Safety Data Sheet

Gutta Percha Cartridge

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2020/878
Issue date: 28/02/2018 Revision date: 20/08/2022 Supersedes version of: 28/02/2018 Version: 2.0

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Product form : Mixture
Product name : Gutta Percha Cartridge

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

Relevant identified uses

Main use category : Professional use
Use of the substance/mixture : Preparation intended for dental medical use
Function or use category : Dental materials.

Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

Kerr Italia S.r.l.
Via Passanti, 174
Scafati (SA) 84018 (Italy)
T +39 081 850 3511 / Information Phone Number: 1-800-841-1428 (Customer Service)
safety@envistaco.com

1.4. Emergency telephone number

Emergency number : CHEMTREC® Emergency Call Center. Emergency Telephone Number (for USA only) 001-800-424-9300
International and Maritime Telephone Number +1 (703) 527-3887

Country	Official advisory body	Address	Emergency number	Comment
Gibraltar	GHA Call Centre Zone 2, Level3, St Bernard's Hospital	Harbour Views Road	+350 200 79700 +350 200 72266	
Ireland	National Poisons Information Centre Beaumont Hospital	PO Box 1297 Beaumont Road 9 Dublin	+353 1 809 2566 (Healthcare professionals-24/7) +353 1 809 2166 (public, 8am - 10pm, 7/7)	
Malta	Medicines & Poisons Info Office	Mater Dei Hospital MSD 2090 Msida	+356 2545 6508	
United Kingdom	National Poisons Information Service (Newcastle Unit)	Claremont Place Newcastle-upon-Tyne, Newcastle	+44 191 2606182 +44 191 2606180	Hours of operation: 24hrs

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP]

Aquatic Acute 1 H400
Aquatic Chronic 1 H410

Full text of hazard classes and H-statements : see section 16

Adverse physicochemical, human health and environmental effects

No additional information available

2.2. Label elements

Labelling according to Regulation (EC) No. 1272/2008 [CLP]

Hazard pictograms (CLP) :



GHS09

Signal word (CLP) : Warning

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Hazard statements (CLP)	:	H410 - Very toxic to aquatic life with long lasting effects.
Precautionary statements (CLP)	:	P273 - Avoid release to the environment. P501 - Dispose of Contents and container to a hazardous or special waste collection point.
Extra phrases	:	The product is seen as a medical device (Directive 90/385/EEC, 93/42/EEC, 98/79/EC) and therefore not subject to labelling (EU-regulation 1272/2008, article 1, paragraph 5d). A safety data sheet is not required for this product under Article 31 of REACH. This Product Safety Information Sheet has been created on a voluntary basis.

2.3. Other hazards

Other hazards which do not result in classification : None under normal conditions.

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

The mixture does not contain substance(s) 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 in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at a concentration equal to or greater than 0,1 %

SECTION 3: Composition/information on ingredients

3.1. Substances

Not applicable

3.2. Mixtures

Name	Product identifier	Conc. (% w/w)	Classification according to Regulation (EC) No. 1272/2008 [CLP]
zinc oxide substance with national workplace exposure limit(s) (IE)	(CAS-No.) 1314-13-2 (EC-No.) 215-222-5 (EC Index-No.) 030-013-00-7 (REACH-no) 01-2119463881-32	25 – 100	Aquatic Acute 1, H400 Aquatic Chronic 1, H410
barium sulphate substance with national workplace exposure limit(s) (GB, GI, IE, MT)	(CAS-No.) 7727-43-7 (EC-No.) 231-784-4 (REACH-no) 01-2119491274-35	< 50	Not classified
2,6-Di-tert-butyl-4-methylphenol substance with national workplace exposure limit(s) (GB, IE)	(CAS-No.) 128-37-0 (EC-No.) 204-881-4 (REACH-no) 01-2119480433-40	< 0.1	Aquatic Acute 1, H400 Aquatic Chronic 1, H410

Full text of H- and EUH-statements: see section 16

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures general	:	Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible).
First-aid measures after inhalation	:	Allow affected person to breathe fresh air. Allow the patient to rest. Get medical advice/attention if you feel unwell.
First-aid measures after skin contact	:	Remove affected clothing and wash all exposed skin area with mild soap and water, followed by warm water rinse. If skin irritation occurs: Get medical advice/attention.
First-aid measures after eye contact	:	Rinse immediately with plenty of water. Obtain medical attention if pain, blinking or redness persists.
First-aid measures after ingestion	:	Rinse mouth. Do NOT induce vomiting. Call a POISON CENTER/doctor if you feel unwell.

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

Symptoms/effects : Not expected to present a significant hazard under anticipated conditions of normal use.

