SAFETY DATA SHEET
According to regulation (EC) No. 453/2010 annex I

Product: ORTHOFAST

SDS No. 263621 / 263622 / 263623
Created on: 16/02/2000
Updated on: 23/12/2015

1. IDENTIFICATION OF THE SUBSTANCE / MIXTURE AND OF THE COMPANY / UNDERTAKING

1.1 PRODUCT identification	**ORTHOFAST**
1.2 Relevant use of mixture	Dental impression material based on alginate
1.3 Information concerning safety data sheet supplier	PRODUITS DENTAIRES PIERRE ROLLAND SAS
Address	Z.I. du Phare – 17 avenue Gustave Eiffel - 33700 MERIGNAC - FRANCE
e-mail	beatrice.laurent@acteongroup.com
Phone:	+ 33 (0)5 56.34.06.07
Fax:	+ 33 (0)5 56.34.92.92
EMERGENCY CALL NUMBER	http://echa.europa.eu/web/guest/support/helpdesks/national-helpdesks/list-of-national-helpdesks

2. HAZARDS IDENTIFICATION

2.1 Classification of substance or mixture

The product is classified as hazardous pursuant to the provisions set forth in EC Regulation 1272/2008 (CLP) (and subsequent amendments and supplements). The product thus requires a safety datasheet that complies with the provisions of EC Regulation 1907/2006 and subsequent amendments.
Any additional information concerning the risks for health and/or the environment are given in sections 11 and 12 of this sheet.

2.1.1. Regulation 1272/2008 (CLP) and following amendments and adjustments.	Hazard classification and indication H412 Aquatic Chronic 3
2.1.2. 67/548/EEC and 1999/45/EC Directives and following amendments and adjustments.	Danger Symbols: - R phrases: 52/53 The full wording of the Risk (R) and hazard (H) phrases is given in section 16 of the sheet.

2.2 Label elements

Hazard labelling pursuant to EC Regulation 1272/2008 (CLP) and subsequent amendments and supplements.	
Hazard pictograms: Signal words	
Hazard statements:	H412 Harmful to aquatic life with long lasting effects.
Precautionary statements:	P273 Avoid release to the environment
2.3 Other hazards	Classification of the mixture is based on the results of an in vitro assay conducted in accordance with the guidelines provided by OCSE (OECD Test Guideline 437 resp. EU Method B.47 – Bovine Corneal Opacity and Permeability (BCOP) Test Method) and GLP certified - Good Laboratory Practices. For more information refer to section 11.

3. COMPOSITION /INFORMATION ON INGREDIENTS

3.1 Substances Information not relevant.

3.2 Mixtures Contains :

Identification.	Conc. %.	Classification 67/548/EEC.	Classification 1272/2008 (CLP).
DIPOTASSIUM HEXAFLUOROTITANATE			
CAS. 16919-27-0 EC. 240-969-9 INDEX. -	1 - 3	Xn R22, Xi R37/38, Xi R41	Acute Tox. 4 H302, Eye Dam. 1 H318, Skin Irrit. 2 H315, STOT SE 3 H335
ZINC OXIDE			
CAS. 1314-13-2 EC. 215-222-5 INDEX. 030-013-00-7 Reg. no. 01-2119463881-32-XXXX	0,5 - 2,5	N R50/53	Aquatic Acute 1 H400 M=1, Aquatic Chronic 1 H410
VASELINE OIL			
CAS. 8042-47-5 EC. 232-455-8 INDEX. - Reg. no. 01-2119487078-27-XXXX	1 - 3	Xn R65	Asp. Tox. 1 H304
ACETIC ACID			
CAS. 64-19-7 EC. 200-580-7 INDEX. 607-002-00-6	0 - 0,2	R10, C R35, Note B	Flam. Liq. 3 H226, Skin Corr. 1A H314, Note B
FORMIC ACID			
CAS. 64-18-6 EC. 200-579-1 INDEX. 607-001-00-0	0 - 0,2	C R35, Note B	Skin Corr. 1A H314, Note B

Note: Upper limit is not included into the range.
The full wording of the Risk (R) and hazard (H) phrases is given in section 16 of the sheet.

