

No additional information available

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

D-Glucopyranose, oligomeric, decyl octyl glycosides (54549-24-5)	
DNEL/DMEL (Workers)	
Long-term - systemic effects, dermal	595000 mg/kg bodyweight/day
Long-term - systemic effects, inhalation	420 mg/m³
DNEL/DMEL (General population)	
Long-term - systemic effects, oral	35.7 mg/kg bodyweight/day
Long-term - systemic effects, inhalation	124 mg/m³
Long-term - systemic effects, dermal	357000 mg/kg bodyweight/day
PNEC (Water)	
PNEC aqua (freshwater)	0.176 mg/l
PNEC aqua (marine water)	0.018 mg/l
PNEC (Sediment)	
PNEC sediment (freshwater)	0.722 mg/kg dwt
PNEC sediment (marine water)	0.072 mg/kg dwt
PNEC (Soil)	
PNEC soil	0.654 mg/kg dwt

8.2. Exposure controls

Hand protection:

not required

Eye protection:

safety goggles (EN 166)

Protective equipment:

No special required clothing

Respiratory protection:

Not required

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state : Liquid
Physical state/form : Liquid.
Colour : Yellow.
Odour : Slight.
Odour threshold : No data available
pH : 10.5
Relative evaporation rate (butylacetate=1) : No data available
Melting point/range : No data available
Freezing point : No data available
Boiling point/Boiling range : No data available
Flash point : Not applicable

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

Autoignition temperature	: No data available
Decomposition temperature	: No data available
Flammability (solid, gas)	: No data available
Vapour pressure	: No data available
Relative vapour density at 20 °C	: No data available
Relative density	: 1.059
Solubility	: Water: 100% (20°C)
Log Pow	: No data available
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

No additional information available

10.2. Chemical stability

Stable in use and storage conditions as recommended in item 7.

10.3. Possibility of hazardous reactions

No additional information available

10.4. Conditions to avoid

Temperatures below 0°C. High temperatures.

10.5. Incompatible materials

Do not mix with other products.

10.6. Hazardous decomposition products

Hazardous decomposition products may be released during prolonged heating like smokes, carbon monoxide and dioxide.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity : Not classified

(L+)Lactic acid (79-33-4)	
LD50 oral rat	3543 mg/kg
LD50 dermal rabbit	> 2000 mg/kg
LC50 inhalation rat (mg/l)	> 7.94 mg/l/4h

Skin corrosion/irritation	: Not classified pH: 10.5
Serious eye damage/irritation	: Causes serious eye damage. pH: 10.5
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 : Not classified according 1272/2008/CE.

(L+)Lactic acid (79-33-4)	
LC50 fish 1	130 mg/l

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

(L+)Lactic acid (79-33-4)	
EC50 Daphnia 1	130 mg/l
ErC50 (algae)	2800 mg/l
NOEC (acute)	1900 mg/l
D-Glucopyranose, oligomeric, decyl octyl glycosides (54549-24-5)	
LC50 fish 1	> 100 mg/l
EC50 Daphnia 1	> 100 mg/l

12.2. Persistence and degradability

PHAGO'WASH LD	
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.
(L+)Lactic acid (79-33-4)	
Persistence and degradability	Readily biodegradable.
D-Glucopyranose, oligomeric, decyl octyl glycosides (54549-24-5)	
Persistence and degradability	Readily biodegradable.
Biodegradation	> 70 %

12.3. Bioaccumulative potential

(L+)Lactic acid (79-33-4)	
Log Pow	-0.62
Bioaccumulative potential	not bioaccumulative.

12.4. Mobility in soil

(L+)Lactic acid (79-33-4)	
Ecology - soil	Small adsorption.

12.5. Results of PBT and vPvB assessment

Component	
Sodium cumenesulfonate (15763-76-5)	This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII
(L+)Lactic acid (79-33-4)	This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII
D-Glucopyranose, oligomeric, decyl octyl glycosides (54549-24-5)	This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII

12.6. Other adverse effects

No additional information available

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste treatment methods	: Dispose of this material and its container at hazardous or special waste collection point.
Waste / unused products	: Avoid undiluted product to come into sewer or superficial water.
European List of Waste (LoW) code	: 20 01 29* - detergents containing dangerous substances

SECTION 14: Transport information

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

14.1. UN number

UN-No. (ADR)	: Not applicable
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14.2. UN proper shipping name

Proper shipping name	: Not applicable
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14.3. Transport hazard class(es)

ADR

Transport hazard class(es) (ADR)	: Not applicable
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14.4. Packing group

Packing group (ADR)	: Not applicable
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14.5. Environmental hazards

PHAGO'WASH LD

Safety Data Sheet

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

Dangerous for the environment : No
Other information : No supplementary information available

14.6. Special precautions for user

- Overland transport

No data available

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

CESIO recommendations : 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.

