AGENȚIA MEDICAMENTULUI
ȘI DISPOZITIVELOR MEDICALE

REGISTRUL DE STAT AL DISPOZITIVELOR MEDICALE

Tip	Denumire
I.2. Declarația de conformitate CE	Declaratia de comformitate CE
I.3. Certificatul CE	Certificat CE

Введите текст для поиска...

Nr	Denumire	Den.comerc.	Model	Nr. catalog	Tara	Producatorul	Reprezentant	Ordin	Data	Cod vamal
			Proteazone							
DM000238756	DEZINFECTANT PENTRU SUPRAFEȚE ȘI DIPOZITIVE MEDICALE		PROTEAZONE		Italia	CANTEL MEDICAL (ITALY) S.R.L.	DATACONTROL S.R.L.	Rg04-000246	30-09-2019	
DM000239356	DEZINFECTANT PENTRU SUPRAFEȚE ȘI DIPOZITIVE MEDICALE		PROTEAZONE ERS		Italia	CANTEL MEDICAL (ITALY) S.R.L.	DATACONTROL S.R.L.	Rg04-000246	30-09-2019	

Содержит([Model], 'Proteazone') Очистить

Digitally signed by Grabazei Alexandru
Date: 2021.04.15 15:31:18 EEST
Reason: MoldSign Signature
Location: Moldova

EC-CERTIFICATE

(Full quality assurance system)

This is to certify that the company

BHT Hygienetechnik GmbH
Division

Messerschmittstr. 11
86368 Gersthofen
Germany

has implemented and maintains a full quality assurance system which applies to the products at every stage from design to final controls.

Through an audit, documented in a report, performed by DQS Medizinprodukte GmbH, it was verified that the management system fulfills the requirements of

Annex II – excluding Section 4 of Council Directive 93/42/EEC concerning medical devices

with respect to the following medical devices:

Device family	Device	Class
Disinfection equipment	INNOVA Serie M2 / E2 / E2 CMS INNOVA Serie M2s / E2s / E2s CMS INNOVA Serie M3 / E3 / E3CMS INNOVA Serie M4 / E4 / E4CMS INNOVA Serie M5 / E5 / E5CMS / E5CMS EFF INNOVA Serie 3s INNOVA Serie 4s	IIb

The manufacturer is subject to surveillance according to Annex II, Section 5. The CE marking with the Notified Body Identification Number (0297) may be affixed on the devices listed in the certificate. An EC Design Examination Certificate according to Annex II, Section 4 is required for class III devices covered by this certificate. The certificate is in the case of class I(s) devices (I(s) = class I products placed on the market in sterile conditions) limited to the aspects of manufacture concerned with securing and maintaining sterile conditions. The certificate is in the case of class I(m) devices (I(m) = class I devices with a measuring function) limited to the aspects of manufacture concerned with the conformity of the products with the metrological requirements.

Certificate registration no.	019906 MR2
Certificate unique ID	170722750
Effective date	2018-09-22
Expiry date	2022-07-15
Frankfurt am Main	2018-09-22

DQS Medizinprodukte GmbH

Sigrid Uhlemann
Managing Director

Dr. Thomas Feldmann
Head of Certification Body

August-Schanz-Straße 21, 60433 Frankfurt am Main,
Tel. +49 (0) 69 95427-300, medical.devices@dqs-med.de

DQS Medizinprodukte GmbH is a Notified Body according to Council Directive 93/42/EEC concerning medical devices with the Identification Number 0297.

CERTIFICATE

This is to certify that the company

BHT Hygienetechnik GmbH
Division

Messerschmittstr. 11
86368 Gersthofen
Germany

Scope:
Design and development, manufacturing, sales, installation and maintenance of units and equipment for cleaning, disinfection, drying of contaminated material in hospitals, medical practices, industry and laboratories.

Through an audit, documented in a report, performed by DQS Medizinprodukte GmbH, it was verified that the management system fulfills the requirements of the following standard:

EN ISO 13485 : 2012 + AC : 2012

Certificate registration no.	019906 MP2012
Certificate unique ID	170686045
Effective date	2017-07-16
Expiry date	2020-07-15
Frankfurt am Main	2017-07-12

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-16021-01-01

DQS Medizinprodukte GmbH

Sigrid Uhlemann
Managing Director

Dr. Thomas Feldmann
Head of Certification Body

Accredited Body: DQS Medizinprodukte GmbH, August-Schanz-Str. 21, 60433 Frankfurt a. M., Germany

CERTIFICATO CE - SISTEMA COMPLETO DI GARANZIA DI QUALITÀ

EC CERTIFICATE - FULL QUALITY ASSURANCE SYSTEM

APPROVAZIONE DEL SISTEMA DI QUALITÀ ATTUATO DA
APPROVAL OF THE QUALITY SYSTEM OPERATED BY

CANTEL MEDICAL (ITALY) S.R.L.

IT - 00071 POMEZIA (RM) - VIA LAURENTINA 169

SITI / SITES

IT - 00071 POMEZIA (RM) - VIA LAURENTINA 169

PER I SEGUENTI DISPOSITIVI O GRUPPI DI DISPOSITIVI / *FOR THE FOLLOWING DEVICES OR GROUPS OF DEVICES*

Disinfettanti per dispositivi medici

Disinfectants for medical devices

Certiquality S.r.l., Organismo Notificato n° 0546, certifica che il sistema di qualità
Certiquality S.r.l., Notified Body n°0546, certifies that the quality system

è conforme ai requisiti della Direttiva 93/42/CEE, Allegato **II** ad esclusione del punto 4
is in compliance with the requirements of Directive 93/42/EEC, Annex *excluding section 4*

RAPPORTO DI AUDIT N° *AUDIT REPORT NO.* **24884**

CERTIFICATO N. *CERTIFICATE N.* **24884**

IL PRESENTE CERTIFICATO E' SOGGETTO AL RISPETTO DEL REGOLAMENTO PER LA CONCESSIONE E IL MANTENIMENTO DELL'APPROVAZIONE DI SISTEMA QUALITA' AI SENSI DELLA DIRETTIVA 93/42/CEE

THE USE AND THE VALIDITY OF THE CERTIFICATE SHALL SATISFY THE REQUIREMENTS OF THE REGULATIONS FOR AWARDING AND MAINTENANCE OF QUALITY SYSTEM APPROVAL IN ACCORDANCE WITH DIRECTIVE 93/42/EEC

Il SISTEMA QUALITÀ E' SOGGETTO A SORVEGLIANZA PERIODICA
THE QUALITY SYSTEM IS SUBJECT TO PERIODICAL SURVEILLANCE

LA VERIFICA DEL SISTEMA QUALITÀ E' LIMITATA AGLI ASPETTI DELLA FABBRICAZIONE CONCERNENTI LA CONFORMITÀ AI REQUISITI METROLOGICI PER I DISPOSITIVI DI CLASSE I CON FUNZIONE DI MISURA E AGLI ASPETTI DELLA FABBRICAZIONE CHE RIGUARDANO IL RAGGIUNGIMENTO E IL MANTENIMENTO DELLO STATO STERILE PER I DISPOSITIVI DI CLASSE I STERILE.
THE AUDIT OF THE QUALITY SYSTEM IS RESTRICTED TO THE ASPECTS OF MANUFACTURE CONCERNED WITH THE CONFORMITY OF THE DEVICES WITH METROLOGICAL REQUIREMENTS FOR DEVICES IN CLASS I WITH MEASURING FUNCTION AND WITH SECURING AND MAINTAINING STERILE CONDITIONS FOR DEVICE IN CLASSE I IN STERILE CONDITION

IL PRESENTE CERTIFICATO NON E' DA RITENERSI VALIDO SE NON ACCOMPAGNATO DAL RELATIVO ALLEGATO
THIS CERTIFICATE IS NOT VALID WITHOUT THE RELEVANT ANNEX

PRIMA EMISSIONE *FIRST ISSUE* 08/04/1998

EMISSIONE CORRENTE *CURRENT ISSUE* 02/10/2018

DATA DI SCADENZA *EXPIRY DATE* 11/07/2022

CERTIQUALITY S.r.l.

ORGANISMO NOTIFICATO N° 0546

NOTIFIED BODY N° 0546

ALLEGATO AL CERTIFICATO N. **24884**

ANNEX TO CERTIFICATE N.

