SAFETY DATA SHEETS

This SDS packet was issued with item: 077703408

The safety data sheets (SDS) in this packet apply to one or more components included in the items listed below. Items listed below may require one or more SDS. Please refer to invoice for specific item number(s).

077703416 272447860

Zhern	nack S.p.a	Revision nr. 3
		Dated 22/09/2017
-	30001, C203230	Printed on 22/09/2017
GINGIFAST	RIGID - BASE	Page n. 1/12
L		
	Safety data sheet	
SECTION 1. Identification of the subs	stance/mixture and of the company/unc	lertaking
1.1. Product identifier	0404500 0400004 0000000	
Code: Product name	C401520, C430001, C203230 GINGIFAST RIGID - BASE	
1.2. Relevant identified uses of the substance or m	ixture and uses advised against	
Intended use For professional use	only. Addition silicone for the reproduction of gingiva	al masks.
1.3. Details of the supplier of the safety data sheet Name	Zhermack S.p.a	
Full address District and Country	Via Bovazecchino 100 45021 Badia Polesine (RO)	
	Italy	
	Tel. +39 0425-597611	
e-mail address of the competent person	Fax +39 0425-597689	
responsible for the Safety Data Sheet	msds@zhermack.com	
1.4. Emergency telephone number		
For urgent inquiries refer to	UK Emergency number: 844 892 0111 (24 hours)	
SECTION 2. Hazards identification		
2.1. Classification of the substance or mixture		
The product is not classified as hazardous pursuant to the However, since the product contains hazardous substant appropriate information, compliant to EC Regulation 1900 Hazard classification and indication:	ne provisions set forth in EC Regulation 1272/2008 (CLP) nees in concentrations such as to be declared in section r 7/2006 and subsequent amendments.	no. 3, it requires a safety data sheet with
2.2. Label elements		
Hazard labelling pursuant to EC Regulation 1272/2008	CLP) and subsequent amendments and supplements.	
Hazard pictograms:		
Signal words:		
Hazard statements:		
EUH210 Safety data sheet available	on request.	
Precautionary statements:		
2.3. Other hazards		

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On the basis of available data, the product does not contain any PBT or vPvB in percentage greater than 0,1%. There is no exposure to breathable free crystalline silica during normal use of this product. For more information see section 11.

SECTION 3. Composition/information on ingredients

3.1. Substances

Information not relevant

3.2. Mixtures

Contains:

Identification	x = Conc. %	Classification 1272/2008 (CLP)
CRISTOBALITE		
CAS 14464-46-1	19 ≤ x < 29	STOT RE 1 H372
EC 238-455-4		
INDEX -		

The full wording of hazard (H) phrases is given in section 16 of the sheet.

SECTION 4. First aid measures

4.1. Description of first aid measures

EYES: Remove contact lenses, if present. Wash immediately with plenty of water for at least 15 minutes, opening the eyelids fully. If problem persists, seek medical advice.

SKIN: Remove contaminated clothing. Wash immediately with plenty of water. If irritation persists, get medical advice/attention. Wash contaminated clothing before using it again.

INHALATION: Remove to open air. In the event of breathing difficulties, get medical advice/attention immediately.

INGESTION: Get medical advice/attention. Induce vomiting only if indicated by the doctor. Never give anything by mouth to an unconscious person, unless authorised by a doctor.

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

Specific information on symptoms and effects caused by the product are unknown.

 $\underline{\textbf{4.3. Indication of any immediate medical attention and special treatment needed}$

Information not available

SECTION 5. Firefighting measures

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5.1. Extinguishing media

SUITABLE EXTINGUISHING EQUIPMENT

Extinguishing substances are: carbon dioxide, foam, chemical powder. For product loss or leakage that has not caught fire, water spray can be used to disperse flammable vapours and protect those trying to stem the leak. UNSUITABLE EXTINGUISHING EQUIPMENT

Do not use jets of water. Water is not effective for putting out fires but can be used to cool containers exposed to flames to prevent explosions.

5.2. Special hazards arising from the substance or mixture

HAZARDS CAUSED BY EXPOSURE IN THE EVENT OF FIRE Excess pressure may form in containers exposed to fire at a risk of explosion. Do not breathe combustion products.