Other information, restriction and prohibition regulations : Not affected by the conditions of restriction _ ANNEXE XVII.

Detergent Regulation : Labelling of contents:

Component	%
Non-ionic surfactants	<5%

15.1.2. National regulations

No additional information available

15.2. Chemical safety assessment

No additional information available

SECTION 16: Other information

Indication of changes:

Section	Changed item	Change	Comments
2		Modified	
3		Modified	
8.2		Modified	
9.1		Modified	
12.		Modified	
15.1		Modified	
16		Modified	

Other information : It is recommended to pass the information of this safety data sheet, eventually in an appropriated form, to the users. Such information is actually to be best of our knowledge and believes accurate as reliable. This information relates to the specific material designated and may not be valid in combination with other product(s). EC Regulation 1272/2008 and its amendments.

Full text of H- and EUH-statements:

Acute Tox. 4 (Oral)	Acute toxicity (oral), Category 4
Eye Dam. 1	Serious eye damage/eye irritation, Category 1
Eye Irrit. 2	Serious eye damage/eye irritation, Category 2
Met. Corr. 1	Corrosive to metals, Category 1
Skin Irrit. 2	Skin corrosion/irritation, Category 2
H290	May be corrosive to metals
H302	Harmful if swallowed
H315	Causes skin irritation
H318	Causes serious eye damage
H319	Causes serious eye irritation

Classification and procedure used to derive the classification for mixtures according to Regulation (EC) 1272/2008 [CLP]:

Met. Corr. 1	H290	Calculation method
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PHAGO'WASH LD

Safety Data Sheet

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

Eye Dam. 1	H318	Calculation method
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It is the user's responsibility to take mentioned precaution measures and ensure that this information is complete and sufficient for the use of this product

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

1.1. Product identifier

Product form : Mixture
Product name : PHAGO'WASH RINSE
Product code : F164
Type of product : Detergent
Product group : Mixture

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

1.2.1. Relevant identified uses

Main use category : Professional use
Description/Application : Liquid rinse aid
Function or use category : MD

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

CHRISTEYNS France - Division Santé
31. rue de la Maladrie
44120 VERTOU - FRANCE
T 02 40 80 27 27 - F 02 40 03 09 73
health-security@christeyns.fr - www.phagogene.fr

1.4. Emergency telephone number

Country	Organisation/Company	Address	Emergency number	Comment
Ireland	National Poisons Information Centre Beaumont Hospital	PO Box 1297 Beaumont Road 9 Dublin	+353 1 809 2566 (Healthcare professionals-24/7) +353 1 809 2166 (public, 8am - 10pm, 7/7)	
United Kingdom	National Poisons Information Service Medical Toxicology Unit		0870 243 2241	

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

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

Serious eye damage/eye irritation, Category H319

2

Full text of H statements : see section 16

Adverse physicochemical, human health and environmental effects

No additional information available

2.2. Label elements

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

Hazard pictograms (CLP) :



GHS07

CLP Signal word : Warning
Hazard statements (CLP) : H319 - Causes serious eye irritation.
Precautionary statements (CLP) : P280 - Wear eye protection.
P337+P313 - If eye irritation persists: Get medical advice/attention.

2.3. Other hazards

No additional information available

PHAGO'WASH RINSE

Safety Data Sheet

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

SECTION 3: Composition/information on ingredients

3.1. Substances

Not applicable

3.2. Mixtures

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Alcohol ethoxylated	(CAS-no) Not specified by the supplier (REACH-no) exemption polymer	10 - 20	Acute Tox. 4 (Oral), H302 Eye Irrit. 2, H319 Aquatic Chronic 3, H412
Sodium cumenesulfonate	(CAS-no) 15763-76-5 (Einecs nr) 239-854-6 (REACH-no) 01-2119489411-37	< 5	Eye Irrit. 2, H319
Citric acid	(CAS-no) 5949-29-1 (Einecs nr) 201-069-1 (REACH-no) 01-2119457026-42	< 5	Eye Irrit. 2, H319

Full text of H-statements: see section 16

SECTION 4: First aid measures

4.1. Description of first aid measures

General advice : In case of doubt or persistent symptoms, consult always a physician. For symptom description, see item 11.