CANTEL MEDICAL (ITALY) S.R.L.

SITI / *SITES*

IT - 00071 POMEZIA (RM) - VIA LAURENTINA 169

ELENCO PRODOTTI / *PRODUCT LIST*

ADASPOR, ADASPOR ERS, ADASPOR M, ADASPOR MONODIE, ADASPOR PENTADIE, ADASPOR SINGLE SHOT, PROLYSTICA AUTO PAA, BLUESTERIL ALCOLICO, BLUSTERIL FERRI CE, CLOREXAN FERRI, NEO PROTEOZIM PLUS 500, PROTEOZIM PLUS 400, PROTEOZIM PLUS 1000, PROTEAZONE,PROTEAZONE ERS, PROTEAZONE OD, SPOREX, SPOREX OPA, SPOREXIN PLUS DS, SPOREXIN PLUS OD, SPOREXIN PLUS SALVIETTE, SPOREXIN PLUS VACUUM, SPORIDOX, SPORIDOX PLUS, ISASPOR, ISASPOR MONODIE, ISASPOR SINGLE SHOT, ISACLEAN, PROTEODONT, BACTRYL SPRAY, BACTRYL WIPES, ADASPOR PLUS PRONTO (ADASPOR PLUS READY TO USE), ADASPOR PLUS CONCENTRATO, ADASPOR PLUS MONODIE, ADASPOR PLUS SINGLE SHOT, ISASPOR M, ISASPOR PENTADIE, ISASPOR ERS, ADASPOR PLUS M, ADASPOR PLUS PENTADIE, ADASPOR PLUS ERS, ISACLEAN SPRAY, SPOREXIN SPRAY, SPOREXIN VACUUM, SPOREXIN WIPES.

IL PRESENTE ALLEGATO NON E' DA RITENERSI VALIDO SE NON ACCOMPAGNATO DAL RELATIVO CERTIFICATO
THIS ANNEX IS NOT VALID WITHOUT THE RELEVANT CERTIFICATE

PRIMA EMISSIONE *FIRST ISSUE* 08/04/1998

EMISSIONE CORRENTE *CURRENT ISSUE* 02/10/2018

DATA DI SCADENZA *EXPIRY DATE* 11/07/2022

CERTIQUALITY S.r.l.

www.imq.it

CISQ is a member of

IQNet

THE INTERNATIONAL CERTIFICATION NETWORK

www.iqnet-certification.com

IQNet, the association of the world's first class certification bodies, is the largest provider of management System Certification in the world. IQNet is composed of more than 30 bodies and counts over 150 subsidiaries all over the globe.

CERTIFICATO N.
CERTIFICATE N. 1250.2019

SI CERTIFICA CHE IL SISTEMA DI GESTIONE PER LA QUALITA' DI
WE HEREBY CERTIFY THAT THE QUALITY MANAGEMENT SYSTEM OPERATED BY

CANTEL MEDICAL (ITALY) SRL

VIA LAURENTINA 169 - 00071 POMEZIA (RM)

UNITA' OPERATIVE / *OPERATIVE UNITS*

VIA LAURENTINA 169 - 00071 POMEZIA (RM)

E' CONFORME ALLA NORMA / *IS IN COMPLIANCE WITH THE STANDARD*

UNI CEI EN ISO 13485:2016

PER LE SEGUENTI ATTIVITA' / *FOR THE FOLLOWING ACTIVITIES*

Progettazione, sviluppo, produzione e vendita di disinfettanti, sterilizzanti chimici e detergenti per dispositivi medici. Progettazione, sviluppo, produzione, commercializzazione e assistenza tecnica di dispositivi per il lavaggio, la disinfezione e la sterilizzazione di dispositivi medici

Design, development, manufacturing and sales of disinfectants, chemical sterilizing and detergents for medical devices. Design, development, production, sales and technical service of device for washing, disinfection and sterilization of medical devices

Ulteriori informazioni riguardanti l'applicabilità dei requisiti UNI CEI EN ISO 13485:2016 possono essere ottenute consultando l'organizzazione
Further clarifications regarding the applicability of UNI CEI EN ISO 13485:2016 requirements may be obtained by consulting the organization

IL PRESENTE CERTIFICATO E' SOGGETTO AL RISPETTO DEL
REGOLAMENTO PER LA CERTIFICAZIONE DEI SISTEMI DI GESTIONE
THE USE AND THE VALIDITY OF THE CERTIFICATE SHALL SATISFY THE REQUIREMENTS OF THE RULES FOR CERTIFICATION OF MANAGEMENT SYSTEMS

DATE:	PRIMA CERTIFICAZIONE *FIRST CERTIFICATION*	EMISSIONE CORRENTE *CURRENT ISSUE*	SCADENZA *EXPIRY*
	1997-07-25	2019-07-11	2021-07-05

IMQ S.p.A. - VIA QUINTILIANO, 43 - 20138 MILANO ITALY
Management Systems Division - Flavio Ornago

La data di prima certificazione è riferita al rilascio da parte di altro Organismo
First certification date is related to issue date of another Certification Body

ACCREDIA
L'ENTE ITALIANO DI ACCREDITAMENTO

SGQ N° 005 A

Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC
Signatory of EA, IAF and ILAC Mutual Recognition Agreements

La validità del certificato è subordinata a sorveglianza annuale e riesame completo del Sistema di Gestione con periodicità triennale
The validity of the certificate is submitted to annual audit and a reassessment of the entire Management System within three years

IMQ

Organismo di Certificazione Federato CISQ
www.imq.it

FEDERAZIONE CISQ

www.cisq.com

CISQ è la Federazione Italiana di Organismi di Certificazione dei sistemi di gestione aziendale.
CISQ is the Italian Federation of management system Certification Bodies.

THE INTERNATIONAL CERTIFICATION NETWORK

CERTIFICATE

CISQ/IMQ *has issued an IQNet recognized certificate that the organization:*

CANTEL MEDICAL (ITALY) SRL

VIA LAURENTINA 169 - 00071 POMEZIA (RM)

has implemented and maintains a

Quality Management System

for the following scope:

Design, development, manufacturing and sales of disinfectants, chemical sterilizing and detergents for medical devices. Design, development, production, sales and technical service of device for washing, disinfection and sterilization of medical devices

Further clarifications regarding the applicability of UNI CEI EN ISO 13485:2016 requirements may be obtained by consulting the organization

which fulfills the requirements of the following standard:

UNI CEI EN ISO 13485:2016

Issued on: **2019 - 07 - 11**
Expires on: ***2021 - 07 - 05***

This attestation is directly linked to the IQNet Partner's original certificate and shall not be used as a stand-alone document

Registration Number: IT - 126041

Alex Stoichitoiu
President of IQNET

Ing. Claudio Provetti
President of CISQ

IQNet Partners*:
AENOR *Spain* AFNOR Certification *France* APCER *Portugal* CCC *Cyprus* CISQ *Italy*
CQC *China* CQM *China* CQS *Czech Republic* Cro Cert *Croatia* DQS Holding GmbH *Germany* FCAV *Brazil*
FONDONORMA *Venezuela* ICONTEC *Colombia* Inspecta Sertifiointi Oy *Finland* INTECO *Costa Rica*
IRAM *Argentina* JQA *Japan* KFQ *Korea* MIRTEC *Greece* MSZT *Hungary* Nemko AS *Norway* NSAI *Ireland*
NYCE-SIGE *México* PCBC *Poland* Quality Austria *Austria* RR *Russia* SII *Israel* SIQ *Slovenia*
SIRIM QAS International *Malaysia* SQS *Switzerland* SRAC *Romania* TEST St Petersburg *Russia* TSE Turkey YUQS *Serbia*
IQNet is represented in the USA by: AFNOR Certification, CISQ, DQS Holding GmbH and NSAI Inc.

* The list of IQNet partners is valid at the time of issue of this certificate. Updated information is available under www.iqnet-certification.com

Safety Data Sheet

SECTION 1. Identification of the Substance/Mixture and of the Company/Firm

1.1. Product Identifier

Name	**PROTEAZONE ®**
Chemical name and synonyms	

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

Description/Use	Adazone® solution (CAS 267638-83-8) with non-ionic and cationic surfactants. Classification Medical Device Class IIb Directive 93/42/EEC, as amended Decontamination solution and detergent for invasive and non-invasive medical devices and for electro-medical equipment. Professional use only.
Uses advised against	None in particular.

