



AGENȚIA MEDICAMENTULUI
ȘI DISPOZITIVELOR MEDICALE

REGISTRUL DE STAT AL DISPOZITIVELOR MEDICALE

Tip	Denumire
I.2. Declarația de conformitate CE	Declaratia de conformitate CE

Nr	Denumire	Den.comerc.	Model	Nr. catalog	Tara	Producatorul	Reprezentant	Ordin	Data	Cod vamal
						Ecolab	datacontrol			
DM000051457	DETERGENT PENTRU REPROCESOR AUTOMAT AL ENDOSCOAPELO	OLYMPUS	CLEANER ETD		Germania	ECOLAB DEUTSCHLAND GMBH	F.C.P.C. DATACONTROL S.R.L.	A07.PS-01.Rg04-48	15-02-2018	
DM000051462	DEZINFECTANT PENTRU REPROCESOR AUTOMAT AL ENDOSCOAPELO	OLYMPUS	DISINFECTANT ETD		Germania	ECOLAB DEUTSCHLAND GMBH	F.C.P.C. DATACONTROL S.R.L.	A07.PS-01.Rg04-48	15-02-2018	

☒ Содержит([Producatorul], 'Ecolab') И Содержит([Reprezentant], 'datacontrol')

Очисти

Conforms to EU regulation EC 1907/2006 and amendments

OLYMPUS CLEANER

Code : 107501E

Version : 4

Date of revision : 30 May 2008

1. Identification of the substance/preparation and company/undertaking

Identification of the substance or preparation

Product name : OLYMPUS CLEANER
Product use : Instrument cleaner
Product is for professional use only

Company/undertaking identification

Manufacturer/ : Ecolab Export GmbH
Distributor/ Reisholzer Werftstrasse 52
Importer P.O.Box: 130270
DE-40552 Düsseldorf
Germany
Tel: ++49 211 9893 168
Fax: ++ 49 211 9893 207
Commercial-Services.de@ecolab.com
Emergency phone: 0211 797 3350

anti-poison centre : 030 19240 (Beratungsstelle für Vergiftungserscheinungen - Berlin)

2. Hazards identification

The product is not classified as dangerous according to Directive 1999/45/EC and its amendments.

Classification : Not classified.

See section 11 for more detailed information on health effects and symptoms.

3. Composition/information on ingredients

Ingredient declaration according to detergent regulation 648/2004/EC:

≥5 - <15% non-ionic surfactants

contains enzymes

Substance/preparation : Preparation

Ingredient name	EINECS	CAS	%	Classification
Fattyalcohol ethoxylates > 5EO	Polymer.	147993-63-3	5 - 10	Xi; R38 N; R50
See section 16 for the full text of the R-phrases declared above				

Occupational exposure limits, if available, are listed in section 8.

4. First aid measures

First-aid measures

Inhalation : Move exposed person to fresh air. Obtain medical attention if symptoms occur.

Ingestion : Wash out mouth with water. Move exposed person to fresh air. Do not induce vomiting unless directed to do so by medical personnel. Obtain medical attention if symptoms occur.

Skin contact : Flush contaminated skin with plenty of water. Remove contaminated clothing and shoes.

Eye contact : Immediately flush eyes with plenty of water, occasionally lifting the upper and lower eyelids. Get medical attention if irritation occurs.

Specific treatments : Not available.

See section 11 for more detailed information on health effects and symptoms.

5. Fire-fighting measures

Extinguishing media - Suitable : In case of fire, use water spray (fog), foam, dry chemical or CO₂.

Extinguishing media - Not suitable : None known.

Hazardous thermal decomposition products : Decomposition products may include the following materials:
carbon oxides

Special protective equipment for fire-fighters : Fire-fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full face-piece operated in positive pressure mode.

6. Accidental release measures

Personal precautions : Keep unnecessary and unprotected personnel from entering. Do not touch or walk through spilt material. Avoid breathing vapour or mist. Provide adequate ventilation.

Environmental precautions : Avoid dispersal of spilt material and runoff and contact with soil, waterways, drains and sewers.

Small spill: : Dilute with water and mop up if water-soluble or absorb with an inert dry material and place in an appropriate waste disposal container.

Large spill : Prevent entry into sewers, water courses, basements or confined areas. Contain and collect spillage with non-combustible, absorbent material e.g. sand, earth, vermiculite or diatomaceous earth and place in container for disposal according to local regulations (see section 13).

Note: see section 8 for personal protective equipment and section 13 for waste disposal.

7. Handling and storage

Handling : Do not ingest. Avoid contact with eyes, skin and clothing. After handling, always wash hands thoroughly with soap and water.

Storage : Store in accordance with local regulations. Store in original container protected from direct sunlight in a dry, cool and well-ventilated area, away from incompatible materials (see section 10) and food and drink. Keep container tightly closed and sealed until ready for use.

Do not store above the following temperature: 25°C

Packaging materials

Recommended : Use original container.

8. Exposure controls/personal protection

Exposure limit values : Not available.

Exposure controls

Respiratory protection (EN 143, 141) : No respirator is not needed under normal and intended conditions of product use.

Hand protection (EN 374) : No special recommendations.

Eye protection (EN 166) : Safety glasses.

Skin protection (EN 467) : No special recommendations.

9. Physical and chemical properties

General information

Appearance

Physical state	: Liquid.
Colour	: Colourless.
Odour	: Faint odour.

Important health, safety and environmental information

pH	: 5.5 (100%)
Boiling point	: Not available.
Melting point	: Not available.
Flash point	: > 100°C
Flammability (solid, gas)	: Not applicable.
Explosive properties	: Not applicable.
Explosion limits	: Not applicable.
Oxidising properties	: Not available.
Vapour pressure	: Not applicable.
Relative density	: 1.06 g/cm ³ (20 °C)
Solubility	: Soluble in cold water.
Octanol/water partition coefficient	: Not applicable.
Viscosity	: Not available.
Vapour density	: Not available.
Evaporation rate (butyl acetate = 1)	: Not applicable.

10. Stability and reactivity

Stability	: Stable under normal conditions. Do not mix with other products.
-----------	--

11. Toxicological information

Potential acute health effects

Inhalation	: ☒ No known significant effects or critical hazards.
Ingestion	: ☒ No known significant effects or critical hazards.
Skin contact	: ☒ No known significant effects or critical hazards.
Eye contact	: ☒ No known significant effects or critical hazards.
Carcinogenicity	: ☒ No known significant effects or critical hazards.
Mutagenicity	: ☒ No known significant effects or critical hazards.
Reproductive toxicity	: ☒ No known significant effects or critical hazards.

12. Ecological information

Ecotoxicity

The product is not subject to ecological classification according to directive 1999/45/EC.

Persistence and degradability

The ecological evaluation of the product is based on data from the raw material and/or comparable substances. Readily and rapidly degradable. All organic substances contained in the product achieve > 60% BOD/COD or CO₂ liberation, or > 70% DOC reduction in tests for ease of degradability. Threshold values for 'readily degradable' (e.g. to OECD method 301) are reached. The surfactants contained in the product are biodegradable according to the requirements of the detergent regulation 648/2004/EC.

13. Disposal considerations

Methods of disposal : The generation of waste should be avoided or minimised wherever possible. Disposal of this product, solutions and any by-products should at all times comply with the requirements of environmental protection and waste disposal legislation and any regional local authority requirements. Avoid dispersal of spilt material and runoff and contact with soil, waterways, drains and sewers. Can be added to general waste collection after completely emptying. Use packages for recycling only when totally empty.

European waste catalogue (EWC) : 200130

14. Transport information

International transport regulations

Regulatory information	UN number	Proper shipping name	Class	Packing group	Label
ADR/RID Class	Not regulated.	-	-	-	
IMDG Class	Not regulated.	-	-	-	

Follow special pack instructions for air transport.

15. Regulatory information

EU regulations

Risk phrases : This product is not classified according to EU legislation.