5.3. Advice for firefighters

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 full fire prevention gear. Collect extinguishing water to prevent it from draining into the sewer system. Dispose of contaminated water used for extinction and the remains of the fire according to applicable regulations.

SPECIAL PROTECTIVE EQUIPMENT FOR FIRE-FIGHTERS

Normal fire fighting clothing i.e. fire kit (BS EN 469), gloves (BS EN 659) and boots (HO specification A29 and A30) in combination with self-contained open circuit positive pressure compressed air breathing apparatus (BS EN 137).

SECTION 6. Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Block the leakage if there is no hazard.

Wear suitable protective equipment (including personal protective equipment referred to under Section 8 of the safety data sheet) to prevent any contamination of skin, eyes and personal clothing. These indications apply for both processing staff and those involved in emergency procedures.

6.2. Environmental precautions

The product must not penetrate into the sewer system or come into contact with surface water or ground water.

6.3. Methods and material for containment and cleaning up

Collect the leaked product into a suitable container. If the product is flammable, use explosion-proof equipment. Evaluate the compatibility of the container to be used, by checking section 10. Absorb the remainder with inert absorbent material. Make sure the leakage site is well aired. Contaminated material should be disposed of in compliance with the provisions set forth in point 13.

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6.4. Reference to other sections

Any information on personal protection and disposal is given in sections 8 and 13.

SECTION 7. Handling and storage

7.1. Precautions for safe handling

Before handling the product, consult all the other sections of this material safety data sheet. Avoid leakage of the product into the environment. Do not eat, drink or smoke during use. Remove any contaminated clothes and personal protective equipment before entering places in which people eat.

7.2. Conditions for safe storage, including any incompatibilities

Store only in the original container. Store the containers sealed, in a well ventilated place, away from direct sunlight. Keep containers away from any incompatible materials, see section 10 for details.

7.3. Specific end use(s)

See section 1.2.

SECTION 8. Exposure controls/personal protection

8.1. Control parameters

Regulatory References:

DNK	Danmark	Graensevaerdier per stoffer og materialer
FRA	France	JORF n°0109 du 10 mai 2012 page 8773 texte n° 102
ITA	Italia	Decreto Legislativo 9 Aprile 2008, n.81
NLD	Nederland	Databank of the social and Economic Concil of Netherlands (SER) Values, AF 2011:18
SWE	Sverige TLV-ACGIH	Occupational Exposure Limit Values, AF 2011:18 ACGIH 2016

CRISTOBALITE

Threshold Limit Value						
Туре	Country	TWA/8h		STEL/15min		
		mg/m3	ppm	mg/m3	ppm	
TLV	DNK	0,15				RESP
VLEP	FRA	0,05				RESP

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	VLEP	ITA	0,05	RESP	(USA-NIOSH)
	MAC	NLD	0,075	RESP	
	MAK	SWE	0,05	RESP	
	TLV-ACGIH		0,025		

Legend:

(C) = CEILING ; INHAL = Inhalable Fraction ; RESP = Respirable Fraction ; THORA = Thoracic Fraction.

8.2. Exposure controls

As the use of adequate technical equipment must always take priority over personal protective equipment, make sure that the workplace is well aired through effective local aspiration.

When choosing personal protective equipment, ask your chemical substance supplier for advice.

Personal protective equipment must be CE marked, showing that it complies with applicable standards.

Exposure levels must be kept as low as possible to avoid significant build-up in the organism. Manage personal protective equipment so as to guarantee maximum protection (e.g. reduction in replacement times).

HAND PROTECTION

Protect hands with category III work gloves (see standard EN 374).

The following should be considered when choosing work glove material: compatibility, degradation, failure time and permeability.

The work gloves' resistance to chemical agents should be checked before use, as it can be unpredictable. The gloves' wear time depends on the duration and type of use.

SKIN PROTECTION

Wear category III professional long-sleeved overalls and safety footwear (see Directive 89/686/EEC and standard EN ISO 20344). Wash body with soap and water after removing protective clothing.

EYE PROTECTION

Wear airtight protective goggles (see standard EN 166).