Inhalation : In case of malaise, seek medical advice.

Skin contact : Take off contaminated clothes. Rinse with water.

Eye contact : Wash with plenty of water and if necessary take medical advice.

Ingestion : If swallowed, seek medical advice immediately and show this container or label. Do NOT induce vomiting. Give nothing to drink.

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

Acute effects inhalation : Not applicable.

Acute effects skin : Not classified.

Acute effects eyes : Causes serious eye irritation.

Acute effects oral route : No data available.

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

No additional information available

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media : The product itself does not burn. Foam, powder, carbon dioxide (CO₂), water spray.

5.2. Special hazards arising from the substance or mixture

No additional information available

5.3. Advice for firefighters

No additional information available

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

Protective equipment : Concerning personal protective equipment to use, see section 8.

6.1.2. For emergency responders

No additional information available

6.2. Environmental precautions

Prevent liquid from entering sewers, watercourses, underground or low areas.

6.3. Methods and material for containment and cleaning up

Methods for cleaning up : Rinse with water.

6.4. Reference to other sections

No additional information available

SECTION 7: Handling and storage

7.1. Precautions for safe handling

PHAGO'WASH RINSE

Safety Data Sheet

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

Precautions for safe handling : Avoid contact with the skin and the eyes. Do not eat, drink or smoke when using this product.

Hygiene measures : Always wash hands after handling the product.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Store in original container.

Storage temperature : 5 - 40 °C

Material(s) to avoid : Not determined.

7.3. Specific end use(s)

No additional information available

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

No additional information available

8.2. Exposure controls

Hand protection:

not required. wear of household gloves recommended

Eye protection:

safety goggles (EN 166)

Protective equipment:

No special required clothing

Respiratory protection:

Not required

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state : Liquid

Physical state/form : Liquid.

Colour : Colourless.

Odour : characteristic.

Odour threshold : No data available

pH : 2,1 - 2,6 (100 %)

Relative evaporation rate (butylacetate=1) : No data available

Melting point/range : No data available

Freezing point : No data available

Boiling point/Boiling range : No data available

Flash point : Not applicable

Autoignition temperature : No data available

Decomposition temperature : No data available

Flammability (solid, gas) : No data available

Vapour pressure : No data available

Relative vapour density at 20 °C : No data available

Relative density : 1,022 - 1,032

Solubility : Water: 100 %

Log Pow : No data available

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

PHAGO'WASH RINSE

Safety Data Sheet

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

No additional information available

10.2. Chemical stability

Stable in use and storage conditions as recommended in item 7.

10.3. Possibility of hazardous reactions

No additional information available

10.4. Conditions to avoid

Temperatures below 0°C.

10.5. Incompatible materials

No additional information available

10.6. Hazardous decomposition products

Hazardous decomposition products may be released during prolonged heating like smokes, carbon monoxide and dioxide. nitrogen oxides (NOx).

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

Alcohol ethoxylated (Not specified by the supplier)

LD50 oral rat	> 300 (300 - 2000) mg/kg
Skin corrosion/irritation	: Not classified pH: 2,1 - 2,6 (100 %)
Serious eye damage/irritation	: Causes serious eye irritation. pH: 2,1 - 2,6 (100 %)
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

Hazardous to the aquatic environment, short-term (acute) : Not classified

Hazardous to the aquatic environment, long-term (chronic) : Not classified

Alcohol ethoxylated (Not specified by the supplier)

LC50 fish 1	1 - 10 mg/l
EC50 Daphnia 1	1 - 10 mg/l

12.2. Persistence and degradability

PHAGO'WASH RINSE

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.
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Alcohol ethoxylated (Not specified by the supplier)

Chemical oxygen demand (COD)	2,16 g O ₂ /g substance
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12.3. Bioaccumulative potential

No additional information available

12.4. Mobility in soil

No additional information available

PHAGO'WASH RINSE

Safety Data Sheet

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

12.5. Results of PBT and vPvB assessment

Component	
Alcohol ethoxylated (Not specified by the supplier)	This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII
Sodium cumenesulfonate (15763-76-5)	This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII
Citric acid (5949-29-1)	This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII

12.6. Other adverse effects

No additional information available

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste treatment methods : Dispose of this material and its container at hazardous or special waste collection point.
Waste / unused products : Avoid undiluted product to come into sewer or superficial water.