16. Other information

Full text of R-phrases referred to in sections 2 and 3 - Germany : R38- Irritating to skin.
R50- Very toxic to aquatic organisms.

History

Date of printing : 30 May 2008

Date of revision : 30 May 2008

Version : 4

Prepared by : Ecolab Regulatory Department Europe

Notice to reader

The above information is believed to be correct with respect to the formula used to manufacture the product in the country of origin. As data, standards, and regulations change, and conditions of use and handling are beyond our control, NO WARRANTY, EXPRESS OR IMPLIED, IS MADE AS TO THE COMPLETENESS OR CONTINUING ACCURACY OF THIS INFORMATION.

Version 4

Page: 4/4



FISA TEHNICA DE SIGURANTA

In conformitate cu reglementarile UE CE 1907/2007 si amendamentele sale.

SOLUTIE DE CURATARE OLYMPUS

Cod: 107501E

Versiunea: 4

Data reviziei: 30 mai 2008

1. Identificarea substantei/preparatului si a companiei/intreprinderii

Identificarea substantei sau preparatului

Nume produs: Solutie de curatare Olympus

Utilizare produs: Solutie de curatare instrumente

Produsul este destinat doar pentru uz profesional

Identificarea companiei/intreprinderii:

Producator/ Ecolab Export GmbH

Distribuito/ Reisholzer Werftstrasse 52

Importator Casuta Postala: 130270

DE-40552 Dusseldorf

Germania

Tel: ++49 211 9893 168

Fax: ++49 211 9893 207

Commercial-services.de@ecolab.com

Telefon urgente: 0211 797 3350

Centru anti-otravire: 030 19240 (Berlin)

2. Identificarea riscurilor

Produsul este clasificat ca fiind periculos in conformitate cu Directiva 1999/45/CE si amendamentele sale

Clasificare : Nu este clasificat

Consultati sectiunea 11 pentru mai multe informatii amanuntite privind efectele asupra sanatatii si simptome.

3. Compozitie / informatii privind ingredientele

Declaratie privind ingredientele in conformitate cu reglementarile privind detergentii 648/2004/CE

≥5 - <15% agenti activi de suprafata non-ionici
contine enzime

Substanta/preparat:

Preparat

Denumire ingredient	EINECS	CAS	%	Clasificare
Alcoolii grasi etoxilati > 5EO	Polimer	147993-63-3	5-10	Xi; R28 N; R50
Consultati sectiunea 16 pentru textul complet al frazelor R declarate mai sus				



In cazul in care sunt disponibile, limitele de expunere ocupationala sunt specificate in sectiunea 8.

4. Masuri de prim ajutor:

Masuri de prim ajutor

Inhalare:

Mutati persoana expusa intr-un loc cu aer proaspat. Cereti imediat asistenta medicala.

Ingerare:

Clatiti gura cu apa. Mutati persoana expusa intr-un loc cu aer proaspat. Nu induceti varsaturi decat in cazul in care sunteti directionat sa faceti acest lucru de catre personalul medical. Cereti asistenta medicala daca simptomele persista.

Contact cu pielea:

Clatiti pielea contaminata cu apa din abundenta. Inlaturati hainele sau incaltamintea contaminata.

Contactul cu ochii:

Clatiti ochii imediat cu apa din abundenta, ridicand din cand in cand ploapele superioare si inferioare. Cereti asistenta medicala daca apare iritatie.

Tratamente specifice:

Nu sunt disponibile.

Consultati sectiunea 11 pentru mai multe informatii amanuntite privind efectele asupra sanatatii si simptome.

5. Masuri de combatere a incendiilor

Medii de stingere - adecvate:

In cazul unui incendiu, utilizati jet de apa, spuma, chimicale uscate sau CO₂

Medii de stingere – inadecvate:

Nu sunt cunoscute.

Descompunere termica

periculoasa a produselor:

Descompunerea produselor poate contine urmatoarele substante: oxizi de carbon

Echipamente de protectie speciale

Pompierii trebuie sa poarte

pentru pompieri:

echipamente de protectie potrivite si aparate autonome de respiratie (SCBA) care acopera complet fata si sunt operate in mod de presiune pozitiva.

6. Masuri in cazul deversarii accidentale

Precautii personale:

Nu permiteti accesul personalului de prisos sau fara echipamente de protectie. Nu atingeti si nu calcati prin substanta varsata. Evitati inhalarea vaporilor sau pulverizarilor. Asigurati o ventilare adecvata.

Precautii privind mediul inconjurator:

Evitati imprastierea substantei varsate si scurgerea acesteia in sol, cursurilor de apa si canalizare.

Deversari de dimensiuni mici:

Diluati cu apa si adunati cu mopul daca este solubila in apa sau absorbiti cu o substanta uscata inerta si depozitati intr-un container potrivit de eliminare a deseurilor.

Deversari de dimensiuni mari:

Preveniti scurgerea in canalizare, cursuri de apa, subsoluri sau spatii inguste. Opriti si colectati scurgerea cu substante non-combustibile, materiale absorbante cum ar fi nisip, pamant, sol spongios sau diatomit si depozitati intr-un container de eliminare in conformitate cu reglementarile locale (consultati sectiunea 13).

Nota: Consultati sectiunea 8 pentru echipamente personale de protectie si sectiunea 13 pentru eliminarea deseurilor.

7. Manipularea si depozitarea

Manipularea:

Nu ingerati. Evitati contactul cu ochii, pielea sau hainele. Dupa manipulare, intotdeauna clatiti amanuntit mainile cu apa si sapun.

Depozitare:

Depozitati in conformitate cu reglementarile locale. Depozitati in recipientul original protejat de actiunea directa razelor soarelui, intr-o zona uscata, racoroasa si bine ventilata, departe de materiale incompatibile (consultati sectiunea 10) si de mancare sau bautura. Pastrati recipientul strans inchis si sigilat pana cand este gata de utilizare. Nu depozitati la temperaturi mai mari de 25°C

Materiale de ambalare recomandate: Utilizati recipientul original



8. Controlul expunerii/ protectia personalului

Valori limite de expunere: Nu sunt disponibile

Controlul expunerii:

Protectie respiratorie (EN 143, 141)	Nu este necesara o masca de protectie in conditii de uz normal al produsului
Protectie maini (EN 374):	Nu exista recomandari speciale
Protectie ochi (EN 166):	Ochelari de protectie
Protectie piele (EN 467)	Nu exista recomandari speciale



9. Proprietati fizice si chimice

Informatii generale

Aspect

Stare de agregare: Lichid

Culoare: Fara culoare

Miros: Miros slab

Informatii importante privind sanatatea, siguranta si mediul inconjurator.

pH: 5.5 (100%)

Punct de fierbere: Nu este disponibil

Punct de topire: Nu este disponibil

Punct de aprindere: >100 °C

Inflamabilitate (solid, gaz): Nu este cazul

Proprietati explozibile: Nu este cazul

Limite de explozie: Nu este cazul

Proprietati de oxidare: Nu este disponibil

Presiune vapori: Nu este cazul

Densitate relativa: 1.06 g/cm³ (20 °C)

Solubilitate: Solubila in apa rece

Coeficientul de partitie apa- octanol: Nu este cazul

Vascozitate: Nu este cazul

Densitate vapori: Nu este cazul

Rata evaporare (acetat de butil = 1): Nu este cazul

10. Stabilitate si reactivitate:

Stabilitate: Stabil in conditii normale.
Nu amestecati cu alte produse.

11. Informatii toxicologice

Potentiale efecte acute asupra sanatatii

Inhalare:

Nu se cunosc efecte semnificative sau pericole critice.

Ingerare:

Nu se cunosc efecte semnificative sau pericole critice.

Contactul cu pielea:

Nu se cunosc efecte semnificative sau pericole critice.

Contactul cu ochii:

Nu se cunosc efecte semnificative sau pericole critice.

Cancerigenitate:

Nu se cunosc efecte semnificative sau pericole critice.

Mutagenitate:

Nu se cunosc efecte semnificative sau pericole critice.