1.3. Details of the Supplier on the Safety Data Sheet

Company Name	Cantel Medical (Italy) S.R.L.
Address	Via Laurentina, n. 169
Town and Country	00071 Pomezia (RM) ITALY telephone +39.06/9145399 E-mail: info@cantelmedical.it
email address of the person responsible, person responsible for the safety data sheet	Technical Director/Qualified Person (QP): direzionetecnica@cantelmedical.it

1.4. Emergency telephone number

	Telephone numbers of the main poison centers in Italy (open 24 hours a day): Poison Centre Niguarda Ca' Granda 02.66101029 (CAV A.O.Niguarda – Milan)
For urgent inquiries refer to	Emergency telephone number of the company (24/24 hours): tel. +39.06/9145399 *(Technical Support)*

SECTION 2. Hazards Identification.

2.1. Classification of the Substance or Mixture

The product is classified as a dangerous substance pursuant to the provisions laid within in Regulation (EC) 1272/2008 (CLP) (and subsequent amendments). The product requires therefore a safety data sheet in accordance with the provisions of Regulation (EC) 1907/2006 and subsequent amendments.
Any additional information concerning risks to health and/or environment are stated in sections 11 and 12 of this sheet.

2.1.1 Regulation 1272/2008 (CLP) and subsequent amendments.

Classification and hazard statements:

Flam. Liq. 3	H226
Acute Tox. 4	H302
Eye Dam. 1	H318
Skin Irrit. 2	H315
Aquatic Acute 3	H412

2.1.2. Directives 67/548/EEC and 1999/45/CE and subsequent amendments.

Hazard symbols: Xi
R-Phrases: 10-41
The full texts for risk phrases (R) and indications of danger (H) are specified in section 16 of this sheet.

2.2. Label elements.

Hazard labelling pursuant to Regulation (EC) 1272/2008 (CLP) and subsequent amendments.

Warnings:	Danger
H226	Flammable liquid and vapours.
H302	Harmful if swallowed.
H318	Causes serious eye injuries.
H315	Causes skin irritation.
H412	Harmful to aquatic organisms with long-term effects.
EUH208	Contains: SUBTILISIN May cause an allergic reaction.
P210	Keep away from heat sources, hot surfaces, sparks, open flames or other ignition sources. Do not smoke.
P280	Wear protective gloves / clothing / protect your eyes / face.
P305+P351+P338	IF IN EYES: rinse continuously with water for several minutes. Remove contact lenses if present and easy to do. Continue rinsing.
P310	Immediately contact a POISON CENTRE.
P501	Dispose of the product/container in conformity with local/national/international legislation
Contains:	DIDECYLDIMETHYLAMMONIUM CHLORIDE POLY(OXY-1,2-ETHANEDIYL), .ALPHA.-TRIDECYL-.OMEGA.-HIDROXY-,BRANCHED /

2.3. Other Hazards.

Information not available.

SECTION 3. Composition/Information on Ingredients

3.1. Substances.

Information not relevant.

3.2. Mixtures.

Contains:

Identification.	Conc. %.	67/548/EEC Classification.	1272/2008 (CLP) Classification.
POLY(OXY-1,2-ETHANEDIYL), .ALPHA.-TRIDECYL-.OMEGA.-HIDROXY-,BRANCHED / CAS. - CE. - INDEX. - Reg. No.	18 - 19.5	Xn R22, Xi R41	Acute Tox. 4 H302, Eye Dam. 1 H318
ISOPROPANOL CAS. 67-63-0 CE. 200-661-7 INDEX. 603-117-00-0 Reg. No. -	6 - 7	R67, F R11, Xi R36	Flam. Liq. 2 H225, Eye Irrit. 2 H319, STOT SE 3 H336
DIDECYLDIMETHYLAMMONIUM CHLORIDE CAS. 7173-51-5 CE. 230-525-2 INDEX. 612-131-00-6 Reg. No. -	3.5 - 4	C R34, Xn R22, N R50	Acute Tox. 3 H301, Skin Corr. 1B H314, Aquatic Acute 1 H400 M=10
ETHANE-1,2-DIOL CAS. 107-21-1 CE. 203-473-3 INDEX. 603-027-00-1 Reg. No. 01-2119456816-28-XXXX	1 - 1.5	Xn R22	Acute Tox. 4 H302, STOT RE 2 H373
PENTASODIUM DIETHYLENETRIAMINEPENTAACETATE CAS. 140-01-2 CE. 205-391-3 INDEX. - Reg. No. 01-2119474445-33	0.3 - 0.4	Repr. Cat. 3 R63, Xn R20, Xi R36	Repr. 2 H361d, Acute Tox. 4 H332, Eye Irrit. 2 H319
SUBTILISIN CAS. 9014-01-1 CE. 232-752-2 INDEX. 647-012-00-8 Reg. No. 01-2119480434-38	0.1 - 0.2	Xn R22, Xn R42, Xi R37/38, Xi R41, N R50	Acute Tox. 4 H302, Eye Dam. 1 H318, Skin Irrit. 2 H315, STOT SE 3 H335, Resp. Sens. 1 H334, Aquatic Acute 1 H400 M=1

Note: Value exceeding the excluded range.

The full texts for risk phrases (R) and indications of danger (H) are specified in section 16 of this sheet.
T+ = Very Toxic(T+), T = Toxic(T), Xn = Harmful(Xn), C = Corrosive(C), Xi = Irritating(Xi), O = Oxidizing(O), E = Explosive(E), F+ = Extremely flammable(F+), F = Highly Flammable(F), N = Dangerous to the environment(N)

SECTION 4. First Aid Measures.

4.1. Description of First Aid Measures.

EYES: Remove any contact lenses. Wash immediately and thoroughly with water for at least 30/60 minutes, with eyes wide open. Consult a physician immediately.
SKIN: Take off contaminated clothing. Take a shower immediately. Consult a physician immediately.
INGESTION: Drink water as much as possible. Consult a physician immediately. Do not induce vomiting unless expressly recommended by the physician.
INHALATION Seek medical advice immediately. Bring the subject outdoors, away from the place of the accident. If breathing stops, provide artificial respiration. Take adequate precautions for the first aider.
PROTECTION MEASURES FOR THE FIRST AIDERS: for the PPE needed for first aid refer to section 8.2 of this safety data sheet.

4.2. Most Important Symptoms and Effects, both Acute and Delayed.

For the symptoms and effects due to the substances contained in it, see chap. 11.

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

Information not available.

SECTION 5. Fire-Fighting Measures.

5.1. Extinguishing Media.

SUITABLE EXTINGUISHING MEDIA
Extinguishing media are carbon dioxide, foam, chemical powder. For product leaks and spills that did not cause a fire, water spray can be used to disperse the flammable vapours and protect the people involved in stopping the leakage.
UNSUITABLE EXTINGUISHING MEDIA
Do not use water jets. Water is not effective to extinguish the fire but can be used to cool close containers exposed to flames, thus preventing fires and explosions.

5.2. Special Hazards Arising from the Substance or Mixture.

DANGERS FROM EXPOSURE IN CASE OF FIRE
Excess pressure may form in containers exposed to fire with explosion hazard. Avoid breathing the combustion products.

5.3. Advice for Fire-fighters.

GENERAL INFORMATION
Use jets of water to cool the containers to prevent product decomposition and the development of substances potentially hazardous for health. Always wear personal protection devices including fire equipment. Collect contaminated fire fighting water separately, it must not be discharged into the drains. Dispose of the contaminated water used for fire fighting and the residue of the fire according to the rules in force.
EQUIPMENT
Normal equipment for fire fighting such as self-contained breathing apparatus (EN 137), flame retardant turnout gear (EN469), flame-retardant gloves (EN 659) and boots for firemen (HO A29 or A30).

SECTION 6. Measures in Case of Accidental Release.

6.1. Personal Precautions, Protective Equipment and Procedures in Case of Emergency.

Stop leak if without risk. Wear appropriate protective devices (including the personal protective equipment referred to in section 8 of the safety data sheet) in order to prevent contamination of the skin, eyes and personal clothing. These guidelines apply to staff who work under both standard and emergency conditions.