SECTION 14: Transport information

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

14.1. UN number

UN-No. (ADR) : Not applicable

14.2. UN proper shipping name

Proper shipping name : Not applicable

14.3. Transport hazard class(es)

ADR

Transport hazard class(es) (ADR) : Not applicable

14.4. Packing group

Packing group (ADR) : Not applicable

14.5. Environmental hazards

Dangerous for the environment : No
Other information : No supplementary information available

14.6. Special precautions for user

- Overland transport

No data available

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

CESIO recommendations : 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.

Other information, restriction and prohibition regulations : Not affected by the conditions of restriction _ ANNEXE XVII.

Detergent Regulation : Labelling of contents:

Component	%
Non-ionic surfactants	5-15%

15.1.2. National regulations

No additional information available

PHAGO'WASH RINSE

Safety Data Sheet

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

15.2. Chemical safety assessment

No additional information available

SECTION 16: Other information

Indication of changes:

Section	Changed item	Change	Comments
1.1		Modified	
4.1		Modified	
8.2		Modified	
15.1		Modified	
16		Modified	

Other information

: It is recommended to pass the information of this safety data sheet, eventually in an appropriated form, to the users. Such information is actually to be best of our knowledge and believes accurate as reliable. This information relates to the specific material designated and may not be valid in combination with other product(s). EC Regulation 1272/2008 and its amendments.

Full text of H- and EUH-statements:

Acute Tox. 4 (Oral)	Acute toxicity (oral), Category 4
Aquatic Chronic 3	Hazardous to the aquatic environment — Chronic Hazard, Category 3
Eye Irrit. 2	Serious eye damage/eye irritation, Category 2
H302	Harmful if swallowed.
H319	Causes serious eye irritation.
H412	Harmful to aquatic life with long lasting effects.

Classification and procedure used to derive the classification for mixtures according to Regulation (EC) 1272/2008 [CLP]:

Eye Irrit. 2	H319	Calculation method
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It is the user's responsibility to take mentioned precaution measures and ensure that this information is complete and sufficient for the use of this product

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****44120 VERTOU FRANCE****Catégorie du(des) dispositif(s) / Device(s) category****Produits désinfectants de dispositifs médicaux invasifs.***Disinfectants products for invasive medical devices.*

Voir document complémentaire GMED / See GMED additional document

n° 37606

GMED atteste qu'à l'examen des résultats figurant dans le rapport référencé P600289 - P601275, 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 - P601275, 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 : December 3rd, 2020 (included)**Valable jusqu'au / Expiry date : May 26th, 2024 (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
44120 VERTOU FRANCE

pour les activités
for the activities

Conception, production, vente et distribution de désinfectants de dispositifs médicaux invasifs.
Voir addendum

Conception, production, sale and distribution of disinfectants for invasive medical devices.
See addendum

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

CHRISTEYNS FRANCE
31, rue de la Maladrie 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 : June 8th, 2021 (included)

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

Etabli le / Issued on : June 8th, 2021



Accréditation n°4-0608
Liste des sites accrédités
et portée disponible sur
www.cofrac.fr

GMED N° 36451-3

Ce certificat est délivré selon les règles de certification GMED / This certificate is issued according to the rules of GMED certification

Modifie le certificat 36451-2



On behalf of the President
Béatrice LYS
Technical Director

Ce certificat couvre les activités et les sites suivants :

This certificate covers the following activities and sites:

**CHRISTEYNS FRANCE
31, rue de la Maladrie
44120 VERTOU FRANCE**

French version:

Conception, production, vente et distribution de désinfectants de dispositifs médicaux invasifs.

English version:

Conception, production, sale and distribution of disinfectants for invasive medical devices.

- **CHRISTEYNS FRANCE – 31 rue de la Maladrie, 44120 VERTOU - FRANCE**

French version:

Conception, production, vente et distribution de désinfectants de dispositifs médicaux invasifs.

English version:

Conception, production, sale and distribution of disinfectants for invasive medical devices.

- **CHRISTEYNS FOOD HYGIENE – 24580 Rouffignac Saint-Cernin-de-Reilhac - FRANCE**

French version:

Production de désinfectants de dispositifs médicaux invasifs.

