

SECTION 1. Identification of the substance/mixture and of the company/enterprise**1.1. Product identifier**

Product name : BENTOGRAN
Product code: refer to sales department
Chemical Name: Bentonite
CAS #1 : 1302-78-9
EC N. : 215-108-5

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

Clarifying Agents
Sectors of use:
Manufacture of food products[SU4]
Product category:
Technological adjuvant for limited food use

Not recommended uses
Do not use for purposes other than those listed

1.3. Details of the supplier of the safety data sheet

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SECTION 2. Hazards identification**2.1. Classification of the substance or mixture**

CAS 1302-78-9 EINECS 215-108-5

2.1.1 Classification according to Regulation (EC) No 1272/2008:

This product does not meet the criteria for classification in any hazard class according to Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures.

Pictograms:

None

Hazard Class and Category Code(s):

Non hazardous

Hazard statement Code(s):

Non hazardous

2.2. Label elements

Labelling according to Regulation (EC) No 1272/2008:

Pictogram, Signal Word Code(s):

None

Hazard statement Code(s):

Non hazardous

Supplemental Hazard statement Code(s):

not applicable

Precautionary statements:

None in particular.

Contains:

Ingredients: activated bentonite.

Food use. Also for oenological use. Not intended for the final consumer. In accordance with current regulations on the specific matter.

2.3. Other hazards

Based on the available data, no PBT or vPvB substances are present in accordance with Regulation (EC) 1907/2006, annex XIII

Based on available data, there are no substances that interfere with the endocrine system in accordance with Regulation (EU) 2017/2100 and Regulation (EU) 2018/605 in concentrations >0.1.

During handling and use, the product may generate respirable dust. The dust may contain respirable crystalline silica. Prolonged or massive inhalation of respirable crystalline silica may cause pulmonary fibrosis, commonly referred to as silicosis. The main symptoms of pulmonary fibrosis are coughing and breathing difficulties. Occupational exposure to respirable dust and respirable crystalline silica must be monitored and controlled. The product must be handled using methods and techniques that minimise or eliminate dust formation.

The product contains less than 1% crystalline silica (fine fraction) as determined by the SWeRF method. The respirable crystalline silica content can be measured using the 'Size-Weighted Relevant Fine Fraction - SWeRF' method. Full details of the SWeRF method are available at www.crystallinesilica.eu. The data is based on our latest knowledge but does not constitute any guarantee of the product's characteristics and does not give rise to any contractual legal relationship.

This document is outside the scope of Article 31 of REACH

SECTION 3. Composition/information on ingredients**3.1 Substances**

No dangerous substance to report.

Substance	Concentration[w/w]	Classification	Index	CAS	EINECS	REACH
Bentonite substance for which there are Community workplace exposure limits	100%			1302-78-9	215-108-5	

3.2 Mixtures

Irrilevant

SECTION 4. First aid measures**4.1. Description of first aid measures**

Inhalation:

Ventilate the area. Move immediately the contaminated patient from the area and keep him at rest in a well ventilated area. If you feel unwell seek medical advice.

Direct contact with skin (of the pure product).:
Wash thoroughly with soap and running water.

Direct contact with eyes (of the pure product).:
Wash immediately and thoroughly with running water for at least 10 minutes.

Ingestion:
Not dangerous. In case of malaise consult a doctor.

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

Symptoms/Effects of Inhalation: Dust from this material, if present and if excessively inhaled, may cause respiratory irritation. Although no precise data are known to exist regarding the health effects of this material on humans and animals, inhalation of this material is considered to present a risk.

Symptoms/Injuries of Skin Contact: None under normal conditions. Dust may cause irritation in skin folds or if in contact with tight clothing.

Symptoms/Injuries of Eye Contact: None under normal conditions. Dust from this product may cause eye irritation.

Symptoms/Injuries of Ingestion: None under normal conditions.

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

Symptomatic treatment.

SECTION 5. Firefighting measures

5.1. Extinguishing media

Suggested extinguishing media:
Water spray, CO₂, foam, dry chemical, depending on the materials involved in the fire.