Toxicitate reproductiva:

Nu se cunosc efecte semnificative sau pericole critice.

12. Informatii ecologice

Ecotoxicitate

Produsul nu este supus clasificarii ecologice in conformitate cu directiva 1999/45/CE

Persistenta si degradabilitate

Evaluarea ecologica a produsului se bazeaza pe datele provenite de la materiile prime si/sau substante comparabile. Facil si rapid degradabil. Toate substantele organice continute de catre produs ating >60% BOD/COD sau degajare CO₂, sau >70% reducere DOC in teste pentru facilitarea degradabilitatii. Valori prag pentru „degradare rapida” (de exemplu OECD metoda 301) sunt obtinute. Agentii activi de suprafata continuti in produs si biodegradabili in conformitate cu cerintele reglementarii privind detergentii 648/2004/CE.

13. Informatii privind eliminarea

Metode de eliminare:

Producerea deseurilor ar trebui evitata sau redusa atunci cand este posibil. Eliminarea acestui produs, solutii si orice produse secundare trebuie sa fie in conformitate cu cerintele privind protectia mediului si cu legislatia privind eliminarea deseurilor si orice alte cerinte regionale ale autoritatilor locale. Evitati imprastierea sau varsarea materialului si scurgerea si contactul cu solul, cursurile de apa, scurgerile si canalizarea. Poate fi adaugata colectarii generale de deseuri dupa ce a fost golita complet. Utilizati ambalajele pentru reciclare doar atunci cand sunt complet goale.

14. Informatii privind transportul

Reglementari internationale privind transportul

Informatii reglementare	Numar UN	Denumire corespunzatoare a expeditiei	Clasa	Grup ambalaje	Eticheta
Clasa ADR/RID	Nu este reglementat	-	-	-	
Clasa IMDG	Nu este reglementat	-	-	-	

MINIST
MUNA FA
TRADUCA
ENGLEZ
AUT.
TEL.:

Respectati instructiunile speciale de ambalare pentru transportul aerian.

15. Informatii privind reglementarea

Reglementari UE

Fraze de risc:

Acest produs nu este clasificat in conformitate cu legislatie UE.

16. Alte informatii

Textul complet al frazelor R la care : R38 – Irita ochii
se face referire in sectiunile 2 si 3 – R50 – Foarte toxic pentru organismele acvatice
Germania

Istorie

Data imprimarii: 30 mai 2008

Data reviziei: 30 mai 2008

Versiune: 4

Intocmit de: Deoartamentul de Reglementare Ecolab Europa

Nota catre cititor:

Informatiile de mai sus sunt considerate corecte in ceea ce priveste formula folosita pentru fabricarea produsului in tara de origine. Modul in care datele, standardele si reglementarile se modifica si conditiile de utilizare si manipulare sunt dincolo de controlul nostru. NU SE OFERA GARANTII, EXPRIMATE SAU IMPLICITE, PRIVIND CARACTERUL COMPLET SAU ACURATETEA CONTINUTULUI A ACESTOR INFORMATII.

Subsemnata, Mina FANEA-IVANOVICI, traducător autorizat de Ministerul Justiției cu autorizația nr. 22069/2011, certific exactitatea acestei traduceri cu textul documentului în limba engleză, care a fost vizat de mine.

Traducător autorizat,

ROMÂNIA
MINISTERUL JUSTIȚIEI
MINA FANEA-IVANOVICI
TRADUCĂTOR AUTORIZAT
ENGLEZĂ * FRANCEZĂ
AUT. NR. 22069
TEL.: 0745471452

România, București

Biroul Notarului Public Iuliana Alexandra Zarafiu

Înregistrat la Curtea de Apel București sub nr. 765/2010

Cod înregistrare fiscală RO29471405/2011, Cod avp 11311

București, Șos. Mihai Bravu nr. 62A, corp A,

Spectrum Business Center, mezanin, sector 2

Tel / fax: 021 3236597, email: notarizarafiu@cnpb.ro

ÎNCHEIERE DE LEGALIZARE A SEMNĂTURII TRADUCĂTORULUI Nr. 1454

Anul 2012 luna 08 ziua 08

Iuliana Alexandra Zarafiu, notar public, în temeiul art. 8, lit. e) și j) din Legea 36/1995, cu modificările și completările ulterioare, legalizez semnătura de mai sus a Minei FANEA-IVANOVICI, traducător autorizat cu nr. 22069/2011, în baza specimenului de semnătură depus în fața mea, de pe cele 2 exemplare ale înscrisului.

S-a perceput onorariul notarial de 3720 lei, TVA inclus, cu chitanța/bon fiscal/ordin de plată nr. FF198/2012

NOTAR PUBLIC,



Conforms to EU regulation EC 1907/2006 and amendments

OLYMPUS DISINFECATNT

Code : 107524E

Version : 3

Date of revision : 30 May 2008

1. Identification of the substance/preparation and company/undertaking

Identification of the substance or preparation

Product name : OLYMPUS DISINFECATNT
Product use : Instrument Disinfectant
Product is for professional use only

Company/undertaking identification

Manufacturer/ : Ecolab Export GmbH
Distributor/ Reisholzer Werftstrasse 52
Importer P.O.Box: 130270
DE-40552 Düsseldorf
Germany
Tel: ++49 211 9893 168
Fax: ++ 49 211 9893 207
Commercial-Services.de@ecolab.com
Emergency phone: 0211 797 3350

anti-poison centre : 030 19240 (Beratungsstelle für Vergiftungserscheinungen - Berlin)

2. Hazards identification

The product is classified as dangerous according to Directive 1999/45/EC and its amendments.

Classification : Xn; R20/22
C; R34
R42/43

Human health hazards : Harmful by inhalation and if swallowed. Causes burns. May cause sensitisation by inhalation and skin contact.

See section 11 for more detailed information on health effects and symptoms.

3. Composition/information on ingredients

Substance/preparation : Preparation

Ingredient name	EINECS	CAS	%	Classification
glutaral	203-856-5	111-30-8	10 - 20	T; R23/25 C; R34 R42/43 N; R50
ethanol	200-578-6	64-17-5	5 - 10	F; R11
methanol	200-659-6	67-56-1	< 0.1	F; R11 T; R23/24/25, R39/23/24/25
See section 16 for the full text of the R-phrases declared above				

Occupational exposure limits, if available, are listed in section 8.

4. First aid measures

First-aid measures

- Inhalation** : Move exposed person to fresh air. Get medical attention immediately.
- Ingestion** : Wash out mouth with water. Move exposed person to fresh air. Do not induce vomiting unless directed to do so by medical personnel. Get medical attention immediately.
- Skin contact** : Flush contaminated skin with plenty of water. Remove contaminated clothing and shoes. Wash contaminated clothing thoroughly with water before removing it, or wear gloves. Continue to rinse for at least 10 minutes. In the event of any complaints or symptoms, avoid further exposure. Get medical attention immediately.
- Eye contact** : Immediately flush eyes with plenty of water, occasionally lifting the upper and lower eyelids. Get medical attention immediately.
- Specific treatments** : Not available.

See section 11 for more detailed information on health effects and symptoms.

5. Fire-fighting measures

- Extinguishing media - Suitable** : In case of fire, use water spray (fog), foam, dry chemical or CO₂.
- Extinguishing media - Not suitable** : None known.
- Hazardous thermal decomposition products** : Decomposition products may include the following materials:
carbon oxides
- Special protective equipment for fire-fighters** : Fire-fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full face-piece operated in positive pressure mode.

6. Accidental release measures

- Personal precautions** : Keep unnecessary and unprotected personnel from entering. Do not touch or walk through spilt material. Avoid breathing vapour or mist. Provide adequate ventilation.
- Environmental precautions** : Avoid dispersal of spilt material and runoff and contact with soil, waterways, drains and sewers.
- Small spill:** : Dilute with water and mop up if water-soluble or absorb with an inert dry material and place in an appropriate waste disposal container.
- Large spill** : Prevent entry into sewers, water courses, basements or confined areas. Contain and collect spillage with non-combustible, absorbent material e.g. sand, earth, vermiculite or diatomaceous earth and place in container for disposal according to local regulations (see section 13).