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

No additional information available

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media	:	Use extinguishing media appropriate for surrounding fire. Foam, carbon dioxide (CO2) and powder.
Unsuitable extinguishing media	:	Do not use a heavy water stream.

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5.2. Special hazards arising from the substance or mixture

Fire hazard : Non flammable.

Hazardous decomposition products in case of fire : zinc oxide.

5.3. Advice for firefighters

Firefighting instructions : Use water spray or fog for cooling exposed containers. Prevent fire fighting water from entering the environment. Exercise caution when fighting any chemical fire.

Protection during firefighting : Do not enter fire area without proper personal protective equipment, including respiratory protection (EN137).

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General measures : Avoid contact with skin and eyes. Concerning personal protective equipment to use, see section 8. Avoid dust formation. Do not breathe dust.

6.1.1. For non-emergency personnel

Protective equipment : See Section 8.

Emergency procedures : Evacuate unnecessary personnel.

6.1.2. For emergency responders

Protective equipment : Equip cleanup and emergency crew with proper protection.

Emergency procedures : Ventilate area.

6.2. Environmental precautions

Avoid release to the environment. Prevent entry to sewers and public waters.

6.3. Methods and material for containment and cleaning up

For containment : Collect all waste in suitable and labelled containers and dispose according to local legislation.

Methods for cleaning up : Mechanically recover the product. Sweep or shovel into suitable containers. Minimise generation of dust. Wash off with plenty of water. Store away from other materials.

6.4. Reference to other sections

For further information refer to section 13. See Section 8. Exposure controls and personal protection.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : Do not eat, drink or smoke when using this product. Avoid contact with skin and eyes. Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Avoid dust formation. Avoid breathing dust.

Hygiene measures : Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Do not eat, drink or smoke when using this product. Wash contaminated clothing before reuse.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Store in original container. Keep container closed when not in use. Store in a dry place. Protect from sunlight. Store in a well-ventilated place.

Storage area : Store in a well-ventilated place.

7.3. Specific end use(s)

No additional information available

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

8.1.1 National occupational exposure and biological limit values

zinc oxide (1314-13-2)	
Ireland - Occupational Exposure Limits	
Local name	Zinc oxide, fume

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OEL TWA [1]	2 mg/m³ R (Respirable Fraction)
OEL STEL	10 mg/m³
Regulatory reference	Chemical Agents Code of Practice 2021

barium sulphate (7727-43-7)	
Gibraltar - Occupational Exposure Limits	
Local name	Barium (soluble compounds as Ba)
OEL TWA	0.5 mg/m³
Regulatory reference	Factories (Control of Chemical Agents at Work) Regulations 2003 (LN. 2018/181)
Ireland - Occupational Exposure Limits	
Local name	Barium sulphate, respirable dust
OEL TWA [1]	5 mg/m³
Regulatory reference	Chemical Agents Code of Practice 2021
Malta - Occupational Exposure Limits	
Local name	Barium (soluble compounds as Ba) # Barium (kompost li jinħallu bħala Ba)
OEL TWA	0.5 mg/m³
Regulatory reference	S.L.424.24 - Chemical Agents at Work Regulations (L.N.356 of 2021)
United Kingdom - Occupational Exposure Limits	
Local name	Barium sulphate
WEL TWA (OEL TWA) [1]	10 mg/m³ inhalable dust 4 mg/m³ respirable dust
Regulatory reference	EH40/2005 (Fourth edition, 2020). HSE

2,6-Di-tert-butyl-4-methylphenol (128-37-0)	
Ireland - Occupational Exposure Limits	
Local name	2,6-Ditertiary-butyl-para-cresol [Butylated hydroxytoluene (BHT)]
OEL TWA [1]	2 mg/m³
Regulatory reference	Chemical Agents Code of Practice 2021
United Kingdom - Occupational Exposure Limits	
Local name	2,6-Di-tert-butyl-p-cresol
WEL TWA (OEL TWA) [1]	10 mg/m³
Regulatory reference	EH40/2005 (Fourth edition, 2020). HSE

8.1.2. Recommended monitoring procedures

No additional information available

8.1.3. Air contaminants formed

No additional information available

8.1.4. DNEL and PNEC

No additional information available

8.1.5. Control banding

No additional information available

8.2. Exposure controls

8.2.1. Appropriate engineering controls

Appropriate engineering controls:
Ensure good ventilation of the work station.

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8.2.2. Personal protection equipment

Personal protective equipment:
Gloves.



8.2.2.1. Eye and face protection

Eye protection:
In case of dust production: protective goggles. STANDARD EN 166.