Extinguishing media to avoid:
Water jets. Use water jets only to cool the surfaces of the containers exposed to fire.

5.2. Special hazards arising from the substance or mixture

Fire Hazard: Non-flammable.

Explosion Hazard: No direct explosion hazard.

Hazardous Combustion Products in Fire: None.

5.3. Advice for firefighters

Precautionary measures in case of fire: Avoid dust formation. Suitable respiratory equipment may be necessary. Spills are slippery and may cause falls.

Firefighting instructions: Extinguish the fire from a safe distance/protected point. Do not enter the fire area without appropriate protective equipment, including self-contained breathing apparatus.
Protective equipment for firefighters: Use self-contained breathing apparatus and protective clothing. Do not intervene without appropriate protective equipment. Self-contained breathing apparatus. Full body protection.

SECTION 6. Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1 For non-emergency personnel:

Protective equipment: Ensure adequate ventilation. Avoid contact with skin, eyes, and clothing. Avoid dust generation. Avoid prolonged inhalation. See section 8. Avoid breathing dust, mist, or spray.

Caution: Product may make floors slippery.

Emergency procedures: Ventilate the spill area.

6.1.2 For emergency responders:

Protective equipment: Do not intervene without adequate protective equipment. For more information, see section 8: "Exposure controls - personal protection".

Emergency procedures: Avoid inhalation of dust. Avoid the development of dust. Avoid contact with eyes, skin, and clothing. Caution: The product may make the floor slippery. Keep unnecessary personnel away. Eliminate all naked flames and possible sources of ignition. Do not smoke. Provide adequate ventilation. Evacuate the danger area and, if necessary, consult an expert.

6.2. Environmental precautions

Contain spills

Inform the competent authorities.

Dispose of the waste material in compliance with the regulations

6.3. Methods and material for containment and cleaning up

6.3.1 Containment:

Recover the product for reuse, if possible, or for elimination.

6.3.2 Cleaning up:

After wiping up, wash with water the area and materials involved

6.3.3 Other information:

None in particular.

6.4. Reference to other sections

Refer to paragraphs 8 and 13 for more information

SECTION 7. Handling and storage

7.1. Precautions for safe handling

At work do not eat or drink.

See also paragraph 8 below.

7.2. Conditions for safe storage, including any incompatibilities

Keep in original container closed tightly. Do not store in open or unlabelled containers.
Keep containers upright and safe by avoiding the possibility of falls or collisions.
Store in a cool and dry place, away from heat sources and direct exposure to sunlight.

7.3. Specific end use(s)

Manufacture of food products:
Handle with care.
Store in a clean, dry, ventilated area away from heat and direct sunlight.
Keep container tightly closed.

SECTION 8. Exposure controls/personal protection**8.1. Control parameters**

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Related to contained substances:

Bentonite:

INHALABLE, DUST

Limit value – Eight hours

(ppm)/(mg/m³)

Austria: x/10

Belgium: x/10

Denmark: x/10

France: x/4 (1)

Germany (AGS): x/10(1)(2)(3)

Germany (DFG): x/4

Hungary: x/10

Ireland: x/10

Italy: x/10

Poland: x/10

Singapore: x/10

Spain: x/10

Sweden: x/10

Switzerland: x/10

UK: x/10

Limit value – Short term

(ppm)/(mg/m³)

Austria: x/20

Denmark: x/20

Germany (AGS): x/20(1)(2)(3)

Remarks:

France: (1) Bold type: Restrictive statutory limit values

Germany (AGS): (1) Insoluble particulates (2) not applicable for ultra-fine dusts and dusts with specific toxicity (3) the limit value is a general upper limit for technical measures, as long as no specific regulations for toxic or carcinogenic substances are available.