4. FIRST AID MEASURES

4.1 Description of the 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. Rinse skin with a shower immediately. Get medical advice/attention immediately. Wash contaminated clothing before using it again.

Inhalation Remove to open air. If the subject stops breathing, administer artificial respiration. Get medical advice/attention immediately.

Ingestion	Get medical advice/attention immediately. Do not induce vomiting. Do not administer anything not explicitly authorised by a doctor.
4.2 Most important symptoms and effects, both acute and delayed	For symptoms and effects caused by the contained substances, see chap. 11.
4.3 Indications of possible immediate medical attention and particular treatment needed	Information not available.

5. FIREFIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media	The extinguishing equipment should be of the conventional kind: carbon dioxide, foam, powder and water spray.
Unsuitable extinguishing equipment	None in particular.
5.2 Special hazards resulting from substance or mixture	HAZARDS CAUSED BY EXPOSURE IN THE EVENT OF FIRE Do not breathe combustion products. The product is combustible and, when the powder is released into the air in sufficient concentrations and in the presence of a source of ignition, it can create explosive mixtures with air. Fires may start or get worse by leakage of the solid product from the container, when it reaches high temperatures or through contact with sources of ignition.
5.3 Advice to 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 firefighting 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).

6. ACCIDENTAL RELEASE MEASURES

6.1 <u>Personal precautions, protective equipment and emergency procedures.</u>

	If there are no contraindications, spray powder with water to prevent the formation of dust. Avoid breathing vapours/mists/gases. 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 of confinement and cleaning up

Use spark-proof mechanical equipment to collect the leaked product and place it in containers for recovery or disposal.
If there are no contraindications, use jets of water to eliminate product residues.
Make sure the leakage site is well aired.
Check incompatibility for container material in section 7.
Contaminated material should be disposed of in compliance with the provisions set forth in point 13.

6.4 Reference to other sections

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

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

Conditions of storage

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 Special end use(s)

Information not available.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

8.1 Control parameters

Regulatory References:

United Kingdom	EH40/2005 Workplace exposure limits. Containing the list of workplace exposure limits for use with the Control of Substances Hazardous to Health Regulations (as amended).
Éire	Code of Practice Chemical Agent Regulations 2011.
OEL EU	Directive 2009/161/EU; Directive 2006/15/EC; Directive 2004/37/EC; Directive 2000/39/EC.
TLV-ACGIH	ACGIH 2012

ZINC OXIDE

Threshold Limit Value.

Type	Country	TWA/8h mg/m3	TWA/8h ppm	STEL/15min mg/m3	STEL/15min ppm
OEL	IRL	2			
TLV-ACGIH		2		10	

VASELINE OIL

Threshold Limit Value.

Type	Country	TWA/8h mg/m3	TWA/8h ppm	STEL/15min mg/m3	STEL/15min ppm
TLV-ACGIH		5			

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
Oral.			VND	40 mg/kg/d				
Inhalation.			VND	35 mg/m3			VND	160 mg/m3
Skin.			VND	92 mg/kg/d			VND	220 mg/kg/d

ACETIC ACID

Threshold Limit Value.

Type	Country	TWA/8h mg/m3	TWA/8h ppm	STEL/15min mg/m3	STEL/15min ppm
OEL	EU	25	10		
OEL	IRL	25	10	37	15
TLV-ACGIH		25	10	37	15

FORMIC ACID

Threshold Limit Value.