In the presence of risks of exposure to splashes or squirts during work, adequate mouth, nose and eye protection should be used to prevent accidental absorption.

RESPIRATORY PROTECTION

If the threshold value (e.g. TLV-TWA) is exceeded for the substance or one of the substances present in the product, use a mask with a type B filter whose class (1, 2 or 3) must be chosen according to the limit of use concentration. (see standard EN 14387). In the presence of gases or vapours of various kinds and/or gases or vapours containing particulate (aerosol sprays, fumes, mists, etc.) combined filters are required.

Respiratory protection devices must be used if the technical measures adopted are not suitable for restricting the worker's exposure to the threshold values considered. The protection provided by masks is in any case limited.

If the substance considered is odourless or its olfactory threshold is higher than the corresponding TLV-TWA and in the case of an emergency, wear open-circuit compressed air breathing apparatus (in compliance with standard EN 137) or external air-intake breathing apparatus (in compliance with standard EN 138). For a correct choice of respiratory protection device, see standard EN 529.

ENVIRONMENTAL EXPOSURE CONTROLS

The emissions generated by manufacturing processes, including those generated by ventilation equipment, should be checked to ensure compliance with environmental standards.

SECTION 9. Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance
Colour
Odour

fluid pink odourless

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9.2. Other information

Information not available

SECTION 10. Stability and reactivity

10.1. Reactivity

There are no particular risks of reaction with other substances in normal conditions of use.

10.2. Chemical stability

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

10.3. Possibility of hazardous reactions

No hazardous reactions are foreseeable in normal conditions of use and storage.

10.4. Conditions to avoid

None in particular. However the usual precautions used for chemical products should be respected.

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10.5. Incompatible materials

Information not available

10.6. Hazardous decomposition products

Information not available

SECTION 11. Toxicological information

11.1. Information on toxicological effects

Metabolism, toxicokinetics, mechanism of action and other information Information not available

Information on likely routes of exposure Information not available

Delayed and immediate effects as well as chronic effects from short and long-term exposure Information not available

Interactive effects Information not available

ACUTE TOXICITY

LC50 (Inhalation) of the mixture: Not classified (no significant component) LD50 (Oral) of the mixture: Not classified (no significant component) LD50 (Dermal) of the mixture: Not classified (no significant component)

SKIN CORROSION / IRRITATION

Does not meet the classification criteria for this hazard class SERIOUS EYE DAMAGE / IRRITATION Does not meet the classification criteria for this hazard class RESPIRATORY OR SKIN SENSITISATION Does not meet the classification criteria for this hazard class GERM CELL MUTAGENICITY Does not meet the classification criteria for this hazard class CARCINOGENICITY Does not meet the classification criteria for this hazard class REPRODUCTIVE TOXICITY Does not meet the classification criteria for this hazard class STOT - SINGLE EXPOSURE Does not meet the classification criteria for this hazard class STOT - REPEATED EXPOSURE Does not meet the classification criteria for this hazard class ASPIRATION HAZARD Does not meet the classification criteria for this hazard class CRISTOBALITE Acute Toxicity: No data available.

Irritation/Corrosion Skin irritation: Not irritating (MSDS supplier). Eye irritation: Slightly irritating (MSDS supplier).

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Sensitization: Not sensitizing (MSDS supplier).

Mutagenicity: Does not meet the classification criteria for this hazard class (MSDS supplier).

Carcinogenicity: IARC (group 1), NTP (RAHC), ACGIH (A2) (IARC).

Toxicity to reproduction: Does not meet the classification criteria for this hazard class (MSDS supplier).

Toxicity for aspiration: Not applicable. STOT Repeated Exposure: Adverse effects on lungs (fibrosis-silicosis)(MSDS supplier).

In 1997, IARC (the International Agency for Research on Cancer) concluded that crystalline silica inhaled from occupational sources can cause lung cancer in humans. However it pointed out that not all industrial circumstances, nor all crystalline silica types, were to be incriminated (IARC Monographs on the evaluation of the carcinogenic risks of chemicals to humans, Silica, silicates dust and organic fibres, 1997, Vol. 68, IARC, Lyon, France).