RESPIRABLE DUST

Limit value – Eight hours

(ppm)/(mg/m³)

Austria: x/5

Belgium: x/3

France: x/0.9 (1)

Germany (AGS): x/1,25 (1)(2)(3)(4)(5)

Germany (DFG): x/0.3 (1)

Hungary: x/6

Ireland: x/4

Italy: x/3

Spain: x/3

Switzerland: x/3

UK: x/4

USA – OSHA: x/5

Limit value – Short term

(ppm)/(mg/m³)

Austria: x/10

Germany (DFG): x/2.4 (1)(2)

Remarks:

Austria: STV 15 minutes average value

France: (1) Bold type: Restrictive statutory limit values

Germany (AGS): (1) Insoluble particulates (2) not applicable for ultra-fine dusts and dusts with specific toxicity (3) the limit value is a general upper limit for technical measures, as long as no specific regulations for toxic or carcinogenic substances are available (4) the limit value was derived for dusts with an average density of 2.5 mg/m³ (5) at work areas where all technical and further measures are state of the art but the LV is still not adhered, the old LV can be applied for a transitional period until 31st December 2018 (8 h-LV: 3.0 mg/m³, 15 minutes average value: 6.0 mg/m³)

Germany (DFG): (1) For granular, bio-resistant dusts, except ultra-fine particles (2) 15 minutes average value

SILICA, CRYSTALLINE, RESPIRABLE

Limit value – Eight hours

(ppm)/(mg/m³)

Australia: x/0.05

Austria: x/0.15

Belgium: x/0.1

Canada - Québec: x/0.05

Denmark: x/0.05

European Union: x/0.1

Finland: x/0.05

Ireland: x/0.1

Israel: x/0.1

Italy: x/10

Japan (JSHO): x/0.03 (1)

Latvia: x/0.1

New Zealand: x/0.025(1)

Spain: x/0.05

Switzerland: x/0.15 (1)

The Netherlands: x/0.0758(1)

USA (NIOSH): x/0.05

UK: x/0.1 (1)

Remarks:

(1) Respirable fraction

8.2. Exposure controls

Appropriate engineering controls:

Manufacture of food products:

No specific monitoring foreseen (act according to good practice and specific rules for the type of risk associated)

8.2.2 Individual protection measures:

(a) Eye / face protection

Not needed for normal use, unless otherwise provided by the employer and / or by assessments of environmental hygiene investigations.

(b) Skin protection

(i) Hand protection

Not needed for normal use, unless otherwise provided by the employer and / or by assessments of environmental hygiene investigations.

(ii) Other

Wear normal work clothing.

(c) Respiratory protection

Not needed for normal use, unless otherwise provided by the employer and / or by assessments of environmental hygiene investigations.

(d) Thermal hazards

No hazard to report

Environmental exposure controls:

Use according to good working practices and avoid to disperse the product into the environment.

SECTION 9. Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical and chemical properties	Value	Determination method
Physical state	Granular powder	
Colour	Beige	
Odour	odorless	
Odour threshold	not determined as considered not relevant for the characterization of the product	
Melting point/freezing point	not determined as considered not relevant for the characterization of the product	
Boiling point or initial boiling point and boiling range	not determined as considered not relevant for the characterization of the product	
Flammability	not determined as considered not relevant for the characterization of the product	
Lower and upper explosion limit	not determined as considered not relevant for the characterization of the product	
Flash point	not determined as considered not relevant for the characterization of the product	ASTM D92

Physical and chemical properties	Value	Determination method
Auto-ignition temperature	not determined as considered not relevant for the characterization of the product	
Decomposition temperature	not determined as considered not relevant for the characterization of the product	
pH	9,5 ± 0,5 (20°C; sol. 2%)	
Kinematic viscosity	not determined as considered not relevant for the characterization of the product	
Solubility	not determined as considered not relevant for the characterization of the product	
Water solubility	not determined as considered not relevant for the characterization of the product	
Partition coefficient n-octanol/water (log value)	not determined as considered not relevant for the characterization of the product	
Vapour pressure	not determined as considered not relevant for the characterization of the product	
Density and/or relative density	0,85 ± 0,05 (20°C)	
Relative vapour density	not determined as considered not relevant for the characterization of the product	
Particle characteristics	not determined as considered not relevant for the characterization of the product	

9.2. Other information

9.2.1 Information with regard to physical hazard classes

Irrilevant

9.2.2 Other safety characteristics

Irrilevant

SECTION 10. Stability and reactivity

10.1. Reactivity

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Related to contained substances:

Bentonite:

The product is non-reactive under normal conditions of use, storage and transport.