Note: see section 8 for personal protective equipment and section 13 for waste disposal.

7. Handling and storage

- Handling** : Do not get in eyes or on skin or clothing. Do not ingest. Use only with adequate ventilation. Wear appropriate respirator when ventilation is inadequate. After handling, always wash hands thoroughly with soap and water.
- Storage** : Store in accordance with local regulations. Store in original container protected from direct sunlight in a dry, cool and well-ventilated area, away from incompatible materials (see section 10) and food and drink. Keep container tightly closed and sealed until ready for use.
Do not store above the following temperature: 25°C
- Packaging materials**
- Recommended** : Use original container.

8. Exposure controls/personal protection

<u>Ingredient name</u>	<u>Occupational exposure limits</u>
ethanol	TRGS900 AGW (Germany, 3/2007). PEAK: 1920 mg/m ³ 15 minute(s). PEAK: 1000 ppm 15 minute(s). TWA: 960 mg/m ³ 8 hour(s). TWA: 500 ppm 8 hour(s).
methanol	TRGS900 AGW (Germany, 3/2007). Absorbed through skin. PEAK: 1080 mg/m ³ 15 minute(s). PEAK: 800 ppm 15 minute(s). TWA: 270 mg/m ³ 8 hour(s). TWA: 200 ppm 8 hour(s).

Exposure controls

Occupational exposure controls	: If workers are exposed to concentrations above the exposure limit, they must use appropriate, certified respirators.
Respiratory protection (EN 143, 141)	: Use appropriate respiratory protection if there is a risk of exceeding any exposure limits.
Hand protection (EN 374)	: 1 - 4 hours : butyl rubber , nitrile rubber
Eye protection (EN 166)	: Safety glasses. Goggles, face shield, or other full-face protection.
Skin protection (EN 467)	: Safety apron . Suitable protective footwear.

9. Physical and chemical properties

General information

Appearance	
Physical state	: Liquid.
Colour	: Colourless.
Odour	: disinfectant

Important health, safety and environmental information

pH	: 3.5 (100%)
Boiling point	: Not available.
Melting point	: Not available.
Flash point	: 55 °C (Closed cup) Product does not support combustion.
Flammability (solid, gas)	: Not applicable.
Explosive properties	: Not applicable.
Explosion limits	: Not applicable.
Oxidising properties	: Not available.
Vapour pressure	: Not applicable.
Relative density	: 1.04 g/cm ³ (20 °C)
Solubility	: Easily soluble in cold water.
Octanol/water partition coefficient	: Not applicable.
Viscosity	: Not available.
Vapour density	: Not available.
Evaporation rate (butyl acetate = 1)	: Not applicable.

10. Stability and reactivity

Stability : Stable under normal conditions.
Do not mix with other products.

11. Toxicological information

Potential acute health effects

Inhalation : Harmful by inhalation. May give off gas, vapor or dust that is very irritating or corrosive to the respiratory system. May cause sensitisation by inhalation.
Ingestion : Harmful if swallowed. May cause burns to mouth, throat and stomach.
Skin contact : Causes burns. May cause sensitisation by skin contact.
Eye contact : Causes burns.
Carcinogenicity : No known significant effects or critical hazards.
Mutagenicity : No known significant effects or critical hazards.
Reproductive toxicity : No known significant effects or critical hazards.

12. Ecological information

Ecotoxicity

The product is not subject to ecological classification according to directive 1999/45/EC.

Persistence and degradability

The total of the organic components contained in the product achieve > 60% BOD/COD or CO₂ liberation, or > 70% DOC reduction in tests for ease of degradability - threshold values for 'readily degradable' (e.g. to OECD method 301).

13. Disposal considerations

Methods of disposal : The generation of waste should be avoided or minimised wherever possible. Disposal of this product, solutions and any by-products should at all times comply with the requirements of environmental protection and waste disposal legislation and any regional local authority requirements. Avoid dispersal of spilt material and runoff and contact with soil, waterways, drains and sewers. Can be added to general waste collection after completely emptying. Use packages for recycling only when totally empty.

European waste catalogue (EWC) : 200129*

14. Transport information

International transport regulations

Regulatory information	UN number	Proper shipping name	Class	Packing group	Label
ADR/RID Class	UN2924	FLAMMABLE LIQUID, CORROSIVE, N.O.S. (Ethanol, Glutaraldehyde)	3	III	3, 8
IMDG Class	UN2924	FLAMMABLE LIQUID, CORROSIVE, N.O.S. (Ethanol, Glutaraldehyde)	3	III	3, 8

Follow special pack instructions for air transport.

15. Regulatory information

EU regulations

Hazard symbol/symbols :



Corrosive

Contains : glutaral

Risk phrases :

R20/22- Harmful by inhalation and if swallowed.
R34- Causes burns.
R42/43- May cause sensitisation by inhalation and skin contact.

Safety phrases :

S2- Keep out of the reach of children.
S23- Do not breathe spray.
S26- In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
S36/37/39- Wear suitable protective clothing, gloves and eye/face protection.
S45- In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).

16. Other information

Full text of R-phrases referred
to in sections 2 and 3 -
Germany

R11- Highly flammable.
R23/25- Toxic by inhalation and if swallowed.
R23/24/25- Toxic by inhalation, in contact with skin and if swallowed.
R39/23/24/25- Toxic: danger of very serious irreversible effects through inhalation, in contact with skin and if swallowed.
R20/22- Harmful by inhalation and if swallowed.
R34- Causes burns.
R42/43- May cause sensitisation by inhalation and skin contact.
R50- Very toxic to aquatic organisms.

History

Date of printing : 30 May 2008

Date of revision : 30 May 2008

Version : 3

Prepared by : Ecolab Regulatory Department Europe

Notice to reader

The above information is believed to be correct with respect to the formula used to manufacture the product in the country of origin. As data, standards, and regulations change, and conditions of use and handling are beyond our control, NO WARRANTY, EXPRESS OR IMPLIED, IS MADE AS TO THE COMPLETENESS OR CONTINUING ACCURACY OF THIS INFORMATION.

Version 3

Page: 5/5



FISA TEHNICA DE SIGURANTA

In conformitate cu reglementarile UE CE 1907/2007 si amendamentele sale.

DEZINFECTANT OLYMPUS

Cod: 107524E

Versiunea: 3

Data reviziei: 30 mai 2008

1. Identificarea substantei/preparatului si a companiei/intreprinderii

Identificarea substantei sau preparatului

Nume produs: Dezinfectant Olympus

Utilizare produs: Dezinfectant instrumente
Produsul este doar pentru uz profesional

Identificarea companiei/intreprinderii:

Producator/ Ecolab Export GmbH

Distribuitoar/ Reisholzer Werftstrasse 52

Importator Casuta Postala: 130270

De-40552 Dusseldorf

Germania

Tel: ++49 211 9893 168

Fax: ++49 211 9893 207

Commercial-services.de@ecolab.com

Telefon urgente: 0211 797 3350

Centru anti-otravire: 030 19240 (Berlin)

2. Identificarea riscurilor

Produsul este clasificat ca fiind periculos in conformitate cu Directiva 1999/45/CE si amendamentele sale

Clasificare : Xn; R20/22
C; R34
R42/43

Pericole privind sanatatea omului: Dauneaza daca este inhalat sau inghitit. Cauzeaza arsuri.
Poate cauza sensibilitate prin inhalare sau contact cu pielea

Consultati sectiunea 11 pentru mai multe informatii amanuntite privind efectele asupra sanatatii si simptome.