6.2. Environmental Precautions.

Prevent the product from entering sewers, surface waters, and groundwater.

6.3. Methods And Material For Containment And Remediation.

Suck up the spilled product into an appropriate container. Assess the compatibility of the container to use with the product, checking section 10. Absorb the remaining product with inert absorbent.
Ensure adequate ventilation of the area affected by the loss. Check any incompatibility for the material of the containers in section 7. Disposal of contaminated material must be carried out in accordance with the provisions of section 13.

6.4. References to Other Sections

Any information relating to personal protective equipment and disposal are given in sections 8 and 13.

SECTION 7. Handling And Storage.

7.1. Precautions for Safe Handling

Keep away from heat, sparks and flames, do not smoke or use matches or lighters. The vapours can be ignited with an explosion, so you must avoid accumulation holding open doors and windows and ensuring a cross ventilation. Without proper ventilation, the fumes can accumulate on the ground and ignite even from a distance, if ignited, with danger of backfiring. Avoid the accumulation of electrostatic charges. Connect to a grounded socket in the case of large packaging during the decanting process and wear anti-static shoes. The strong shaking and vigorous flow of liquid in the pipes and equipment may cause formation and accumulation of electrostatic charges. To avoid the danger of fire and explosion, never use compressed air in the movement. Open the containers with caution, because they may be pressurized. Do not eat, drink or smoke during use. Avoid release to the environment.

7.2. Conditions for Safe Storage, Including any Incompatibilities.

Keep only in original container. Keep the containers closed, in a well ventilated place, sheltered from direct sunlight. Store in a cool, well-ventilated area away from heat sources, open flames, sparks and other sources of ignition. Store containers away from any incompatible materials, refer to section 10.

7.3. Specific end uses.

No use other than those indicated in section 1.2 of this safety data sheet.

SECTION 8. Exposure controls/personal protection.

8.1. Control Parameters.

Reference Standards:

Italy	Legislative Decree April 9, 2008, n.81.
Switzerland	Valeurs limites d`exposition aux postes de travail 2012.
OEL EU	Directive 2009/161/UE; Directive 2006/15/CE; Directive 2004/37/CE; Directive 2000/39/CE.
TLV-ACGIH	ACGIH 2012

ISOPROPANOL

Threshold value.

Type	Status	TWA/8h		STEL/15min		
		mg/m3	ppm	mg/m3	ppm	
TLV-ACGIH		492	200	983	400	

ETHANE-1,2-DIOL

Threshold value.

Type	Status	TWA/8h		STEL/15min		
		mg/m3	ppm	mg/m3	ppm	
TLV	I	52	20	104	40	SKIN
OEL	EU	52	20	104	40	SKIN
TLV-ACGIH				100 (C)		

PENTASODIUM DIETHYLENETRIAMINEPENTAACETATE

Concentration with no predicted effect on the environment - PNEC.

Reference value for ground compartment	0.853	mg/kg
Reference value in fresh water.	6.4	mg/l
Reference value for water, discontinuous release	3.1	mg/l
Reference value in seawater	0.64	mg/l
Reference value for sediments in fresh water	23	mg/kg
Reference value for sediments in seawater	2.3	mg/kg
Reference value for STP microorganisms	51	mg/l

Health - Derived no-effect level - DNEL / DMEL

Route of Exposure	Effects on consumers. Acute local	Acute systemic	Chronic local	Chronic systemic	Effects on workers Acute local	Acute systemic	Chronic local	Chronic systemic
Inhalation.					2.5 mg/m3	2.5 mg/m3	2.5 mg/m3	2.5 mg/m3
Dermal absorption.							VND	11718 mg/kg/day

SUBTILISIN

Threshold value.

Type	Status	TWA/8h		STEL/15min		
		mg/m3	ppm	mg/m3	ppm	
TLV-ACGIH				0.00006 (C)		

Concentration with no predicted effect on the environment - PNEC.

Reference value for ground compartment	0.568	mg/kg
Reference value in fresh water.	0.06	microg/l
Reference value for water, discontinuous release	0.009	microg/l
Reference value in seawater	0.006	microg/l
Reference value for sediments in fresh water	NEA	
Reference value for sediments in seawater	NEA	
Reference value for STP microorganisms	65000	microg/l

Health - Derived no-effect level - DNEL / DMEL

Route of Exposure	Effects on consumers. Acute local	Acute systemic	Chronic local	Chronic systemic	Effects on workers Acute local	Acute systemic	Chronic local	Chronic systemic
Inhalation.							60 ng/m3	60 ng/m3
Dermal absorption.					0.2 mg/kg	VND		

SODIUM HYDROXIDE

Threshold value.								
Type	Status	TWA/8h		STEL/15min				
		mg/m3	ppm	mg/m3	ppm			
TLV-ACGIH				2 (C)				

Health - Derived no-effect level - DNEL / DMEL								
	Effects on consumers.				Effects on workers			
Route of Exposure	Acute local	Acute systemic	Chronic local	Chronic systemic	Acute local	Acute systemic	Chronic local	Chronic systemic
Inhalation.							1 mg/m3	VND

Legend:
(C) = CEILING ; INALAB = Inhalable fraction ; RESPIR = Respirable fraction ; TORAC = Thoracic fraction.
VND = danger identified but no DNEL/PNEC available ; NEA = negative exposure assessment ; NPI = no danger identified.

8.2. Exposure controls.

Considered that the use of appropriate technical measures should always prevail over personal protective devices, ensure good ventilation in the workplace using an effective local exhaust system.
The personal protective equipment should bear the CE marking to certify their compliance with applicable standards.
Provide emergency shower and eye wash facilities.

HAND PROTECTION
Protect your hands with gloves of category III (ref. standard EN 374).
Final selection of glove material must be made taking into account these factors: compatibility, degradation, permeation and time to failure.
In the case of preparations the resistance to chemical agents of gloves material should be tested before use, since unpredictable. The gloves have a wear time that depends on the duration and the mode of use.

SKIN PROTECTION
Wear long-sleeved overalls and safety footwear for professional use, Category II (ref. Directive 89/686/EEC and standard EN ISO 20344). Wash with soap and water after removing protective clothing.
Assess the opportunity to provide antistatic clothing if the work area may present a risk of explosion.

EYE PROTECTION
It is recommended to wear a faceshield with helmet or faceshield with goggles (REF. EN 166).
If there is a risk of exposure to splashes or squirts during work performed, adequate protection of the mucous membranes (mouth, nose, eyes) must be provided in order to prevent accidental absorption.

RESPIRATORY PROTECTION
If the threshold value (e.g. TLV-TWA) of the substance or of one or more of the substances present in the product is exceeded, it is recommended to wear a mask with filter type A, class 1, 2 or 3, to be chosen in relation to the concentration limit of use. (ref. standard EN 14387). In the presence of gases or vapours of a different nature and/or gas or vapours with particles (aerosols, fumes, mists, etc.) you should provide combined filters.
The use of respiratory protection is necessary if technical measures taken are not sufficient to limit the exposure of the worker to the threshold values taken into consideration. The protection provided by masks is in any case limited.
In the case where the substance in question is odourless or its olfactory threshold is higher than the corresponding TLV-TWA and in case of emergency, wear a self-contained breathing apparatus (ref. EN 137) or a respiratory device with external air intake (ref. standard EN 138). To choose the respiratory protection device correctly, refer to the standard EN 529.

ENVIRONMENTAL EXPOSURE CONTROLS.
Emissions from manufacturing processes, including those from ventilation equipment, should be controlled for the purposes of compliance with the rules and regulations on environmental protection.
The product residues should not be disposed of uncontrollably in waste water or water courses.

SECTION 9. Physical And Chemical Properties.

9.1. Information on Basic Physical and Chemical Properties.

Physical State	clear liquid
Colour	blue
Odour	pungent
Olfactory threshold.	Not available.
pH	7.5 +-1.0
Melting o Freezing Point.	Not available.
Initial boiling point.	> 100 °C.
Boiling point.	Not available.
Flash Point.	43 °C.
Evaporation rate	Not available.
Flammability of solids and gases	Not available.
Lower Flammability Limit.	Not available.
Upper Flammability Limit.	Not available.
Lower Explosive Limit.	Not available.
Upper Explosive Limit.	Not available.
Vapor pressure.	Not available.
Vapour Density.	Not available.
Relative density.	1.0 ± 0.2 Kg/l
Solubility	soluble in water at 25°C
Partition coefficient: n-octanol/water:	Not available.
Ignition Temperature.	Not available.
Decomposition Temperature.	Not available.
Viscosity	Not available.
Explosive properties	Product not explosive considering its composition
Oxidizing properties	Product not oxidizing given its composition

9.2. Other Information.

VOC (Directive 1999/13/CE) :	7,40 %	-	74,00	g/litre.
VOC (volatile carbon):	3,59 %	-	35,94	g/litre.