In June 2003, SCOEL (the EU Scientific Committee on Occupational Exposure Limits) concluded that the main effect in humans of the inhalation of respirable crystalline silica dust is silicosis. "There is sufficient information to conclude that the relative risk of lung cancer is increased in persons with silicosis (and, apparently, not in employees without silicosis exposed to silica dust in quarries and in the ceramic industry). Therefore preventing the onset of silicosis will also reduce the cancer risk..." (SCOEL SUM Doc 94-final, June 2003).

There is a body of evidence supporting the fact that increased cancer risk would not be limited to people already suffering from silicosis. According to the current state of the art, worker protection against silicosis can be consistently assured by respecting the existing regulatory occupational exposure limits. Occupational exposure to nuisance dust (total and respirable) and respirable crystalline silica should be monitored and controlled.

"For the purposes of classification of health hazards (part 3), the route of exposure, information on mechanisms and metabolism studies are useful for determining the relevance of effects in humans. If this information raises doubts as to their relevance in humans, in spite of the indisputable data legitimacy and quality, a lower classification may be justified. When there is scientific evidence that the mechanism or mode of action is not relevant to humans, the substance or mixture should not be classified (annex I, section 1.1.1.5, EC Regulation 1272/2008)".

Monitoring activities conducted at the company related to possible inhalation exposure, in accordance with industrial hygiene standards for paste and fluid products, showed levels of exposure to free crystalline silica (breathable part) below the limit of quantification of the method, therefore exposure is not expected during the use indicated in section 1.2 for this specific product.

However, the actual levels of free crystalline silica (breathable part) present in the workplace must be obtained through monitoring as required by regulations for the safety and health of workers.

SECTION 12. Ecological information

12.1. Toxicity

Information not available

12.2. Persistence and degradability

CRISTOBALITE

NOT rapidly degradable

12.3. Bioaccumulative potential

Information not available

12.4. Mobility in soil

Information not available

12.5. Results of PBT and vPvB assessment

On the basis of available data, the product does not contain any PBT or vPvB in percentage greater than 0,1%.

12.6. Other adverse effects

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Information not available

SECTION 13. Disposal considerations

13.1. Waste treatment methods

Reuse, when possible. Product residues should be considered special hazardous waste. The hazard level of waste containing this product should be evaluated according to applicable regulations.

Disposal must be performed through an authorised waste management firm, in compliance with national and local regulations. CONTAMINATED PACKAGING

Contaminated packaging must be recovered or disposed of in compliance with national waste management regulations.

SECTION 14. Transport information

The product is not dangerous under current provisions of the Code of International Carriage of Dangerous Goods by Road (ADR) and by Rail (RID), of the International Maritime Dangerous Goods Code (IMDG), and of the International Air Transport Association (IATA) regulations.

14.1. UN number

Not applicable

14.2. UN proper shipping name

Not applicable

14.3. Transport hazard class(es)

Not applicable

14.4. Packing group

Not applicable

14.5. Environmental hazards

Not applicable

14.6. Special precautions for user

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Not applicable

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

Information not relevant

SECTION 15. Regulatory information

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

Seveso Category - Directive 2012/18/EC: None

Restrictions relating to the product or contained substances pursuant to Annex XVII to EC Regulation 1907/2006

None

Substances in Candidate List (Art. 59 REACH)

On the basis of available data, the product does not contain any SVHC in percentage greater than 0,1%.

Substances subject to authorisarion (Annex XIV REACH)

None

Substances subject to exportation reporting pursuant to (EC) Reg. 649/2012:

None

Substances subject to the Rotterdam Convention:

None

Substances subject to the Stockholm Convention:

None

Healthcare controls

Information not available

15.2. Chemical safety assessment

No chemical safety assessment has been processed for the mixture and the substances it contains.