3. Compozitie / informatii privind ingredientele

Substanta/preparat:

Preparat

Denumire ingredient	EINECS	CAS	%	Clasificare
Glutaral	203-856-5	111-30-8	10-20	T; R23/25 C; R34 R42/43 N; R50
Etanol	200-578-6	64-17-5	5-10	F; R11
Metanol	200-659-6	67-56-1	<0,1	F; R11 T; R23/24/25 R39/23/24/25
Consultati sectiunea 16 pentru textul complet al frazelor R declarate mai sus				



In cazul in care sunt disponibile, limitele de expunere profesionala sunt specificate in sectiunea 8.

4. Masuri de prim ajutor:

Masuri de prim ajutor

Inhalare:

Mutati persoana expusa intr-un loc cu aer proaspat. Cereti imediat asistenta medicala.

Ingerare:

Clatiti gura cu apa. Mutati persoana expusa intr-un loc cu aer proaspat. Nu induceti varsaturi decat in cazul in care sunteti directionat sa faceti acest lucru de catre personalul medical. Cereti imediat asistenta medicala.

Contact cu pielea:

Clatiti pielea contaminata cu apa din abundenta. Inlaturati hainele sau incaltamintea contaminata. Spalati foarte bine cu apa hainele contaminate inainte de ale inlatura, sau utilizati manusi. Continuati sa clatiti timp de cel putin 10 minute. In cazul oricarei indispozitii sau simptome, evitati expunerea suplimentara. Cereti imediat asistenta medicala.

Contactul cu ochii:

Clatiti ochii imediat cu apa din abundenta, ridicand din cand in cand ploapele superioare si inferioare. Cereti imediat asistenta medicala.

Tratamente specifice:

Nu sunt disponibile.

Consultati sectiunea 11 pentru mai multe informatii amanuntite privind efectele asupra sanatatii si simptome.

5. Masuri de combatere a incendiilor

Medii de stingere - adecvate:

In cazul unui incendiu, utilizati jet de apa, spuma, chimicale uscate sau CO₂

Medii de stingere – inadecvate:

Nu sunt cunoscute.

Descompunere termica

Descompunerea produselor poate contine urmatoarele substante: oxizi de carbon

Periculoasa a produselor:

Pompierii trebuie sa poarte

Echipamente de protectie speciale pentru pompieri:

echipamente de protectie potrivite si aparate autonome de respiratie (SCBA) care acopera complet fata si sunt operate in mod de presiune pozitiva.

6. Masuri in cazul deversarii accidentale

Precautii personale:

Nu permiteti accesul personalului de prisos sau fara echipamente de protectie. Nu atingeti si nu calcati prin substanta varsata. Evitati inhalarea vaporilor sau pulverizarilor. Asigurati o ventilare adecvata.

Precautii privind mediul inconjurator:

Evitati imprastierea substantei varsate si scurgerea acesteia in sol, cursurile de apa si canalizare.

Deversari de dimensiuni mici:

Diluati cu apa si adunati cu mopul daca este solubila in apa sau absorbiti cu o substanta uscata inerta si depozitati intr-un container potrivit de eliminare a deseurilor.

Deversari de dimensiuni mari:

Preveniti scurgerea in canalizare, cursuri de apa, subsoluri sau spatii inguste. Opriti si colectati scurgerea cu substante non-combustibile, materiale absorbante cum ar fi nisip, pamant, sol spongios sau diatomit si depozitati intr-un container de eliminare in conformitate cu reglementarile locale (consultati sectiunea 13).

Nota: Consultati sectiunea 8 pentru echipamente personale de protectie si sectiunea 13 pentru eliminarea deseurilor.

7. Manipularea si depozitarea

Manipularea:

Nu aduceti substanta in contact cu ochii, pielea sau hainele. Nu ingerati. Folositi doar cu ventilare adecvata. Utilizati respirator potrivit atunci cand ventilatia este inadecvata. Dupa manipulare, intotdeauna clatiti amanuntit mainile cu apa si sapun.

Depozitare:

Depozitati in conformitate cu reglementarile locale.
Depozitati in recipientul original protejat de actiunea directa razelor soarelui, intr-o zona uscata, racoroasa si bine ventilata, departe de materiale incompatibile (consultati sectiunea 10) si de mancare sau bautura. Pastrati recipientul strans inchis si sigilat pana cand este gata de utilizare.

Nu depozitati la temperaturi mai mari de 25°C

Materiale de ambalare recomandate: Utilizati recipientul original

RO
MINISTER
MUNICIPA
TRADUCAT
ENGLEZA
AUT. N
TEL.: 01

8. Controlul expunerii/ protectia personala

Nume ingredient	Limite de expunere profesionala
Etanol	TRGS900 AGW (Germania, 3/2007) Valoare de varf: 1920 mg/m ³ 15 minute Valoare de varf: 1000 ppm 15 minute Timp mediu ponderat: 960 mg/ m ³ 8 ore Timp mediu ponderat: 500 ppm 8 ore
Metanol	TRGS900 AGW (Germania, 3/2007). Absorbit prin piele Valoare de varf: 1080 mg/m ³ 15 minute Valoare de varf: 800 ppm 15 minute Timp mediu ponderat: 270 mg/ m ³ 8 ore Timp mediu ponderat: 200 ppm 8 ore

Controlul expunerii:

Controlul expunerii profesionale: In cazul in care muncitorii sunt expusi unor concentratii care depasesc limita de expunere, trebuie sa utilizeze respiratoare corespunzatoare, certificate.

Protectie respiratorie
(EN 143, 141) Utilizati protectie respiratorie adecvata in cazul in care exista riscul depasirii oricarei limite de expunere.

Protectie maini (EN 374): 1-4 ore: cauciuc butilic, cauciuc nitrilic

Protectie ochi (EN 166): Ochelari de protectie. Scut fata sau orice alt mijloc de protectie completa a fetei.

Protectie piele (EN 467) Sort de protectie. Incaltaminte adecvata de protectie.

9. Proprietati fizice si chimice

Informatii generale

Aspect

Stare de agregare: Lichid

Culoare: Fara culoare

Miros: Dezinfectant

Informatii importante privind sanatatea, siguranta si mediul inconjurator.

pH:	3.5 (100%)
Punct de fierbere:	Nu este disponibil
Punct de topire:	Nu este disponibil
Punct de aprindere:	55 °C (cu capacul inchis)
	Produsul nu sustine arderea
Inflamabilitate (solid, gaz):	Nu este cazul
Proprietati explozibile:	Nu este cazul
Limite de explozie:	Nu este cazul
Proprietati de oxidare:	Nu este disponibil
Presiune vapori:	Nu este cazul
Densitate relativa:	1.04 g/cm ³ (20 °C)
Solubilitate:	Usor solubila in apa calda
Coeficientul de partitie apa- octanol:	Nu este cazul
Vascozitate:	Nu este cazul
Densitate vapori:	Nu este cazul
Rata evaporare (acetat de butil = 1):	Nu este cazul

10. Stabilitate si reactivitate:

Stabilitate:	Stabil in conditii normale.
	Nu amestecati cu alte produse.

11. Informatii toxicologice

Potentiale efecte acute asupra sanatatii

Inhalare:	Nociv prin inhalare. Poate emana gaze, vapori sau pulbere care sunt foarte iritante sau corozive pentru sistemul respirator. Poate cauza sensibilizare prin inhalare
Ingerare:	Nociv daca este inghitit. Poate cauza arsuri gurii, gatului si stomacului.
Contactul cu pielea:	Cauzeaza arsuri. Poate cauza sensibilizarea prin contactul cu pielea.
Contactul cu ochii:	Cauzeaza arsuri
Cancerigenitate:	Nu se cunosc efecte semnificative sau pericole critice.
Mutagenitate:	Nu se cunosc efecte semnificative sau pericole critice.
Toxicitate reproductiva:	Nu se cunosc efecte semnificative sau pericole critice.