SECTION 10. Stability and Reactivity.

10.1. Reactivity.

Under normal conditions of use there are no particular risk of reaction with other substances.

10.2. Chemical Stability.

The product is stable under normal conditions of use and storage.

10.3. Possibility of Hazardous Reactions.

None under normal and intended conditions of use. No polymerization reactions.

10.4. Conditions to Avoid.

Avoid overheating. Avoid the accumulation of electrostatic charges. Avoid any ignition source.

10.5. Incompatible Materials.

If used according to the indications, the Medical Device is compatible with regular components of the devices to be treated.

10.6. Hazardous Decomposition Products.

As a result of thermal decomposition, or in case of fire, gases and vapours dangerous to health can be released.

SECTION 11. Toxicological Information.

In the absence of the toxicological data on the experimental product itself, the possible hazards to health related to the product have been evaluated based on the properties of the substances contained, according to the criteria provided by the legislation of reference on the classification of hazardous substances. Consider therefore the concentration of the single hazardous substances eventually mentioned in sect. 3, to assess the toxicological effects arising from exposure to the product.
Acute effects: the product is harmful if swallowed and even the smallest amount ingested can cause significant disturbance to health (abdominal pain, nausea, vomiting, diarrhea).
The product will cause serious eye injury and may cause opacity of the cornea, iris lesion, irreversible coloration of the eye.
Acute effects: contact with skin may cause irritation, erythema, oedema, dryness and cracking skin. Inhalation of vapours may cause moderate irritation of the upper respiratory tract. Ingestion may cause health problems, including stomach pain and heartburn, nausea and vomiting.

11.1. Information on Toxicological Effects.

Data referring to the mixture:
ACUTE INHALATION TOXICITY: Data not available.
ACUTE ORAL TOXICITY: Harmful if swallowed due to its composition specified in section 3.2 .
ACUTE DERMAL TOXICITY: Data not available.
SKIN CORROSION/ IRRITATION: irritating to the skin due to its composition specified in section 3.2.
SEVERE EYE LESIONS/SEVERE EYE IRRITATIONS: it causes serious eye lesions due to its composition specified in section 3.2.
IRRITATION OF THE RESPIRATORY TRACT: Data not available.
RESPIRATORY OR SKIN SENSITISATION: it may trigger an allergic reaction due to SUBTILISIN (see section 3.2)
CARCINOGENICITY: Data not available.
MUTAGENICITY OF GERM CELLS: Data not available.
REPRODUCTIVE TOXICITY: Data not available.
SPECIFIC TOXICITY TO TARGET ORGANS (STOT)- SINGLE EXPOSURE: Data not available.
SPECIFIC TOXICITY TO TARGET ORGANS (STOT)- REPEATED EXPOSURE: Data not available.
DANGER IN THE CASE OF SUCTION: Data not available.

Data referred to the hazardous substances in the mixture:

ETHANE-1,2-DIOL
LD50 (Oral): 7712 mg/kg Rat (Source:site of dissemination ECHA). Harmful if swallowed as per Annex VI of Reg. 1272/2008 CLP.

ISOPROPANOL
SEVERE DAMAGE TO THE EYE/EYE IRRITATION: irritating, in vivo test on rabbit, OECD T 405;
SPECIFIC TOXICITY TO TARGET ORGANS (STOT)- SINGLE EXPOSURE: data not available;
SPECIFIC TOXICITY TO TARGET ORGANS (STOT)- REPEATED EXPOSURE: NOEC: 5000 ppm, rat, OECD TG 413.

DIDECYLDIMETHYLAMMONIUM CHLORIDE
LD50 (Oral). 238 mg/kg Rat (Method: OECD TG 401)
SKIN CORROSION/ IRRITATION: corrosive, in vivo test on rabbit (Method: OECD TG 404).

SUBTILISIN
ACUTE TOXICITY
LD50 (Oral). 1800 mg/kg Rat (Method: OECD TG 401)
SKIN CORROSION/ IRRITATION: slightly irritating to the skin, in vivo test on rabbit (Method: OECD TG 404)
SEVERE DAMAGE TO THE EYE/EYE IRRITATION: slightly irritating, in vivo test on rabbit (Method: OECD TG 405)
RESPIRATORY OR SKIN SENSITISATION: it may trigger allergic or asthmatic symptoms or difficulties in breathing if inhaled as per Annex VI of Reg. 1272/2008 CLP.
SPECIFIC TOXICITY TO TARGET ORGANS (STOT)- SINGLE EXPOSURE: it may irritate the respiratory tract as per Annex VI of Reg. 1272/2008 CLP.

POLY(OXY-1,2-ETHANEDIYL), .ALPHA.-TRIDECYL-.OMEGA.-HIDROXY-,BRANCHED
ACUTE TOXICITY
LD50 (Oral). 500 mg/kg Rat (Method: OECD TG 423)
SKIN CORROSION/ IRRITATION: non irritating to the skin, in vivo test on rabbit (Method OECD TG 404)
SEVERE DAMAGE TO THE EYE/EYE IRRITATION: irritating, in vivo test on rabbit, (Method OECD TG 405).

SECTION 12. Ecological Information.

The product is to be regarded as dangerous for the environment and highly toxic to aquatic organisms.

12.1. Toxicity.

DIDECYLDIMETHYLAMMONIUM CHLORIDE
LC50 - Fish.
0.19 mg/l/96h Pimephales promelas (Method: US-EPA)
EC50 - Shellfish.
0.062 mg/l/48h Daphnia Magna (Method: EPA-FIFRA)
EC50 - Algae / Aquatic plants.
0.026 mg/l/96h Pseudokirchneriella subcapitata (Information available in the SDS of the supplier)
Chronic NOEC fish.
0.032 mg/l/34 d Danio Rerio (Method: OECD TG 210)
NOEC Chronic shellfish.
0.01 mg/l/21 d Daphnia Magna (Reproductive test, method: OECD TG 211)

Chronic toxicity shellfish.
NOEC = 530 mg/l
Species = Chironomus sp.
Exposure time: 28 d
Method: OECD TG 218

Toxicity to bacteria:
CE50 = 11 mg/l
Species: active fungi
Respiration inhibitor
Exposure time: 3 h
Method: OECD TG 209

Toxicity for terrestrial organisms:
NOEC >= 1000 mg/kg
Species: eisenia fetida
Exposure time: 14 d
Method: OECD TG 207

Toxicity for terrestrial plants:
CE50 = 283 -1670 mg/kg
Exposure time: 14 d
Method: OECD TG 208.

POLY(OXY-1,2-ETHANEDIYL), .ALPHA.-TRIDECYL-.OMEGA.-HIDROXY-,BRANCHED /
LC50 - Fish.
> 1 mg/l/96h Leuciscus Idus (Information available in the SDS of the supplier)
EC50 - Shellfish.
> 1 mg/l/48h Information available in the SDS of the supplier
EC50 - Algae / Aquatic plants.
> 1 mg/l/72h Information available in the SDS of the supplier

Microorganisms/Effects on active fungi:
CE10 (17 h) > 10.000 mg/l (DIN 38412 part 8).