10.2. Chemical stability

Stable under normal conditions of use and storage

10.3. Possibility of hazardous reactions

No dangerous reactions are known under normal conditions of use.

10.4. Conditions to avoid

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Related to contained substances:

Bentonite:

Dust generation in enclosed and confined areas

10.5. Incompatible materials

No further information available

10.6. Hazardous decomposition products

Under normal conditions of storage and use, no hazardous decomposition products should be produced.

SECTION 11. Toxicological information**11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008**

(a) acute toxicity: based on available data the classification criteria are not met

ATE(mix) oral = Not classified (no relevant component)

ATE(mix) dermal = Not classified (no relevant component)

ATE(mix) inhal = Not classified (no relevant component)

(b) skin corrosion/dermal irritation: based on available data the classification criteria are not met

(c) severe eye damage/eye irritation: based on available data the classification criteria are not met

(d) respiratory or skin sensitisation: based on available data the classification criteria are not met

(e) germ cell mutagenicity: based on available data the classification criteria are not met

(f) carcinogenicity: based on available data the classification criteria are not met.

(g) reproductive toxicity: based on available data, the classification criteria are not met.

(h) specific target organ toxicity (STOT) single exposure: based on available data, the classification criteria are not met.

(i) specific target organ toxicity (STOT) repeated exposure: based on available data, the classification criteria are not met.

(j) Aspiration hazard: based on available data, the classification criteria are not met.

Related to contained substances:

(a) acute toxicity: Bentonite: Ingestion - LD50 rat (mg/kg/24h bw): >2000
Contact with skin - LC50 rat / rabbit (mg/kg/24h bw): nd Bentonite is insoluble and has low absorption through the skin.
Inhalation - LD50 rat (mg/l/4h): >5.27

(b) skin corrosion/irritation: Bentonite: Not classified (Based on available data, the classification criteria are not met)
pH: Not determined, (OECD 405 method)
Bentonite: Not classified (Based on available data, the classification criteria are not met) pH: Not determined, (OECD method 404)

(c) serious eye damage/irritation: Bentonite: Not classified (Based on available data, the classification criteria are not met) pH: Not determined, (OECD 405 method)
Bentonite: Not classified (Based on available data, the classification criteria are not met) pH: Not determined, (OECD method 404)

(d) respiratory or skin sensitisation: Bentonite: Not classified ((OECD method 429))

(e) germ cell mutagenicity: Bentonite: Not classified ((OECD 471 - Ames test); (OECD method 473); (OECD method 476); negative.)

(f) carcinogenicity: Bentonite: Not classified (Data not available)

(g) reproductive toxicity: Bentonite: Not classified (Based on available data, the classification criteria are not met)

(h) specific target organ toxicity (STOT) single exposure: Bentonite: Not classified (Based on available data, the classification criteria are not met)

(i) specific target organ toxicity (STOT) repeated exposure Bentonite: Not classified.

Oral: Short-term repeated dose toxicity studies (28 days) and sub-chronic toxicity studies (90 days) were conducted with bentonite in mice. The mice were fed bentonite at 10%, 25% or 50% for 61 days. Hepatoma was observed in mice treated with a 50% bentonite diet. This is due to bentonite being an exchange silicate and thus removing choline from the mice's intestinal contents after more than 200 days of feeding 50% bentonite. Hepatomas developed in 11 out of 12 mice. The livers of mice fed a 50% bentonite diet were severely damaged. The liver damage observed in the bentonite-fed group is consistent with that expected during prolonged choline deficiency; exchange silicate is put forward as a partial explanation for the development of hepatomas in mice in these experiments.

Observed effect on the liver. However, the studies were conducted in mice at a very high concentration and the effects observed are considered to be secondary to digestive dysfunction. Therefore, the classification of bentonite for toxicity in case of prolonged oral exposure is not justified.

Inhalation: Animal and in vitro data indicate a difference between crystalline quartz and the quartz content of bentonite. A quantitative assessment based on animal data is not possible as no relevant repeated-dose inhalation studies are available. Human data are limited to clinical cases suggesting a relationship between high exposure to bentonite (exposures in the 20th century without state-of-the-art protective measures and without maximum dust exposure limits). The link between exposure to bentonite and silicosis is not considered to be sufficiently proven.