12. Informatii ecologice

Ecotoxicitate

Produsul nu este supus clasificarii ecologice in conformitate cu directiva 1999/45/CE

Persistenta si degradabilitate

Totalul componentelor organice continute in produs atinge >60% BOD/COD sau degajare CO₂

Sau >70% reducere DOC in teste pentru facilitarea degradabilitatii – valori prag pentru „degradare rapida” (de exemplu OECD metoda 301)

RO
MINISTER
MIND FANI
TRADUCĂȚI
ENGLIZĂ
AUT. N
TEL.: 07

13. Informatii privind eliminarea

Metode de eliminare:

Producerea deseurilor ar trebui evitata sau redusa atunci cand este posibil. Eliminarea acestui produs, solutii si orice produse secundare trebuie sa fie in conformitate cu cerintele privind protectia mediului si cu legislatia privind eliminarea deseurilor si orice alte cerinte regionale ale autoritatilor locale. Evitati imprastierea sau varsarea materialului si scurgerea si contactul cu solul, cursurile de apa, scurgerile si canalizarea. Poate fi adaugata colectarii generale de deseuri dupa ce a fost golita complet. Utilizati ambalajele pentru reciclare doar atunci cand sunt complet goale.

Catalogul european al deseurilor: 200129*

14. Informatii privind transportul

Reglementari internationale privind transportul

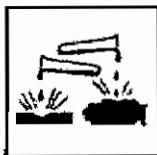
Informatii reglementare	Numar UN	Denumire corespunzatoare a expeditiei	Clasa	Grup ambalaje	Eticheta
Clasa ADR/RID	UN2924	LICHID INFLAMABIL, COROZIV, N.O.S. (etanol, glutaraldehida)	3	III	3,8
Clasa IMDG	UN2924	LICHID INFLAMABIL, COROZIV, N.O.S. (etanol, glutaraldehida)	3	III	3,8

Respectati instructiunile speciale de ambalare pentru transportul aerian.

15. Informatii privind reglementarea

Reglementari UE

Simbol/simboluri pericol:



Contine:

Fraze de risc:

Fraze de siguranta:

Coroziv

glutaral

R20/22 – Daunator prin inhalare si daca este inghitit

R34 – Cauzeaza arsuri

R42/43 – Poate cauza sensibilizare prin inhalare si contact cu pielea

S2 – Nu lasati la indemana copiilor

S23 – Nu inhalati jet pulverizat

S26 – In cazul contactului cu ochii, clatiti imediat cu apa in abundenta si solicitati sfat medical

S36/37/39 – Purtati haine de protectie adecvate, manusi si protectie ochi/fata

S45 - În caz de accident sau dacă vă simțiți rău, a se consulta imediat medicul. (dacă este posibil, i se arată eticheta).

16. Alte informatii

Textul complet al frazelor R la care : R11 – Foarte inflamabil

se face referire in sectiunile 2 si 3 – R23/25 – Toxic prin inhalare sau daca este inghitit

Germania R23/24/25 - Toxic prin inhalare, in contactul cu pielea si daca este inghitit

R39/23/24/25 – Toxic: pericol de efecte serioase ireversibile prin inhalare, in contact cu pielea si daca este inghitit

R20/22 – Daunator prin inhalare si daca este inghitit

R34 – Cauzeaza arsuri

R42/43 – Poate cauza sensibilizare prin inhalare si contact cu pielea

R50 – Foarte toxic pentru organismele acvatice

Istorie

Data imprimării: 30 mai 2008

Data reviziei: 30 mai 2008

Versiune: 3

Intocmit de: Departamentul de Reglementare Ecolab Europa

Nota catre cititor:

Informatiile de mai sus sunt considerate corecte in ceea ce priveste formula folosita pentru fabricarea produsului in tara de origine. Modul in care datele, standardele si reglementarile se modifica si conditiile de utilizare si manipulare sunt dincolo de controlul nostru. NU SE OFERA GARANTII, EXPRIMATE SAU IMPLICITE, PRIVIND CARACTERUL COMPLET SAU ACURATETEA CONTINUA A ACESTOR INFORMATII.

R
MINISTERE
MINA FAN
TRADUCĂT
ENGLEZĂ
AUT. N
TEL.: 07

Subsemnata, Mina FANEA-IVANOVICI, traducător autorizat de Ministerul Justiției cu autorizația nr. 22069/2011, certific exactitatea acestei traduceri cu textul documentului în limba engleză, care a fost vizat de mine.

Traducător autorizat,



România, București

Biroul Notarului Public Iuliana Alexandra Zarafiu

Înregistrat la Curtea de Apel București sub nr. 765/2010

Cod înregistrare fiscală RO29471405/2011, Cod avp 11311

București, Șos. Mihai Bravu nr. 62A, corp A,

Spectrum Business Center, mezanin, sector 2

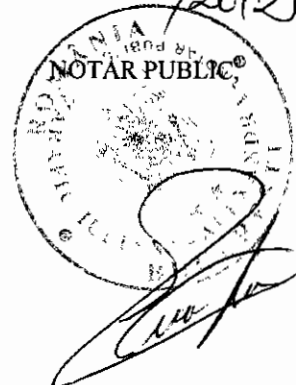
Tel / fax: 021 3236597, email: notarizarafiu@cnpb.ro

ÎNCHEIERE DE LEGALIZARE A SEMNĂTURII TRADUCĂTORULUI Nr. 1762

Anul 2012 luna 08 ziua 08

Iuliana Alexandra Zarafiu, notar public, în temeiul art. 8, lit. e) și j) din Legea 36/1995, cu modificările și completările ulterioare, legalizez semnătura de mai sus a Minei FANEA-IVANOVICI, traducător autorizat cu nr. 22069/2011, în baza specimenului de semnătură depus în fața mea, de pe cele 2... exemplare ale înscrisului.

S-a perceput onorariul notarial de 37.20 lei, TVA inclus, cu chitanța/bon fiscal/ordin de plată nr. FF 198/2012



KONFORMITÄTSERKLÄRUNG / DECLARATION OF CONFORMITY	Revision: 4
	Page: 1 of 1

Wir / we

Name + Adresse der Firma: Name + address of manufacturer:	Ecolab Deutschland GmbH Ecolab-Allee 1 40789 Monheim am Rhein - Germany
--	--

erklären in alleiniger Verantwortung, dass / declare on our own responsibility that

das Medizinprodukt / the medical device	Name / Name Olympus Cleaner
Typ / type	Reiniger für Endoskop-Maschinen Cleaner for automated endoscope re-processors
Klasse / class gemäß / according	I Anhang IX, Regel 1 / annex IX, rule 1
Stock Keeping Unit (SKU)	Ecolab - 3056770 Olympus – WD00216A

allen Anforderungen der Richtlinie 93/42/EWG entspricht.
meets all the provisions of the Directive 93/42/EEC.

Angewandte harmonisierte Normen: Applied harmonized standards:	ISO 14971 ISO 13485
Konformitätsbewertungsverfahren Conformity assessment procedure	Artikel 11 Absatz 5 93/42/EEC gem. Anhang VII article 11 paragraph 5 93/42/EEC acc. to annex VII
Gültigkeitsdauer / Validity	26.05.2021

Pouravi Krefting Digitally signed by
Pouravi Krefting
Date: 2020.05.20
14:53:06 +02'00'

Monheim am Rhein,
19.05.2020

Pouravi Mate
Regulatory Affairs Specialist II

Ort, Datum / place, date	Name und Funktion / name and function
--------------------------	---------------------------------------

KONFORMITÄTSERKLÄRUNG / DECLARATION OF CONFORMITY	Revision: 5
	Page: 1 of 1

Wir / we

Name + Adresse der Firma: Name + address of manufacturer:	Ecolab Deutschland GmbH Ecolab-Allee 1 40789 Monheim am Rhein - Germany
--	--

erklären in alleiniger Verantwortung, dass / declare on our own responsibility that

das Medizinprodukt / the medical device	Name / Name Olympus Disinfectant
Typ / type	Desinfektionsmittel für maschinelle Aufbereitung von Endoskopen Disinfectant for automated endoscope reprocessors
Klasse / class gemäß / according	II b Anhang IX, Regel 15 / annex IX, rule 15

allen Anforderungen der Richtlinie 93/42/EWG entspricht.
meets all the provisions of the Directive 93/42/EEC.