ETHANE-1,2-DIOL
LC50 - Fish.
72860 mg/l/96h Pimephales promelas (Source: published on the site of dissemination of the ECHA)
EC50 - Shellfish.
> 100 mg/l/48h Daphnia magna (Method: OECD Guideline 202)

ISOPROPANOL
LC50 - Fish.
9640 mg/l/96h Pimephales promelas (Equivalent method or similar to OECD TG 203)
EC50 - Shellfish.
> 10000 mg/l/48H (24h) Daphnia magna (Equivalent method or similar to OECD TG 202)
EC50 - Algae / Aquatic plants.
1800 mg/l/72h (7d) Scenedesmus quadricauda (Published on ECHA website, no reference guidelines)

SUBTILISIN
LC50 - Fish.
8.2 mg/l/96h Oncorhynchus mykiss (Method: OECD TG 203)
EC50 - Shellfish.
0.306 mg/l/48h Daphnia Magna (Method: OECD TG 202)
EC50 - Algae / Aquatic plants.
0.83 mg/l/72h Pseudokirchnerella subcapitata (Method: OECD TG 201)

12.2. Persistence and Degradability.

ISOPROPYL ALCOHOL: Rapidly biodegradable (EU Method C.5)

DIDECYLDIMETHYLAMMONIUM CHLORIDE (Information available in SDS of the supplier)
Stability in water: abiotic degradation, hydrolytically stable (Method EPA-FIFRA)
Modified Sturn essay: 72%
Rapidly degradable
Experiment duration: 28 d
Method: OECD TG 301 B

Die-Away test: 93.3%
Experiment duration: 28 d
OECD Confirmatory Test: 91%
Experiment duration: 24 - 70 d
Method: OECD TG 303 A.

OLY(OXY-1,2-ETHANEDIYL), .ALPHA.-TRIDECYL-.OMEGA.-HIDROXY-,BRANCHED
Disposal Considerations:
>= 90% bismuth active substance (Method: OECD 301E)
Analogy: assessment deriving from chemically similar products.

> 60% CO2 formation of theoretical value (28d) (Method: OECD 301B; ISO 9439; 92/69/EEC, C.4-C)
Easily biodegradable
Analogy: assessment deriving from chemically similar products.

ETHANE-1,2-DIOL: Rapidly Biodegradable.

ISOPROPANOL: Rapidly Biodegradable.

DIDECYLDIMETHYLAMMONIUM CHLORIDE: Rapidly Biodegradable.

SUBTILISIN: Rapidly Biodegradable.

POLY(OXY-1,2-ETHANEDIYL), .ALPHA.-TRIDECYL-.OMEGA.-HIDROXY-,BRANCHED /: Rapidly Biodegradable.

12.3. Bioaccumulation Potential.

POLY(OXY-1,2-ETHANEDIYL), .ALPHA.-TRIDECYL-.OMEGA.-HIDROXY-,BRANCHED: accumulation in organisms is not expected (Information available in the SDS of the supplier).

12.4. Mobility in Soil.

POLY(OXY-1,2-ETHANEDIYL), .ALPHA.-TRIDECYL-.OMEGA.-HIDROXY-,BRANCHED: the substance does not evaporate from the water surface in the environment. Absorption in solid soil phase is possible.

12.5. Results of PBT and vPvB Assessment.

Based on the available data, the product does not contain substances classified as PBT or vPvB in percentage greater than 0.1 %.

12.6. Other Adverse Effects

POLY(OXY-1,2-ETHANEDIYL), .ALPHA.-TRIDECYL-.OMEGA.-HIDROXY-,BRANCHED (Information available in SDS of the supplier)
Chemical oxygen demand (COD): 2100 mg/g
With correct insertion of small concentrations in suitable biological purification plants, there should be no inconveniences during the active fungi degradation activity. Do not insert the product in the water without preventive treatment.

SECTION 13. Disposal Considerations.

13.1. Methods of Waste Treatment.

Product residues should be considered special hazardous waste. The dangerousness of the wastes that contain part of this product should be evaluated according to the legislative provisions proposed in the Legislative Decree no. 152/2006 and subsequent amendments.
Disposal should be entrusted to an authorized waste management firm, in compliance with national and local regulations.
Avoid absolutely to disperse the product into the soil, in sewer systems or water courses.
Waste transportation may be subject to ADR.
CONTAMINATED PACKAGING
Contaminated packaging must be recovered or disposed of in compliance with national waste management regulations.

SECTION 14. Transport Information.

14.1. ONU Number
(ADR, RID, IMDG Code, ICAO): UN 2924

14.2. ONU shipping name
(ADR, RID): FLAMMABLE LIQUID, CORROSIVE, N.O.S. (ISOPROPANOL; DIDECYLDIMETHYLAMMONIUM CHLORIDE)

(IMDG Code, ICAO): FLAMMABLE LIQUID, CORROSIVE, N.O.S. (PROPAN-2-OL; DIDECYLDIMETHYLAMMONIUM CHLORIDE)

14.3. Transportation hazard classification
(ADR, RID):
Class: 3
Label: 3 (8)

(IMDG Code):
Class: 3
Label: 3 (8)

(ICAO):

Class: 3
Label: 3 (8)
For air transport, the mark of environmental hazard is compulsory only for the N. UN 3077 and 3082.

14.4. Packing group
(ADR, RID, IMDG Code, ICAO): III

14.5. Dangers for the environment : YES

14.6. Special precautions for users
Dangerous goods must be consigned for loading/transport according to the relevant requirements depending on the chosen transport means: road (A.D.R.), rail (RID), by sea (IMDG Code), air (IATA) and the relevant national provisions. Products should be transported in their original packaging and in any case in packages that are made from materials resistant to their content and unlikely to cause dangerous reactions with it. People loading and unloading dangerous goods must be trained on all the risks deriving from the substance and on all actions to be taken in the event of emergencies.

14.7. Transport of bulk cargo according to the attachment II of MARPOL 73/78 and the IBC code
(ADR, RID, ICAO): not applicable.
(IMDG Code): not applicable.

Additional indications

(ADR, RID):

Nr. Kemler:	38
Limited Quantity.	5 L – 30 kg lordi
Code of restriction in tunnels.	(D/E)

(IMDG Code):

EMS:	F-E, S-C
Marine Pollutant.	YES
Limited Quantity.	5 L – 30 kg gross

(ICAO):
Cargo:

Packaging Instructions:	365	Maximum quantity:	60 L
Pass.:			
Packaging Instructions:	354	Maximum quantity:	5 L
Special instructions:	A3		

SECTION 15. Regulatory Information.

15.1. Standards and Legislation on Health, Safety and Environmental Specifications for the Substance or Mixture.

Seveso Category. 6. FLAMMABLE

Restrictions concerning the product or substances contained as per Annex XVII Regulation (EC) 1907/2006.

Product:

Point.	3. *The substances or the liquid mixtures that are considered dangerous for the purposes of Directive 1999 /45/CE or that match the criteria for one of the following classes or categories of danger referred to in Annex I to Council Regulation (EC) no. 1272/2008:* *a) classes of danger from 2.1 to 2.4 , 2.6 and 2.7 , 2.8 types A and B, 2.9 , 2.10 , 2.12 , 2.13 categories 1 and 2, 2.14 categories 1 and 2, 2.15 types A to F;* *b) classes of danger from 3.1 to 3.6 , 3.7 harmful effects on sexual function and fertility or development, 3.8 effects other than narcotic effects, 3.9 and 3.10;* *c) hazard class 4.1 ; d) hazard class 5.1 .*
Point.	40 *Substances classified as flammable gases of category 1 or 2, flammable liquids of category 1, 2 or 3, flammable solids of category 1 or 2, substances and mixtures which, in contact with water, release flammable gases of category 1, 2 or 3, pyrophoric liquids category 1 or pyrophoric solids of category 1, even if not listed in Annex VI, part 3 of Regulation (EC) n. 1272/2008.*

Candidate List Substances (Art. 59 REACH).

None.

Substances subject to authorisation (Annex XIV REACH).

None.

Substances subject to export notification Reg. (CE) 649/2012:

Substances subject to the Rotterdam Convention:

None.

Substances subject to the Stockholm Convention:

None.

Public health control.

Workers exposed to this chemical agent must undergo health checks for the health surveillance carried out in accordance with the provisions of art. 41 of Legislative Decree no. 81 of 9 April 2008, unless the risk to the safety and health of the worker has been assessed irrelevant, in accordance with art. 224 paragraph 2.

Law Decree 152/2006 and subsequent amendments.

Emissions:

TAB. D Class 3 01,40 %
TAB. D Class 4 06,00 %

Ingredients according to Regulation CE NO.648/2004

Lower 5% cationic surfactants
Between 15% and 30% non ionic surfactants

Enzymes

15.2. Chemical Safety Assessment.

A chemical safety assessment for the mixture and substances contained therein was not prepared.

SECTION 16. Other Information.