SECTION 16. Other information

Obtained by Global Safety Management, www.globalsafetynet.com, (877) 683-7460

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Text of hazard (H) indications mentioned in section 2-3 of the sheet: STOT RE 1 Specific target organ toxicity - repeated exposure, category 1 H372 Causes damage to organs through prolonged or repeated exposure. EUH210 Safety data sheet available on request. LEGEND: ADR: European Agreement concerning the carriage of Dangerous goods by Road CAS NUMBER: Chemical Abstract Service Number CE50: Effective concentration (required to induce a 50% effect) CE NUMBER: Identifier in ESIS (European archive of existing substances) CLP: EC Regulation 1272/2008 DNEL: Derived No Effect Level EmS: Emergency Schedule GHS: Globally Harmonized System of classification and labeling of chemicals IATA DGR: International Air Transport Association Dangerous Goods Regulation IC50: Immobilization Concentration 50% IMDG: International Maritime Code for dangerous goods IMO: International Maritime Organization INDEX NUMBER: Identifier in Annex VI of CLP LC50: Lethal Concentration 50% LD50: Lethal dose 50% **OEL: Occupational Exposure Level** PBT: Persistent bioaccumulative and toxic as REACH Regulation PEC: Predicted environmental Concentration PEL: Predicted exposure level PNEC: Predicted no effect concentration REACH: EC Regulation 1907/2006 RID: Regulation concerning the international transport of dangerous goods by train TLV: Threshold Limit Value TLV CEILING: Concentration that should not be exceeded during any time of occupational exposure. TWA STEL: Short-term exposure limit TWA: Time-weighted average exposure limit VOC: Volatile organic Compounds vPvB: Very Persistent and very Bioaccumulative as for REACH Regulation WGK: Water hazard classes (German). GENERAL BIBLIOGRAPHY 1. Regulation (EU) 1907/2006 (REACH) of the European Parliament 2. Regulation (EC) 1272/2008 (CLP) of the European Parliament 3. Regulation (EU) 790/2009 (I Atp. CLP) of the European Parliament 4. Regulation (EU) 2015/830 of the European Parliament 5. Regulation (EU) 286/2011 (II Atp. CLP) of the European Parliament 6. Regulation (EU) 618/2012 (III Atp. CLP) of the European Parliament 7. Regulation (EU) 487/2013 (IV Atp. CLP) of the European Parliament 8. Regulation (EU) 944/2013 (V Atp. CLP) of the European Parliament 9. Regulation (EU) 605/2014 (VI Atp. CLP) of the European Parliament 10. Regulation (EU) 2015/1221 (VII Atp. CLP) of the European Parliament 11. Regulation (EU) 2016/918 (VIII Atp. CLP) of the European Parliament - The Merck Index. - 10th Edition Handling Chemical Safety INRS - Fiche Toxicologique (toxicological sheet) Patty - Industrial Hygiene and Toxicology N.I. Sax - Dangerous properties of Industrial Materials-7, 1989 Edition IFA GESTIS website ECHA website Database of SDS models for chemicals - Ministry of Health and ISS (Istituto Superiore di Sanità) - Italy Note for users: The information contained in the present sheet are based on our own knowledge on the date of the last version. Users must verify the suitability and thoroughness of provided information according to each specific use of the product.

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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, users must, under their own responsibility, comply with the current health and safety laws and regulations. The producer is relieved from any liability arising from improper uses. Provide appointed staff with adequate training on how to use chemical products.

Changes to previous review:

The following sections were modified:

01/02/03/04/07/09/10/11/12/13/14/15/16.

ZHERMACK S.P.A. Safety Data Sheet according to the Dir. 2001/58/EEC GINGIFAST RIGID Revision date: 09/06/03

Print Date: 09/06/03

1. IDENTIFICATION OF THE PREPARATION AND OF THE COMPANY

- Identification of the preparation:

 Trade name:
 GINGIFAST RIGID

 Trade code:
 C203230/C401520/C401530
- 1.2 Utilization of the substance or of the preparation: Gingival of polivinisiloxane for gingival masks riproduction.
 1.3 Identification of the company:

Supplire: ZHERMACK S.P.A. VIA Bovazecchino, 100 -45021- Badia Polesine (RO) ITALY Emergency telephone number of the company: 0039 0425 597611

2. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous components within the meaning of EEC directive 67/548 and corresponding classification: None

3. HAZARDS IDENTIFICATION

PREPARATION NOT CLASSIFIED DANGEROUS

No specific hazards are encountered under normal product use.