8.2.2.2. Skin protection

Skin and body protection:
Wear suitable protective clothing

Hand protection:
Wear suitable gloves. Chemical resistant PVC gloves (to European standard EN 374 or equivalent). Layer thickness : 0,09mm. Breakthrough time : >480 min

8.2.2.3. Respiratory protection

Respiratory protection:
Not required. In case of insufficient ventilation, wear suitable respiratory equipment. Dust production: dust mask with filter type P2. Standard EN 143:2021

8.2.2.4. Thermal hazards
No additional information available

8.2.3. Environmental exposure controls

Other information:
Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Do not eat, drink or smoke during use.
Personal protective equipment should be chosen according to the CEN standards and in discussion with the supplier of the protective equipment.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	:	Solid
Colour	:	pink.
Appearance	:	Little spheres.
Odour	:	Slight. aromatic.
Odour threshold	:	Not determined.
Melting point	:	≈ 68 °C
Freezing point	:	Not determined.
Boiling point	:	The substance decomposes
Flammability	:	Non flammable.
Explosive properties	:	Product is not explosive.
Oxidising properties	:	Non flammable.
Explosive limits	:	Not determined.
Lower explosive limit (LEL)	:	Not applicable
Upper explosive limit (UEL)	:	Not applicable
Flash point	:	Not determined.
Auto-ignition temperature	:	Not determined.
Decomposition temperature	:	> 220 °C
pH	:	Not determined.
pH solution	:	Not available
Viscosity, kinematic	:	Not determined.
Viscosity, dynamic	:	Not determined.
Solubility	:	Material insoluble in water.
Partition coefficient n-octanol/water (Log Kow)	:	Not available
Partition coefficient n-octanol/water (Log Pow)	:	Not determined.
Vapour pressure	:	Not determined.
Vapour pressure at 50 °C	:	Not available
Density	:	Not available
Relative density	:	Not determined.
Relative vapour density at 20 °C	:	Not determined.
Particle size	:	Not available

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Particle size distribution	:	Not available
Particle shape	:	Not available
Particle aspect ratio	:	Not available
Particle aggregation state	:	Not available
Particle agglomeration state	:	Not available
Particle specific surface area	:	Not available
Particle dustiness	:	Not available

9.2. Other information

9.2.1. Information with regard to physical hazard classes

No additional information available

9.2.2. Other safety characteristics

Relative evaporation rate (butylacetate=1)	:	Not determined.
Additional information	:	None to our knowledge.

SECTION 10: Stability and reactivity

10.1. Reactivity

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

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

No polymerization.

10.4. Conditions to avoid

None under recommended storage and handling conditions (see section 7).

10.5. Incompatible materials

No data available.

10.6. Hazardous decomposition products

No decomposition if stored and used normally.

SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Acute toxicity (oral)	:	Not classified
Acute toxicity (dermal)	:	Not classified
Acute toxicity (inhalation)	:	Not classified
Additional information	:	Based on available data, the classification criteria are not met

zinc oxide (1314-13-2)	
LD50 oral rat	> 5000 mg/kg
LD50 dermal rat	> 2000 mg/kg
LC50 Inhalation - Rat (Dust/Mist)	5.7 mg/l/4h

barium sulphate (7727-43-7)	
LD50 oral rat	> 20000 mg/kg

calcium carbonate (471-34-1)	
LD50 oral rat	6450 mg/kg

Beeswax (8012-89-3)	
LD50 oral rat	> 5000 mg/kg bodyweight

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2,6-Di-tert-butyl-4-methylphenol (128-37-0)	
LD50 oral rat	> 6000 mg/kg bodyweight
LD50 dermal rat	> 2000 mg/kg bodyweight

Skin corrosion/irritation : Not classified
pH: Not determined.
Additional information : Based on available data, the classification criteria are not met
Serious eye damage/irritation : Not classified
pH: Not determined.
Additional information : Based on available data, the classification criteria are not met
Respiratory or skin sensitisation : Not classified
Additional information : Based on available data, the classification criteria are not met
Germ cell mutagenicity : Not classified
Additional information : Based on available data, the classification criteria are not met
Carcinogenicity : Not classified
Additional information : Based on available data, the classification criteria are not met

Reproductive toxicity : Not classified
Additional information : Based on available data, the classification criteria are not met

STOT-single exposure : Not classified
Additional information : Based on available data, the classification criteria are not met

STOT-repeated exposure : Not classified
Additional information : Based on available data, the classification criteria are not met

Aspiration hazard : Not classified
Additional information : Based on available data, the classification criteria are not met

Gutta Percha Cartridge	
Viscosity, kinematic	Not determined.