Text of hazard indications (H) mentioned in sections 2-3 of this sheet:

Flam. Liq. 2	Flammable liquid, Category 2
Flam. Liq. 3	Flammable liquid, Category 3
Repr. 2	Reproductive toxicity, category 2
Acute Tox. 3	Acute toxicity, category 3
Acute Tox. 4	Acute toxicity, category 4
STOT RE 2	Specific target organ toxicity - repeated exposure, category 2
Skin Corr. 1B	Skin corrosion, category 1B
Eye Dam. 1	Severe eye damage, category 1
Eye Irrit. 2	Eye irritation, category 2
Skin Irrit. 2	Skin irritation, category 2
STOT SE 3	Specific target organ toxicity - single exposure, category 3
Resp. Sens. 1	Respiratory sensitization, category 1
Aquatic Acute 1	Hazardous to the aquatic environment, acute toxicity, category 1
H225	Liquid and vapors highly flammable.
H226	Flammable liquid and vapours.
H361d	Suspected that it might affect the unborn child.
H301	Toxic if swallowed.
H302	Harmful if swallowed.
H332	Harmful if inhaled.
H373	It may damage the organs in case of prolonged or repeated exposure.
H314	Causes severe skin burns and eye damage.
H318	Causes serious eye injuries.
H319	Causes severe eye irritation.
H315	Causes skin irritation.
H335	May cause respiratory irritation
H334	It may trigger allergic or asthmatic symptoms or difficulties in breathing if inhaled
H336	May cause drowsiness or dizziness.
H412	Harmful to aquatic organisms with long-term effects.

Text of risk phrases (R) mentioned in sections 2-3 of this sheet:

R10	FLAMMABLE
R11	HIGHLY FLAMMABLE.
R20	HARMFUL IF INHALED.
R22	HARMFUL IF SWALLOWED.
R34	CAUSES BURNS.
R36	IRRITATING TO THE EYES.

R37/38	IRRITATING TO THE RESPIRATORY SYSTEM AND THE SKIN.
R41	RISK OF SERIOUS DAMAGE TO EYES.
R42	MAY CAUSE SENSITISATION BY INHALATION.
Repr. Cat. 3	Reproductive toxicity, development, category 3.
R63	POSSIBLE RISK OF HARM TO THE UNBORN CHILD.
R67	VAPOURS MAY CAUSE DROWSINESS AND DIZZINESS

Training for workers:
Training of workers must provide content, updates, and duration relating to the types of risks assigned to the specific work areas, according to the regulations laid down in Legislative Decree 81/2008.

LEGEND:
- ADR: European Agreement concerning the transport of dangerous goods by road
- CAS NUMBER: Chemical Abstract Service Number
- CE50: Concentration that has effect on 50% of the population subject to test
- CE NUMBER: Identification number in ESIS (European archive of existing substances)
- CLP: Regulation CE 1272/2008
- DNEL: Derived no effect level.
- EmS: Emergency Schedule
- GHS: Harmonized global system for the classification and labelling of chemical products
- IATA DGR: Regulation for the transport of dangerous goods of International Air Transport Association
- IC50: Concentration of immobilization of 50% of the population subject to test
- IMDG: International maritime code for transport of dangerous goods
- IMO: International Maritime Organization
- INDEX NUMBER: Identification number in the Annex VI of the CLP
- LC50: Lethal concentration 50%
- LD50: Lethal dose 50%
- OEL: Occupational exposure level
- PBT: Persistent, bioaccumulative and toxic according to REACH
- PEC: Predictable environmental concentration
- PEL: Predictable exposure level
- PNEC: Predictable no effect concentration
- REACH: Regulation CE 1907/2006
- RID: Regulation for the international transport of dangerous goods by train
- TLV: Threshold value
- TLV CEILING: Concentration that must not be exceeded during any time of exposure during work.
- TWA STEL: Short-term exposure limit
- TWA: Weighed average exposure limit
- VOC: Volatile organic compound
- vPvB: Very persistent and very bioaccumulative according to REACH.

GENERAL BIBLIOGRAPHY:
1. Directive 1999/45/EC and subsequent amendments
2. Directive 67/548/EEC and subsequent amendments and adjustments
3. European Parliament Regulation (EC) 1907/2006 (REACH)
4. European Parliament Regulation (EC) 1272/2008 (CLP)
5. European Parliament Regulation (EC) 790/2009 (I Atp. CLP)
6. European Parliament Regulation (EC) 453/2010
7. European Parliament Regulation (EC) 286/2011 (II Atp. CLP)
8. The Merck Index. Ed. 10
9. Handling Chemical Safety
10. Niosh - Registry of Toxic Effects of Chemical Substances
11. INRS - Fiche Toxicologique
12. Patty - Industrial Hygiene and Toxicology
13. N.I. Sax - Dangerous properties of Industrial Materials-7 Ed., 1989
14. Agency ECHA website

Note for user: The information contained in this sheet are based on knowledge achieved on the date of the last version. User must verify the suitability and thoroughness of provided information according to each specific use of the product. This document must not be regarded as a guarantee on any specific product property. The use of this product is not subject to our direct control; therefore, the user must, under his own responsibility, comply with

the current health and safety laws and regulations. We accept no liability for any unauthorised or improper use. Provide adequate training for personnel assigned to use chemical products.

Changes made since the previous revision.
Changes have been made to the following sections:
01/ 02 / 03 / 04 / 05 / 06 / 07 / 08 / 10 / 11 / 12 / 13 / 14 / 15 / 16.

Ed.	Rev.	Date	STATUS AND REASON OF REVISIONS
1	0	18.02.2002	First issue
1	1	27.06.2003	Different concentration of use
1	2	26.07.2007	Update of regulations
1	3	01.09.2008	Improvement of surfactant functionalities
1	4	17.10.2008	Modifications to points 9 and 14
1	5	05.03.2010	Compliance to EU Directive 2007/47/EC
1	6	13.09.2011	Data update par. 3
1	7	17.11.2011	Compliance to the 453/2010 Regulation
1	8	30.10.2015	Adaptation to REACH and CLP Regulation, company name change with logo
1	9	17.02.2016	Specification of flashpoint

CANTEL MEDICAL

CANTEL MEDICAL (ITALY) S.R.L. Via Laurentina 169 - 00071 Pomezia (RM) – Italia

DICHIARAZIONE DI CONFORMITA CE
EC DECLARATION OF CONFORMITY

Nome del Fabbricante Manufacturer's Name	**Cantel Medical (Italy) S.r.l.**
Indirizzo del Fabbricante Manufacturer's address	**Via Laurentina, 169-00071 Pomezia (Roma)-Italy**
Nome del Dispositivo Medico Name of the Medical Device	**PROTEAZONE® - PROTEAZONE® ERS**
Codice Identificativo Identification code	**PAZ/CE/22**
Classe del prodotto Device Class	**II b**
Destinazione d'uso Fields covered	Soluzione decontaminante e detergente per dispositivi medici Disinfectant and detergent solution for medical devices
Sistema di Qualità Quality System	UNI EN ISO 9001-UNI CEI EN ISO 13485 Ultime revisioni Direttiva 93/42/CEE e s.m.i. UNI EN ISO 9001-UNI CEI EN ISO 13485 Recent revisions Directive 93/42/CEE and next renewals
Organismo Notificato Notified Body	CERTIQUALITY Srl Via Gaetano Giardino, 4-20123 Milan – (Italy)
Numero Certificato A Q Q A Certificate no.	No. 995/CE001 rilasciato in data 08.04.1998 e successivi rinnovi No. 995/CE001 released on 08.04.1998 and next renewals

La Società Cantel Medical (Italy) S.r.l. dichiara che i Dispositivi Medici **PROTEAZONE® - PROTEAZONE® ERS** sono conformi ai requisiti essenziali dell'allegato I della Direttiva 93/42/CEE e modifiche apportate dalla Direttiva 2007/47/CE e che il Sistema di Gestione della Qualità è conforme all'allegato II della Direttiva 93/42/CEE approvato dall'Organismo notificato Certiquality n. 0546.

Dichiara, altresì, che **PROTEAZONE® - PROTEAZONE® ERS** rientrano nella famiglia dei disinfettanti per Dispositivi Medici così come descritto nel Certificato n. 995/CE/001 rilasciato in data 08.04.1998 dall'Istituto di certificazione "Certiquality" e successivi rinnovi.