Type	Country	TWA/8h mg/m3	TWA/8h ppm	STEL/15min mg/m3	STEL/15min ppm
OEL	EU	9	5		
OEL	IRL	9	5		
TLV-ACGIH		9,4	5	18,8	10
WEL	UK	9,6	5		

Legend:
(C) = CEILING ; INHAL = Inhalable Fraction ; RESP = Respirable Fraction ; THORA = Thoracic Fraction.
VND = hazard identified but no DNEL/PNEC available ; NEA = no exposure expected ; NPI = no hazard identified.

During the risk assessment process, it is essential to take into consideration the ACGIH occupational exposure levels for inert particulate otherwise classified (PNOC respirable fraction: 3 mg/m3; PNOC inhalable fraction: 10 mg/m3). For values above these limits, use a P type filter, whose class (1, 2 or 3) must be chosen according to the outcome of risk assessment.

8.2 Exposure controls

During the risk assessment process, it is essential to take into consideration the ACGIH occupational exposure levels for inert particulate otherwise classified (PNOC respirable fraction: 3 mg/m3; PNOC inhalable fraction: 10 mg/m3). For values above these limits, use a P type filter, whose class (1, 2 or 3) must be chosen according to the outcome of risk assessment.

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.

Provide an emergency shower with face and eye wash station.

Hand protection	In the case of prolonged contact with the product, protect the hands with penetration-resistant work gloves (see standard EN 374). Work glove material must be chosen according to the use process and the products that may form. Latex gloves may cause sensitivity reactions.
Skin protection	Wear category I 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).
Respiratory protection	Use a type P filtering facemask (see standard EN 149) or equivalent device, whose class (1, 2 or 3) and effective need, must be defined according to the outcome of risk assessment.

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance	Powder
Colour	Orange
Odour	Apricot
Odour threshold.	Not available.
pH.	Not available.
Melting point / freezing point.	Not available.
Initial boiling point.	Not available.
Boiling range.	Not available.
Flash point.	Not available.
Evaporation Rate	Not applicable.
Flammability of solids and gases	Not available.
Lower inflammability limit.	Not available.
Upper inflammability limit.	Not available.
Lower explosive limit.	Not available.
Upper explosive limit.	Not available.
Vapour pressure.	Not available.
Vapour density	Not available.
Relative density.	Not available.
Solubility	Partially soluble in water
Partition coefficient: n-octanol/water	Not available.
Auto-ignition temperature.	Not available.
Decomposition temperature.	Not applicable.

Viscosity	Not applicable.
Explosive properties	Not available.
Oxidising properties	Not available.
9.2 Other information	Information not available.

10. STABILITY AND REACTIVTY

10.1 Reactivity
There are no particular risks of reaction with other substances in normal conditions of use.
FORMIC ACID: decomposes under the effect of heat. At room temperature it can release carbon monoxide. Dissolves various types of plastic materials.

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.
FORMIC ACID: risk of explosion on contact with: sodium hypochlorite, nitromethane, hydrogen peroxide, furfuryl alcohol. Can react dangerously with: alkaline hydroxides, alkaline earth metals, aluminium, palladium-carbon, heat, oxidising agents, phosphorus pentoxide, nitroc acid, concentrated sulphuric acid, trihydrate thallium trinitrate. Forms explosive mixtures with the air.
ACETIC ACID: risk of explosion on contact with: chromium (IV) oxide, potassium permanganate, sodium peroxide, perchloric acid, phosphorus chloride, hydrogen peroxide. Can react dangerously with: alcohols, bromine pentafluoride, chlorosulphuric acid, dichromate-sulphuric acid, ethane diamine, ethylene glycol, potassium hydroxide, strong bases, sodium hydroxide, strong oxidising agent, nitric acid, ammonium nitrate, potassium tert-butoxide, oleum. Forms explosive mixtures with air.

10.4 Conditions to avoid
None in particular. However the usual precautions used for chemical products should be respected.
FORMIC ACID: avoid exposure to light, sources of heat and naked flames.
ACETIC ACID: avoid exposure to sources of heat and naked flames.