Angewandte harmonisierte Normen: Applied harmonized standards:	ISO 14971 ISO 13485
Benannte Stelle / Notified body	DQS Medizinprodukte GmbH August-Schanz-Str. 21 60433 Frankfurt am Main Deutschland CE 0297
Konformitätsbewertungsverfahren Conformity assessment procedure	Artikel 11 Absatz 3a 93/42/EEC gem. Anhang II article 11 paragraph 3a 93/42/EEC acc. to annex II
Gültigkeitsdauer / validity	26.05.2024



Monheim am Rhein,
15.04.2020

Pouravi Krefting
Regulatory Affairs Specialist II

Ort, Datum / place, date	Name und Funktion / name and function
--------------------------	---------------------------------------

EC Certificate
Directive 93/42/EEC Annex II, excluding Section 4
Full Quality Assurance System
Medical Devices

Registration No.: HD 60123878 0001

Report No.: 12018179 022

Manufacturer: OLYMPUS MEDICAL SYSTEMS CORP.
2951 Ishikawa-cho,
Hachioji-shi, Tokyo 192-8507
Japan

Products: Design and Development, Manufacture of Medical Endoscopy
Systems, Diagnostic, Operation and Treatment Products

(see attachments for products and additional sites included)

Replaces Approval, Registration No.: HD 60078827 0001

Expiry Date: 2022-11-02

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II, section 4 is required.

Effective Date: 2017-11-03

Date: 2017-10-12



Notified Body

M. Aihara
M.Sc. M. Aihara

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

Traducere din limba engleza



APROBARE
Directiva CE 93/42/CEE Anexa II, excluzând Secțiunea 4
Sistem complet de asigurare a calității
Echipamente medicale

Nr. Înregistrare: HD 60123878 0001
Nr. Raport: 12018179 022

Producător: Olympus Medical Systems Corp.
2951 Ishikawa-cho
HACHIOJI-SHI, TOKIO 192-8507
JAPONIA

Produse: Proiectare și dezvoltare, producție de sisteme de endoscopie medicală, produse de diagnostic, operație și tratament.
(a se vedea atasamentele pentru produse și locații suplimentare incluse)
Înlocuiește Aprobarea cu nr. de înregistrare: HD 60078827 0001

Data expirării: 02.11.2022

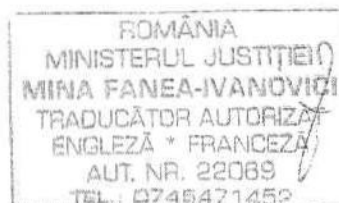
Organismul Notificat declară prin prezenta că au fost îndeplinite cerințele Anexei II, excluzând secțiunea 4 a directivei 93/42/CEE pentru produsele specificate. Producătorul mai sus menționat a stabilit și aplică un sistem de asigurare a calității, care este supus unei supravegheri periodice, definită în Anexa II, secțiunea 5 a directivei menționate anterior. Pentru comercializarea echipamentelor din clasa III acoperite de acest certificat, este necesar un certificat CE de examinare proiectare în conformitate cu Anexa II, secțiunea 4.

Data intrării în vigoare: 03-11-2017

Data: 12.10.2017

Organism notificat
Șampilă:
TUV Rheinland LGA Products GmbH
Zertifizierungsstelle
M.Sc. M. Aihara
(semnătură indescifrabilă)

TÜV Rheinland LGA Products GmbH – Tillystraße 2 – 90431 Nürnberg
TÜV Rheinland LGA Products GmbH este un Organism Notificat în conformitate cu Directiva 93/42/CEE cu privire la echipamentele medicale, cu numărul de identificare 0197



TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Doc. 1/1, Rev.0

**Attachment to
Certificate**

Registration No.: HD 60123878 0001
Report No.: 12018179 022

Manufacturer: OLYMPUS MEDICAL SYSTEMS CORP.
2951 Ishikawa-cho,
Hachioji-shi, Tokyo 192-8507
Japan

Products included:

Medical Endoscopy Systems:

- Endoscopes
- Endotherapy Devices
- Imaging Processors
- Pumps for Endoscopy
- Light Sources
- Position Detecting Units
- Electrothermal Cautery Units
- Integrated Endosurgery Systems
- Endoscopic Regulation/Control Units

Electrosurgical Equipment

Probes and Transducers for Ultrasonic Lithotriptors

Laparoscopic Insufflators

Ultrasound Surgical Equipment

Disinfecting Units

Capsule Endoscopes and Systems

Ultrasound Diagnostic Imaging Systems



Notified Body

Date: 2017-10-12

M.Sc. M. Aihara

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Atasament la
Certificat

Nr. de inregistrare: HD 60123878 0001
Nr. raport: 12018179 022

Producător: Olympus Medical Systems Corp.
2951 Ishikawa-cho
HACHIOJI-SHI, TOKIO 192-8507
JAPONIA

Produse incluse:

- Sisteme medicale de endoscopie:
 - Endoscoape
 - Echipamente endoterapie
 - Procesoare de imagine
 - Pompe pentru endoscopie
 - Surse de lumină
 - Unități de detectare poziție
 - Unități de cauterizare electrotermică
 - Sisteme endochirurgicale integrate
 - Unitati de control/reglare endoscopice
- Echipamente electrochirurgicale
- Sonde și traductoare pentru litotriptoare cu ultrasunete
- Insuflatoare laparoscopice
- Echipamente chirurgicale cu ultrasunete
- Unitati de sterilizare
- Sisteme și endoscoape capsulă
- Sisteme de imagistica pentru diagnostic cu ultrasunete

Data: 12.10.2012

Organism notificat
Stampilă:
TUV Rheinland LGA Products GmbH
Zertifizierungsstelle
M.Sc. M. Aihara
(semnătură indescifrabilă)



EC Certificate
Directive 93/42/EEC Annex V
Production Quality Assurance
Medical Devices

Registration No.: DD 60123877 0001

Report No.: 12018179 022

Manufacturer: OLYMPUS MEDICAL SYSTEMS CORP.
2951 Ishikawa-cho,
Hachioji-shi, Tokyo 192-8507
Japan

Products: Sterile Endotherapy Devices used in conjunction with
Endoscopes, Sterile Non Active Instruments used in
conjunction with Endoscopes and Sterile Non Active
Instruments used in conjunction with Medical Ultrasound
Diagnostic Imaging Systems
Replaces Approval, Registration No.: DD 60116725 0001

Expiry Date: 2022-11-02

The Notified Body hereby declares that the requirements of Annex V of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex V, section 4 of the aforementioned directive. For placing on the market of class IIb and class III devices covered by this certificate an EC type-examination certificate according to Annex III is required.

Effective Date: 2017-11-03

Date: 2017-10-12



Notified Body

M. Aihara
M.Sc. M. Aihara

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

Traducere din limba engleza



CERTIFICAT CE
Directiva CE 93/42/CEE Anexa V
Asigurarea calității producției
Echipamente medicale

Nr. Înregistrare: DD 60123877 0001

Nr. Raport: 12018179 022

Producător: Olympus Medical Systems Corp.
2951 Ishikawa-cho
HACHIOJI-SHI, TOKIO 192-8507
JAPONIA

Produse: Echipamentelor sterile pentru endoterapie, utilizate împreună cu endoscoape, instrumente sterile non-active utilizate împreună cu endoscoape și instrumente sterile non-active utilizate împreună cu sisteme medicale de imagistică diagnostic cu ultrasunete.
Înlocuiește Aprobarea, nr. înregistrare: DD 60116725 0001

Data expirării: 02.11.2022

Organismul Notificat declară prin prezenta că au fost îndeplinite cerințele Anexei V a directivei 93/42/CEE pentru produsele specificate. Producătorul mai sus menționat a stabilit și aplică un sistem de asigurare a calității, care este supus unei supravegheri periodice, definită în Anexa V, secțiunea 4 a directivei menționate anterior. Pentru comercializarea echipamentelor din clasa IIb și clasa III acoperite de acest certificat, este necesar un certificat CE de examinare tip în conformitate cu Anexa III.