The undersigned Co Cantel Medical (Italy) S.r.l. company declares that the Medical Devices **PROTEAZONE® - PROTEAZONE® ERS** conform with the Essential Requinements of the attachment I of the Directive no. 93/42/EEC, and modifications within Directive 2007/47/EC and that the Quality System conform with attachment II of the Directive no. 93/42/EEC, approved by the Notified Body Certiquality no. 0546.

Cantel Medical (Italy) Srl declares also that **PROTEAZONE® - PROTEAZONE® ERS** are part of the Medical Device disinfectant family as indicated in the Certificate no. 995/CE/001 released on 08.04.1998 by Certiquality Notified Body and successive renewals.

Data/date 25.09.2017

GIORNO/DAY - MESE/MONTH - ANNO/YEAR

AMMINISTRAZIONE

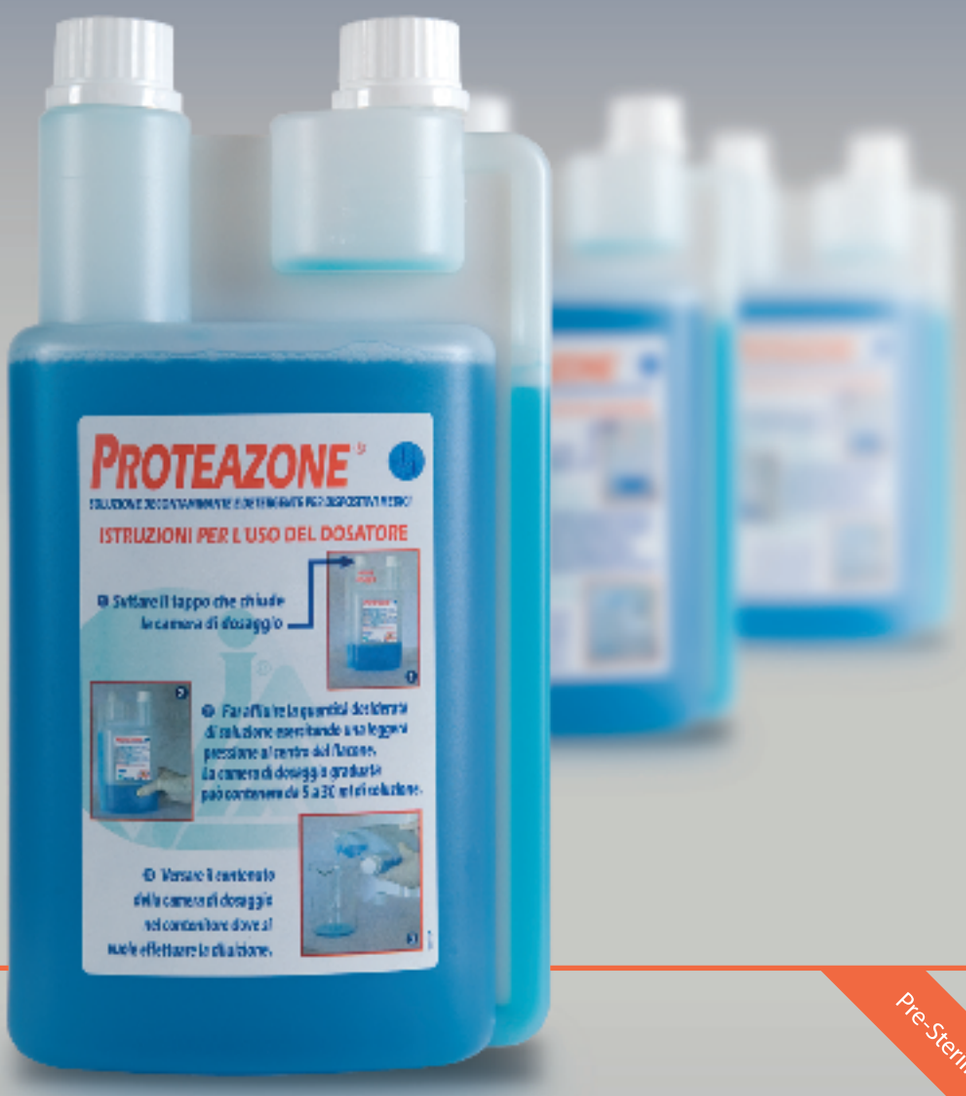
CEO

VINIT MARK SUPEKAR

CANTEL MEDICAL

PROTEAZONE®

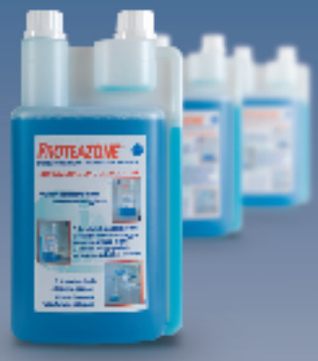
Pre-Sterilisation • Detergent/Decontaminant
Active and tested against microbial biofilm



Pre-Sterilisation

CANTEL HAS DEVELOPED **PROTEAZONE®** TO SERVE HOSPITALS AND CLINICS WITH A UNIQUE, SELECTIVE AND POWERFUL DETERGENT/DECONTAMINANT TO MAXIMISE MICROBIAL REMOVAL INCLUDING BIOFILMS.

PROTEAZONE® IS THE ELECTIVE PRODUCT FOR: **STERILISATION CENTRES**, **ENDOSCOPY**, **UROLOGY**, **HEAD&NECK**, **OPERATING THEATRES** AND MANY OTHER WARDS THAT REQUIRE **ABSOLUTE CLEANSING** AND **DECONTAMINATION** ACCORDING TO INTERNATIONAL MICROBIOLOGICAL STANDARDS.



PROTEAZONE®

Pre-Sterilisation • Detergent/Decontaminant
Active and tested against microbial biofilm

4 ENZYMES ACTIVE AGAINST:

Proteins, lipids/fats, carbohydrates/sugars, cellular components
The only tested product against Microbial Biofilm
Germicide surfactant complex
Disinfection action
Synergic effect of ADAZONE (patented new microbicidal agent)

5 minute contact time only
pH 7
Biodegradable
Dilution 1:400 (400 lt of ready to use solution)
Powerful removal of organic material
Associated decontamination and microbial removal

TESTED AGAINST:

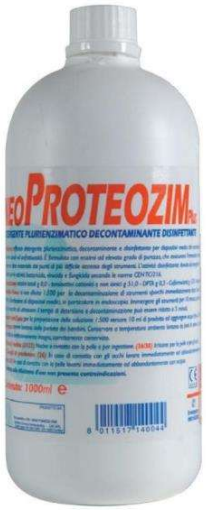
Mycobacteria, HIV, EMC, Candida Albicans
Aspergillus Niger, Pseudomonas Aeruginosa
Staphilococcus Aureus, E.Coli,
Enterococcus Hirae and many more

EN14348/EN14563 (Mycobactericidal)
EPA USA DIS/TSS 07 (Virucidal)
EN1650/EN13624/EN14562 (Fungicidal)
EN13727/EN1276/EN14561 (Bactericidal)
EN13697 (Bactericidal/Fungicidal)

CANTEL MEDICAL

Via Laurentina 169, 00040 - I Pomezia (RM)
Quality System UNI ISO 9001, UNI CEI EN ISO 13485 Certified - Authorised Test Facility

Neo Protoeozim Plus 500



Multienzymatic concentrated detergent and disinfectant

COMPOSITION

Total 8.0 g of enzymes, cationic and anionic surfactants 51.0 g, 0.3 g DPTA, coformulants 13.0 g, purified water q.s. to 100.0 ml.

EFFECTIVENESS

Detergent with bactericidal, virucidal, fungicidal action. Contact times:
10 min., at a dilution of 1: 500 (10 ml in 5 litres of water).
In ultrasonic tanks reduced contact time - 5 min.

USE

Perfect solution for:
- Decontamination of soiled instruments immediately after use;
- Cleaning and disinfection of laparoscopy, arthroscopy, gastroscopes and other medical devices, critical and semi-critical;

AVAILABILE IN

Plastic bottle 1000 ml.

CANTEL MEDICAL

Cantel Medical (Italy) S.r.l. a socio unico
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00071 Pomezia (RM)-Italia