10.5 Incompatible materials
FORMIC ACID: strong oxidising agents, strong bases, sulphuric acid and furfuryl acid.
ACETIC ACID: carbonates, hydroxides, many oxides and phosphates. Oxidising substances and bases.

10.6 Hazardous decomposition products
FORMIC ACID: carbon monoxide, hydrogen.

11. TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects
Internal test carried out on a similar alginate with a higher content of corrosive components
Eye irritation/corrosion: negative (oecd 437 resp. eu method b.47, glp, in vitro, study report 2014).

ACETIC ACID
LD50 (Oral). 3310 mg/kg Rat
LD50 (Dermal). 1060 mg/kg Rabbit
LC50 (Inhalation). 11,4 mg/l/4h Rat
Irritation/Corrosion
Skin irritation: Corrosive (MSDS supplier).

Eye irritation: Corrosive (MSDS supplier).
Skin Sensitization: No data available.
STOT –
Repeated exposure: No data available.
Genotoxicity in vitro: No data available.
Genotoxicity in vivo: No data available.
Carcinogenicity: No data available.
Toxicity to reproduction: The administration of up to 1600 mg/kg (body weight) to pregnant rats for 10 consecutive days had no clearly discernible effect on nidation or on maternal or fetal survival. (EU Method B.31, ECHA dossier).

ZINC OXIDE
LD50 (Oral). > 5000 mg/kg (OECD 401, rat, ECHA dossier).
LD50 (Dermal). > 2000 mg/kg (OECD 402, GLP, rat, ECHA dossier).
LC50 (Inhalation). > 5,7 mg/l (OECD 403, rat, ECHA dossier).
Irritation/Corrosion
Skin irritation: Not irritating (publication, in vivo, guinea pig, ECHA dossier).
Eye irritation: Not irritating (OECD 405, GLP, in vivo, rabbit, ECHA dossier).
Skin Sensitization: Insufficient data (OECD 406, GLP, Guinea pig maximisation test, ECHA dossier).
STOT –
Repeated/single exposure: Negative (subchronic, inhalation exposure, rat, ECHA dossier).
Genotoxicity: Negative (in vivo, in vitro, ECHA dossier).
Carcinogenicity: No data available.
Toxicity to reproduction: No data available.

VASELINE OIL
LD50 (Oral). > 5000 mg/kg (similar or equivalent to OECD 401, rat, dossier ECHA)
LD50 (Dermal). > 2000 mg/kgbw (similar or equvalent to OECD 402, rabbit, dossier ECHA)
LC50 (Inhalation). > 5 mg/L (OECD 403, rat, 4h, dossier ECHA)
Irritation/Corrosion
Skin irritation: No data available.
Eye irritation: No data available.
Skin Sensitization: No data available.
STOT –
Repeated/single exposure: No data available.
CMR effects: No data available.
Aspiration toxicity: toxic for aspiration (MSDS supplier).

DIPOTASSIUM HEXAFLUOROTITANATE
LD50 (Oral). 200 mg/kg guinea pig
LD50 (Dermal). 360 mg/kg (subcutaneous, frog, MSDS supplier).
Acute Toxicity
Inhalation: No data available.

Irritation/Corrosion
Skin irritation:No data available.
Eye irritation: Corrosive (according to OECD 405, in vivo, rabbit, ECHA dossier).
Skin sensitization: Not sensitising (OECD 406, GLP, Guinea pig maximisation test, ECHA dossier).
STOT Repeated/single exposure: No data available.
CMR effects: No data available.

12. ECOLOGICAL INFORMATION

12.1 Toxicity

DIPOTASSIUM HEXAFLUOROTITANATE
EC50 = 18 mg/l (microorganisms, 24h, MSDS supplier).