Data intrării în vigoare: 03-11-2017

Data: 12.10.2017

Organism notificat

Stampilă:

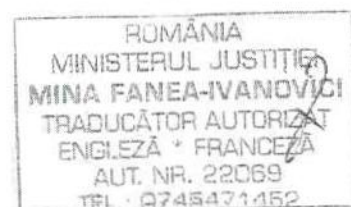
TUV Rheinland LGA Products GmbH

Zertifizierungsstelle

M.Sc. M. Aihara

(semnătură indescifrabilă)

TÜV Rheinland LGA Products GmbH – Tillystraße 2 – 90431 Nürnberg
TÜV Rheinland LGA Products GmbH este un Organism Notificat în conformitate cu Directiva 93/42/CEE cu privire la echipamentele medicale, cu numărul de identificare 0197





Reprocessing of Flexible Endoscopes Olympus Compatibility Statement

1. Reprocessing with the Olympus ETD System

Based on the Olympus Tokyo test reports and our practical experience, we herewith state that below listed automatic processes for endoscope reprocessing have been found compatible with Olympus flexible endoscopes. The processes have been tested for the following machines: ETD4, ETD3, ETD2, miniETD2, miniETD, ETD Double.

The hygienic efficacy of the ETD processes has been thoroughly tested by independent hygienic institutes. For details on test methods and results, please ask for the ETD certificates.

Product Name	Distributor	Major Ingredient
ETD PAA Process with - Olympus EndoDet - Olympus EndoDis - Olympus EndoAct	OLYMPUS	Peracetic Acid
ETD GA Process with (*) - Olympus CLEANER (CETD) - Olympus DISINFECTANT (DETD)	OLYMPUS	Glutaraldehyde

(*) not for ETD Double

REMARKS

It is known from our field experience that applying a combination of different processes for the reprocessing of endoscopes might accelerate damages to materials of the instruments. The above information is only valid for the exclusive influence of the mentioned process using the products named above.

2. Detergents for PreCleaning & Manual Reprocessing

For precleaning or manual endoscope cleaning purposes the use of suitable products with the following main characteristics shall be considered:

- Detergents classified by the manufacturer as Medical grade class I products
- Products with low foaming characteristics
- Products which are pH neutral
- Products mainly based on tenside or enzymatic functional compounds

Please consult your local detergent manufacturer if the above criteria are met.

3. Disinfectants for Manual Reprocessing

Based on the Olympus Tokyo test reports we herewith state that the below listed disinfectants for manual endoscope reprocessing have been found compatible with Olympus flexible endoscopes.

Product Name	Manufacturer/Distributor	Major Ingredient
CIDEX	Johnson & Johnson	Glutaraldehyde
CIDEX OPA ⁽¹⁾ ⁽²⁾	Johnson & Johnson	Ortho-phthalaldehyde
GIGASEPT	Schulke & Mayr	Glutaraldehyde + Formaldehyde
Nu-CIDEX	Johnson & Johnson	Peracetic acid
SEKUSEPT Aktiv	Ecolab GmbH & Co.	Peracetic acid
SEKUSEPT Forte S	Ecolab GmbH & Co.	Glutaraldehyde + Formaldehyde
SEKUSEPT Plus ⁽²⁾	Ecolab GmbH & Co.	Glucoprotamine
SEKUSEPT Pulver +Aktivator	Ecolab GmbH & Co.	Peracetic acid
STERANIOS 2%	Anios	Glutaraldehyde

⁽¹⁾ Slight cosmetic changes may be observed (transparency at tubes and glue / greyish colours).

⁽²⁾ Products are compatible with Olympus miniature probes.

REMARKS

- Compatibility for manual reprocessing only. Reprocessing process by WD (Washer Disinfector) is **not** involved.
- For chemicals not supplied by OLYMPUS, OLYMPUS is unable to make any recommendations in relation to the microbiological efficacy of a disinfection agent. An such request should be addressed to the chemical manufacturer or should be investigated and reviewed by the hospital's Infection Control Committee or equivalent authority in conjunction with other relevant hospital departments. The information

provided here only addresses the material and functional compatibility of OLYMPUS flexible endoscopes against these agents.

- The result of the compatibility test is closely related to the product lot that was supplied to Olympus. Any changes to the recipe of the agent that might be made afterwards by the chemical manufacturer may lead to different material compatibility results.
- The test result and conclusions are only valid for the protocol undertaken with the specific working condition of the agent according to its label instructions (i.e. concentration, temperature and contact time, etc.)
- It is known from our field experience that applying a combination of different processes for the reprocessing of endoscopes might accelerate damages to materials of the instruments. The above information is only valid for the exclusive influence of the products named above.

NOTE

In the above list, no differentiation has been made between fully compatible and functionally compatible. Products listed can be either fully compatible or functionally compatible:

- Fully Compatible

No functional and no cosmetic changes were observed with tested instruments.

- Functionally Compatible

No functional changes were observed with tested instruments however some cosmetic changes (i.e. staining, discoloration, etc.) might be observed in use. For disinfectants not listed, Olympus is neither in a position to grant material compatibility nor to accept liability or guarantee claims.

4. Disinfectants not tested by Olympus

The products listed in the previous chapter (3. **Disinfectants for Manual Reprocessing**) have been tested by OLYMPUS for material compatibility. However, there is a broad range of products in the different European countries available and applied for manual endoscope reprocessing, which had not been tested by OLYMPUS for material compatibility with OLYMPUS flexible endoscopes. Based on customer feedback information, such products may be used for endoscope reprocessing purposes. It is up to the hospital service provider to decide for using such products on their own risk. OLYMPUS can not be liable in case of any material compatibility problems on OLYMPUS flexible endoscopes.

Product Name	Manufacturer / Distributor	Comment
SEKU EXTRA	Ecolab GmbH & Co.	Successor Product of Sukucid N which was formerly approved for compatibility by Olympus Tokyo
KORSOLEX extra	BODE	Aldehyde based disinfectant which is comparable to previous Kohrsolin recipes. There is no indication for critical feedback about material compatibility.

Product Name	Manufacturer / Distributor	Comment
GIGASEPT PA	Schuelke & Mayr	Peracetic acid based products! Applied by numerous users and no concrete evidence about compatibility concerns
Anioxyde 1000	Anios	
MEDDIS	MediChem	Product based on non-oxidising compounds. Only limited practical experience when used on OLYMPUS endoscopes

REMARKS

- The above listed products were **not** proven by OLYMPUS for material compatibility aspects.
- OLYMPUS is unable to make any recommendations in relation to the microbiological efficacy of a disinfection agent. Any such request should be addressed to the chemical manufacturer or should be investigated and reviewed by the hospital's Infection Control Committee or equivalent authority in conjunction with other relevant hospital departments.
- It is important to acknowledge that detergents and disinfectants which are applied outside neutral pH range (pH < 6,5 and pH >7,5) may cause increased wear and tear to endoscopes. The manufacturer of such detergent or disinfectant should be asked for clear endoscope compatibility statement.
- The above listed overview is not representative for all products in the market and specified for endoscope reprocessing by their manufacturers or distributors.

5. Reprocessing with other washer-disinfectors

Washer-disinfectors which have passed the type and works testing requirements according to the EN ISO 15883 standards, should be equipped with suitable compliance statements, demonstrating sufficient reprocessing performance and sufficient material compatibility. According the EN ISO 15883-4, the manufacturer of such devices is obliged to provide statements about which reprocessing chemicals are compatible and which endoscopes can be reprocessed. Users shall ask the manufacturer of such products for written statements.

Olympus will be not able to evaluate such systems for material compatibility

Hamburg, July 2015

Product Management Endoscope Reprocessing Systems

Annette Rittich

Reinhard Blum