4. FIRST AID MEASURES

- **4.1 Contact with skin**: Wash with plenty of water and soap.
- **4.2** Contact with eyes: Wash immediately with water for at least 10 minutes.

4.3 Swallowing: Induce vomiting. SEEK A MEDICAL EXAMINATION IMMEDIATELY and present the safety-data sheet. A suspension of activated charcoal in water, or liquid paraffin may be administered.

4.4 Inhalation: Ventilate the premises.

5. FIRE-FIGHTING MEASURES

5.1 Recommended extinguishers: water, CO_2 , foam, chemical powders, according to the materials involved in the fire.

- 5.2 Extinguishers not to be used: none in particular.
- 5.3 Risks arising from combustion: avoid inhaling the fumes.
- 5.4 **Protective equipment**: none in particular.

6. ACCIDENTAL RELEASE MEASURES

6.1 Measures for personal safety: Use gloves and protective clothing.

6.2 Environmental measures: limit leakages with earth or sand. If the product has escaped into a water course, into the drainage system, or has contaminated the ground or vegetation, notify the competent authorities.

6.3 Cleaning methods: recover the product for re-use if possible, or for elimination. After the product has been recovered, rinse the area and materials involved with water.

7. HANDLING AND STORAGE

- 7.1 Handling precautions: See, too, paragraph 8 below. Do not eat or drink while working.
- 7.2 Incompatible materials: none in particular. See, too, paragraph 10 below.

7.3 Storage conditions: keep the closed container a temperature varying from 5°C to 27°C (41-80°F).

7.4 **Technical measures**: satisfactory room ventilation.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

8.1 Precautionary measures: give adequate ventilation to the premises where the product is stored and/or handled.

- 8.2 Respiratory protection: not needed for normal use
- 8.3 Protection for hands: not needed for normal use
- 8.4 Eye protection: not needed for normal use
- 8.5 Protection for skin: no special precaution must be adopted for normal use.

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REVISIONE	DATA	DESCRIZIONE	EMISSIONE	APPROVAZIONE
1	01/03/99	Prima emissione		
2	09/06/03	Aggiornamento Dir. 2001/58/CEE	R&S	RSGQA

ZHERMACK S.P.A. Safety Data Sheet according to the Dir. 2001/58/EEC GINGIFAST RIGID

Revision date: 09/06/03

Print Date: 09/06/03

8.6 Exposure limit(s) (ACGIH): none

9. PHYSICAL AND CHEMICAL PROPERTIES

- 9.1 Appearance and colour: orange fluid.
- 9.2 Odour: odourless
- 9.3 Relative density: 1.417 g/cc
- 9.4 Solubility in water: insoluble

10. STABILITY AND REACTIVITY

- **10.1** Conditions to avoid: stable under normal conditions.
- 10.2 Substances to avoid: none in particular.
- **10.3 Hazardous decomposition:products**: none

11. TOXICOLOGICAL INFORMATION

The product does not contain toxicologically relevant substances. See, too, paragraph 2.

12. ECOLOGICAL INFORMATION

Adopt sound working practices, so that the product is not released into the environment.

13. DISPOSAL CONSIDERATIONS

Recover if possible. In so doing, comply with the local and national regulations currently in force.

14. TRANSPORT INFORMATION

Not classified as dangerous in the meaning of transport regulations.

15. REGULATORY INFORMATION

D.Lgs.65/03 (Classification, Packing and Labelling of the preparation dangerous): The preparation should not be considered as dangerous accordingly to dir. 88/379/EEC.

16. OTHER INFORMATION

The information contained herein is based on our state of knowledge at the above-specified date. It refers solely to the product indicated and constitutes no guarantee of particular quality. It is the duty of the user to ensure that this information is appropriate and complete with respect to the specific use intended. This MSDS cancels and replaces any preceding release.

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REVISIONE	DATA	DESCRIZIONE	EMISSIONE	APPROVAZIONE
1	01/03/99	Prima emissione		
2	09/06/03	Aggiornamento Dir. 2001/58/CEE	R&S	RSGQA