English version:

Production of disinfectants for invasive medical devices.

2 sites / 2 sites

DocuSigned by:
Béatrice LYS
EP33BD48BAADMA3


**On behalf of the President
Béatrice LYS
Technical Director**

DT – F170– 820**Déclaration de conformité UE selon le règlement (UE) 2017/745****Phago'wash LD**

Historique des modifications :

Version	Date	Nature des modifications
V1	02/08/2021	Création de la section. Sommaire du dossier technique lié à cette déclaration : V1 du 02/08/2021

Déclaration de conformité UE selon le règlement (UE) 2017/745**EU declaration of conformity according to regulation 2017/745**

Le fabricant : **Christeyns France**

Manufacturer : **Christeyns France**

Numéro d'enregistrement unique : En cours de réalisation

Single Registration Number : In progress

Adresse : 31 Rue de la Maladrie – 44120 Vertou

Address : 31 Rue de la Maladrie – 44120 Vertou

Pays : France

Country : France

Déclare sous sa seule responsabilité que le dispositif médical :

Declares under its sole responsibility that the medical device :

Phago'wash LD

UDI-DI de base : En cours de réalisation

Basic UDI-DI : In progress

Numéro de la formule : F-170

Formula number : F-170

Numéro du catalogue :

Catalog number :

Flacon Kerdose de 1L / 1L Kerdose bottle	70446
Bidon de 5L / 5L Can	70443
Bidon de 10L / 10L Can	70444

Destination prévue : Détergent liquide à usage manuel, en bac à ultrason et en machine pour l'instrumentation médicale et chirurgicale, le matériel d'endoscopie et les dispositifs médicaux.

Intended indication : Liquid detergent for manual, ultrasonic and machine use for medical and surgical instrumentation, endoscopy equipment and medical devices.

À laquelle cette déclaration se rapporte est classé comme classe de risque I, et est conforme :

To which this declaration relates is classified as a risk class I, and complies with :

- Le règlement (UE) 2017/745 relatif aux dispositifs médicaux modifiant la directive 2001/83/CE, le règlement (CE) n° 178/2002 et le règlement (CE) n° 1223/2009 et abrogeant les directives du Conseil 90/385/CEE et 93/42/CEE.

The Regulation (EU) 2017/745 on medical devices amending Directive 2001/83/EC, Regulation (EC) n° 178/2002 and Regulation (EC) n° 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC.

- Code de la santé publique français.

French public health code.

- Le règlement (UE) 2020/561 du parlement européen et du conseil du 23 avril 2020 modifiant le règlement (UE) 2017/745 relatif aux dispositifs médicaux en ce qui concerne les dates d'application de certaines de ses dispositions.

The regulation (EU) 2020/561 of the european parliament and of the council of 23 april 2020 amending Regulation (EU) 2017/745 on medical devices, as regards the dates of application of certain of its provisions.

- Le règlement (CE) n° 648/2004 du Parlement européen et du Conseil de l'Union européenne, du 31/03/04 relatif aux détergents.

Regulation (EC) n° 648/2004 of the european parliament and of the council of 31 march 2004 on detergents.

La présente déclaration est basée sur :

This declaration is based on :

- Le dossier technique référence DT-F170 démontrant la conformité aux exigences générales en matière de sécurité et de performances.

The technical file reference DT-F170 demonstrating compliance with general safety and performance requirements.

- Le cas échéant, le certificat de conformité CE délivré par l'organisme notifié mentionné ci-dessous.

If applicable, the CE certificate of conformity issued by the Notified Body mentioned below.

- Le cas échéant, le certificat EN ISO 13485 version 2016 délivré par l'organisme notifié mentionné ci-dessous sur la base de l'examen du système de management de la qualité.

If applicable, the EN ISO 13485 version 2016 certificate issued by the Notified Body mentioned below on the basis of the quality management system examination.