ACETIC ACID
LC50 - for Fish.
> 300,82 mg/l/96h (similar to OECD Guideline 203, Oncorhynchus mykiss, freshwayer, ECHA dossier).
EC50 - for Crustacea.
> 300,82 mg/l/48h (OECD Guideline 202, Daphnia magna, freshwater, ECHA dossier).

ZINC OXIDE
LC50 - for Fish.
1,1 mg/l/96h Oncorhynchus mykiss
EC50 - for Crustacea.
1,7 mg/l/48h Daphnia magna
EC50 - for Algae / Aquatic Plants.
0,14 mg/l/72h
Chronic NOEC for Fish.
0,53 mg/l
Chronic NOEC for Algae / Aquatic Plants.
0,024 mg/l

12.2 Persistence and degradability

ZINC OXIDE
Solubility in water.
2,9 mg/l
NOT rapidly biodegradable.

12.3 Bioaccumulation potential

ZINC OXIDE
BCF.
> 175

12.4 Mobility in the soil

Information not available.

12.5 Results of PBT and vPvB assessments

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

Information not available.

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.
Avoid littering. Do not contaminate soil, sewers and waterways.
CONTAMINATED PACKAGING
Contaminated packaging must be recovered or disposed of in compliance with national waste management regulations.

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.

15. REGULATORY INFORMATION

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

Seveso category	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)	None
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 evaluation

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

16. OTHER INFORMATION

Successive modifications:
Version 1 : 16/02/2000 : Created
Version 2 : 10/10/2012 : Changes according to 453/2010/EC regulation
Version 3 : 23/12/2015 : Changes according to CLP 1272/2008/EC

Abbreviations:
Text of hazard (H) indications mentioned in section 2-3 of the sheet:

Flam. Liq. 3	Flammable liquid, category 3
Acute Tox. 4	Acute toxicity, category 4
Asp. Tox. 1	Aspiration hazard, category 1
Skin Corr. 1A	Skin corrosion, category 1A
Eye Dam. 1	Serious 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
Aquatic Acute 1	Hazardous to the aquatic environment, acute toxicity, category 1
Aquatic Chronic 1	Hazardous to the aquatic environment, chronic toxicity, category 1
Aquatic Chronic 3	Hazardous to the aquatic environment, chronic toxicity, category 3
H226	Flammable liquid and vapour.
H302	Harmful if swallowed.
H304	May be fatal if swallowed and enters airways.
H314	Causes severe skin burns and eye damage.
H318	Causes serious eye damage.
H319	Causes serious eye irritation.
H315	Causes skin irritation.
H335	May cause respiratory irritation.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.
H412	Harmful to aquatic life with long lasting effects.

Text of risk (R) phrases mentioned in section 2-3 of the sheet:

R10	Flammable.
R22	Harmful if swallowed.
R35	Causes severe burns.
R37/38	Irritating to respiratory system and skin.
R41	Risk of serious damage to eyes.
R50/53	Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
R52/53	Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
R65	Harmful: may cause lung damage if swallowed.

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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. Directive 1999/45/EC and following amendments
2. Directive 67/548/EEC and following amendments and adjustments
3. Regulation (EC) 1907/2006 (REACH) of the European Parliament
4. Regulation (EC) 1272/2008 (CLP) of the European Parliament
5. Regulation (EC) 790/2009 (I Atp. CLP) of the European Parliament
6. Regulation (EC) 453/2010 of the European Parliament
7. Regulation (EC) 286/2011 (II Atp. CLP) of the European Parliament
8. Regulation (EC) 618/2012 (III Atp. CLP) of the European Parliament
9. The Merck Index. - 10th Edition
10. Handling Chemical Safety
11. Niosh - Registry of Toxic Effects of Chemical Substances
12. INRS - Fiche Toxicologique (toxicological sheet)
13. Patty - Industrial Hygiene and Toxicology
14. N.I. Sax - Dangerous properties of Industrial Materials-7, 1989 Edition
15. ECHA website

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.
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.

End of the document.