With regard to the classification and labelling of bentonite, the study is not considered sufficient to reach a conclusion on the specific classification of bentonite with specific target organ toxicity in case of repeated exposure (STOT-RE). The lungs may be affected by repeated exposure to high doses, as suggested by human case studies. However, this effect only occurs at concentrations that exceed the lung's capacity for purification and is not relevant to humans given the general exposure limits established. Therefore, the classification of bentonite for toxicity in the event of prolonged exposure by inhalation is not justified.

(j) aspiration hazard: Bentonite: Based on available data, the classification criteria are not met.

11.2. Information on other hazards

No data available.

11.2.1. Endocrine disrupting properties

Based on available data, there are no substances that interfere with the endocrine system in accordance with Regulation (EU) 2017/2100 and Regulation (EU) 2018/605 in concentrations >0.1.

SECTION 12. Ecological information**12.1. Toxicity**

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Related to contained substances:

Bentonite:

Acute toxicity - fish LC50 (mg/l/96h): 16000

Acute toxicity - crustaceans EC50 (mg/l/48h): > 100 mg/l Daphnia magna

Acute toxicity - algae ErC50 (mg/l/72-96h): >100

Acute toxicity M-factor = 1

Use according to good working practices and avoid to disperse the product into the environment.

12.2. Persistence and degradability

Not relevant for inorganic substances

12.3. Bioaccumulative potential

Not relevant for inorganic substances

12.4. Mobility in soil

Bentonite is nearly insoluble and therefore has low mobility in most soils.

12.5. Results of PBT and vPvB assessment

This substance/mixture does not meet the PBT criteria of REACH Regulation, Annex XIII. This substance/mixture does not meet the vPvB criteria of REACH Regulation, Annex XIII.

12.6. Endocrine disrupting properties

The substance is not included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or is not identified as having endocrine disrupting properties according to the criteria established by Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605.

12.7. Other adverse effects

No other adverse effects have been identified. According to the criteria of the European classification and labeling system, the substance does not require classification as dangerous for the environment.

SECTION 13. Disposal considerations**13.1. Waste treatment methods**

Do not reuse empty containers. Dispose of them in accordance with the regulations in force. Any remaining product should be disposed of according to applicable regulations by addressing to authorized companies.
Recover if possible. Operate according to local or national regulations

SECTION 14. Transport information**14.1. UN number or ID number**

Not included in the field of application of regulations concerning the transport of dangerous goods: by road (ADR); by rail (RID); by air (ICAO / IATA); by sea (IMDG).

14.2. UN proper shipping name

None

14.3. Transport hazard class(es)

None

14.4. Packing group

None

14.5. Environmental hazards

None

14.6. Special precautions for user

No data available.

14.7. Maritime transport in bulk according to IMO instruments

Transport in bulk is not foreseen

SECTION 15. Regulatory information

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

Restrictions relating to the product or the substances contained (Annex XVII EC Reg. 1907/2006): not applicable
Substances in Candidate list (art. 59 EC Reg. 1907/2006): the product does not contain SVHC in percentage = a 0.1 %.