Nom de l'organisme notifié : Non applicable

Notified Body name : Not applicable

Adresse : Non applicable

Address : Not applicable

Pays : Non applicable

Country : Not applicable

Numéro d'identification : Non applicable

Identification number : Not applicable

	Certificat de conformité CE <i>CE Certificate of conformity</i>	Certificat EN ISO 13485 EN ISO 13485 Certificate
Numéro du certificat <i>Certificate number</i>	Non applicable <i>Not applicable</i>	Non applicable <i>Not applicable</i>
Date de délivrance du certificat <i>Certificate issue date</i>	Non applicable <i>Not applicable</i>	Non applicable <i>Not applicable</i>
Date d'expiration du certificat <i>Certificate expiry date</i>	Non applicable <i>Not applicable</i>	Non applicable <i>Not applicable</i>

Lieu et date d'émission de la déclaration : Vertou, le 02/08/2021

Place and date of issue of the declaration : Vertou, 08/02/2021

Signé par ou pour le compte du fabricant : Christeyns France

Signed by or for the manufacturer : Christeyns France

Nom : Marie Bénédicte Sionneau

Name : Marie Bénédicte Sionneau

Signature et tampon :

Signature and stamp :

Fonction : Directrice Scientifique et Règlementaire

Function : Scientific and Regulatory Director

Marie-Bénédicte Sionneau

Marie-Bénédicte Sionneau (Aug 2, 2021 16:44 GMT+2)

DT-F170-820_Déclaration UE de conformité MDR

Final Audit Report

2021-08-02

Created:	2021-08-02
By:	Noujoud Wahbi (noujoud.wahbi@christeyns.fr)
Status:	Signed
Transaction ID:	CBJCHBCAABAAAnDX-2KQvYEDjzvPMiWVEHXkIW7VkyuA

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REGISTRUL DE STAT AL DISPOZITIVELOR MEDICALE

Nr	Denumire	Den.comerc.	Model	Nr. catalog	Tara	Producatorul	Reprezentant	Ordin	Data
						ch	sofra		
DM000320319	DEZINFECTANT PENTRU DISPOZITIVE MEDICALE		PHAGO'SCOPE APA		Franta	CHRISTEYNS FRANCE	SOFRAGRUP S.R.L.	Rg04-000215	13-09-2021
DM000268297	DETERGENT LICHID PENTRU CURĂȚARE	PHAGO'WASH RINSE	bidon 10 litri	70034	Franta	CHRISTEYNS FRANCE	SOFRAGRUP S.R.L.	Rg04-000041	25-02-2020
DM000268296	DETERGENT LICHID PENTRU CURĂȚARE	PHAGO'WASH RINSE	bidon 5 litri	70033	Franta	CHRISTEYNS FRANCE	SOFRAGRUP S.R.L.	Rg04-000041	25-02-2020
DM000268298	DETERGENT LICHID PENTRU CURĂȚARE	PHAGO'WASH RINSE	bidon 200 litri	70037	Franta	CHRISTEYNS FRANCE	SOFRAGRUP S.R.L.	Rg04-000041	25-02-2020
DM000268258	DETERGENT ENZIMATIC PENTRU INSTRUMENTAR		PHAGOCIDE D, 5L		Franta	CHRISTEYNS FRANCE	SOFRAGRUP S.R.L.	Rg04-000041	25-02-2020
DM000268301	DETERGENT LICHID PENTRU CURĂȚARE	PHAGO'WASH LD	bidon 200 litri	70447	Franta	CHRISTEYNS FRANCE	SOFRAGRUP S.R.L.	Rg04-000041	25-02-2020
DM000268295	DETERGENT LICHID PENTRU CURĂȚARE	PHAGO'CLEAN ENDO	bidon 5 litri	63453	Franta	CHRISTEYNS FRANCE	SOFRAGRUP S.R.L.	Rg04-000041	25-02-2020
DM000268293	DETERGENT LICHID PENTRU CURĂȚARE	PHAGO'CLEAN ENDO	DOZA DE 20 ML	63451	Franta	CHRISTEYNS FRANCE	SOFRAGRUP S.R.L.	Rg04-000041	25-02-2020
DM000268299	DETERGENT LICHID PENTRU CURĂȚARE	PHAGO'WASH LD	bidon 5 litri	70443	Franta	CHRISTEYNS FRANCE	SOFRAGRUP S.R.L.	Rg04-000041	25-02-2020
DM000268294	DETERGENT LICHID PENTRU CURĂȚARE	PHAGO'CLEAN ENDO	flacon 1 Litru	63452	Franta	CHRISTEYNS FRANCE	SOFRAGRUP S.R.L.	Rg04-000041	25-02-2020

Страница 1 из 2 (Всего элементов: 18) 1 2

☒ Содержит('Reprezentant', 'sofra') И Содержит('Producatorul', 'ch')