Regulation (EU) 1169/2011: see point 2.2

Regulation (EU) 1308/2013: see point 2.2

15.2. Chemical safety assessment

No chemical safety assessment was carried out by the supplier

SECTION 16. Other information**16.1. Other information**

Points modified compared to previous release: 1.1. Product identifier, 1.2. Relevant identified uses of the substance or mixture and uses advised against, 1.3. Details of the supplier of the safety data sheet, 1.4. Emergency telephone number, 2.3. Other hazards, 4.1. Description of first aid measures, 4.2. Most important symptoms and effects, both acute and delayed, 4.3. Indication of any immediate medical attention and special treatment needed, 5.1. Extinguishing media, 5.2. Special hazards arising from the substance or mixture, 5.3. Advice for firefighters, 6.1. Personal precautions, protective equipment and emergency procedures, 6.2. Environmental precautions, 6.3. Methods and material for containment and cleaning up, 6.4. Reference to other sections, 7.1. Precautions for safe handling, 7.2. Conditions for safe storage, including any incompatibilities, 7.3. Specific end use(s), 8.1. Control parameters, 8.2. Exposure controls, 9.2.1 Information with regard to physical hazard classes, 9.2.2 Other safety characteristics, 10.1. Reactivity, 10.2. Chemical stability, 10.3. Possibility of hazardous reactions, 10.4. Conditions to avoid, 10.5. Incompatible materials, 10.6. Hazardous decomposition products, 11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008, 11.2. Information on other hazards, 12.1. Toxicity, 12.2. Persistence and degradability, 12.3. Bioaccumulative potential, 12.4. Mobility in soil, 12.5. Results of PBT and vPvB assessment, 12.6. Endocrine disrupting properties, 12.7. Other adverse effects, 13.1. Waste treatment methods, 14.1. UN number or ID number, 14.2. UN proper shipping name, 14.3. Transport hazard class(es), 14.4. Packing group, 14.5. Environmental hazards, 14.6. Special precautions for user, 14.7. Maritime transport in bulk according to IMO instruments, 15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture, 15.2. Chemical safety assessment

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

No hazard to report. Classification procedure: Calculation method

Main normative references:

Reg. (CE) n. 1907 del 18/12/06 REACH (Registration, Evaluation and Authorisation of CHemicals) et seq.

Reg. (CE) 1272/2008 CLP (Classification Labelling and Packaging) et seq.

Directive 2012/18/EU (on the control of major-accident hazards involving dangerous substances) et seq.

Training required: This document must be submitted to the employer to determine the possible need for appropriate training for workers to ensure protection of human health and the environment.

n.a.: not applicable

n.d.: not available

ADR: Accord européen relative au transport International des marchandises dangereuses par route (European Agreement concerning the International Carriage of Dangerous Goods by Road)

ATE: Acute Toxicity Estimati

BFC: BioconCentration Factor

BOD: Biochemical Oxygen Demand

CAS: Chemical Abstract Service number

CAP: Centre AntiPoison

CE/EC number EINECS (European Inventory of existing Commercial Substances) e ELINCS (European List of notified

Chemical Substances)

CL50/LC50: Lethal Concentration 50

DL50/LD50: Lethal Dose 50

COD: Chemical Oxygen Demand

DNEL: Derived No Effect Level

EC50: half maximal Effective Concentration

ERC: Environment Release Classes

EU/UE: European Union

IATA: International Air Transport Association

ICAO: International Civil Aviation Organization

IMDG: International Maritime Dangerous Goods code

Kow: Octanol water partition coefficient

NOEC: No Observed Effect Concentration

OEL: Occupational Exposure Limit

PBT: Persistent Bioaccumulative and Toxic

PC: Product Categories

PNEC: Predicted No Effect Concentration

PROC: Process Categories

RID: Règlement concernant le transport International ferroviaire des marchandises dangereuses (Regulations concerning International rail transport of dangerous goods)

STOT: Target Organ Systemic Toxicity

STOT (RE): Repeated Exposure

STOT (SE): Single Exposure

STP: Sewage Treatment Plants

SU: Sector of Use

SVCH: Substance of Very High Concern

TLV: Threshold Limit Value

vPvB: Very Persistent Very Bioaccumulative

References and Sources:

- ECHA Registered Substances:

<https://echa.europa.eu/web/guest/information-on-chemicals/registered-substances>

- SDS raw material supplier

- GESTIS International Limit Value: <http://limitvalue.ifa.dguv.de>

This msds was made in good faith by technical Office on the basis of the information available at the date of the last revision. The person in charge must regularly inform the employees about the specific risks they encounter when using this substance/product. The information contained here relate only to the substance/the preparation indicated and may not apply if the product is used improperly or in combination with others. Nothing contained herein shall be construed as a guarantee, either express or implied. It is the responsibility of the user to ensure the opportunities and completeness of the information contained herein for their own particular use.

*** this tab annuls and replaces any previous edition. (IIXX)

Changes to the previous edition: general update.