11.2. Information on other hazards

11.2.1. Endocrine disrupting properties

Adverse health effects caused by endocrine disrupting properties : The mixture does not contain substance(s) 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 in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at a concentration equal to or greater than 0,1 %

11.2.2 Other information

Potential adverse human health effects and symptoms : For further information see section 4

SECTION 12: Ecological information

12.1. Toxicity

Hazardous to the aquatic environment, short–term (acute) : Very toxic to aquatic life.
Hazardous to the aquatic environment, long–term (chronic) : Very toxic to aquatic life with long lasting effects.

zinc oxide (1314-13-2)	
LC50 - Fish [1]	1.1 mg/l (96 hours - Rainbow trout)
EC50 - Crustacea [1]	24.6 mg/l (48 hours - Daphnia magna)
ErC50 algae	0.136 mg/l 72 hours - Pseudokirchnerella subcapitata

barium sulphate (7727-43-7)	
LC50 - Fish [1]	> 7600 mg/l
EC50 - Crustacea [1]	> 32 mg/l (48 hours - Daphnia magna)

calcium carbonate (471-34-1)	
LC50 - Fish [1]	> 5600 mg/l (96 hours - Gambusia affinis - Mosquito fish)

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2,6-Di-tert-butyl-4-methylphenol (128-37-0)	
LC50 - Fish [1]	5.3 mg/l Oryzias latipes (Ricefish)
EC50 - Crustacea [1]	0.48 mg/l Daphnia magna, 48 hours
ErC50 algae	1.7 mg/l

12.2. Persistence and degradability

Gutta Percha Cartridge	
Persistence and degradability	May cause long-term adverse effects in the environment.

2,6-Di-tert-butyl-4-methylphenol (128-37-0)	
Biodegradation	10 % (OECD 301D method)

12.3. Bioaccumulative potential

Gutta Percha Cartridge	
Partition coefficient n-octanol/water (Log Pow)	Not determined.
Bioaccumulative potential	No data.

zinc oxide (1314-13-2)	
Partition coefficient n-octanol/water (Log Pow)	< 0

trans-Polyisoprene (9003-31-0)	
Bioconcentration factor (BCF REACH)	25.12
Partition coefficient n-octanol/water (Log Pow)	2.72

calcium carbonate (471-34-1)	
Bioaccumulative potential	No data.

2,6-Di-tert-butyl-4-methylphenol (128-37-0)	
Bioconcentration factor (BCF REACH)	25
Partition coefficient n-octanol/water (Log Pow)	5.1

12.4. Mobility in soil

Gutta Percha Cartridge	
Ecology - soil	Material insoluble in water.

12.5. Results of PBT and vPvB assessment

Gutta Percha Cartridge
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

No additional information available

12.7. Other adverse effects

Other adverse effects : None to our knowledge.
Additional information : Avoid release to the environment.

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SECTION 13: Disposal considerations

13.1. Waste treatment methods

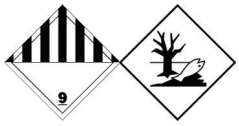
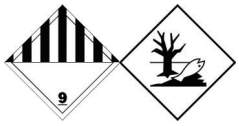
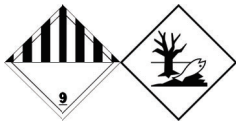
Waste treatment methods : Must not be disposed together with household garbage. Do not allow product to reach the sewage system.

Product/Packaging disposal recommendations : Dispose in a safe manner in accordance with local/national regulations. Empty container completely. After cleaning, recycle or dispose of at an authorised site.

European List of Waste (LoW) code : 18 01 06* - chemicals consisting of or containing dangerous substances

SECTION 14: Transport information

In accordance with ADR / IMDG / IATA / ADN / RID /

ADR	IMDG	IATA	ADN	RID
14.1. UN number or ID number				
UN 3077	UN 3077	UN 3077	UN 3077	UN 3077
14.2. UN proper shipping name				
ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (zinc oxide)	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (zinc oxide)	Environmentally hazardous substance, solid, n.o.s. (zinc oxide)	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (zinc oxide)	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (zinc oxide)
Transport document description				
UN 3077 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (zinc oxide), 9, III, (-)	UN 3077 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (zinc oxide), 9, III, MARINE POLLUTANT	UN 3077 Environmentally hazardous substance, solid, n.o.s. (zinc oxide), 9, III	UN 3077 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (zinc oxide), 9, III	UN 3077 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (zinc oxide), 9, III
14.3. Transport hazard class(es)				
9	9	9	9	9
				
14.4. Packing group				
III	III	III	III	III
14.5. Environmental hazards				
Dangerous for the environment : Yes	Dangerous for the environment : Yes Marine pollutant : Yes	Dangerous for the environment : Yes	Dangerous for the environment : Yes	Dangerous for the environment : Yes
No supplementary information available				

14.6. Special precautions for user

Overland transport

Classification code (ADR) : M7

Special provisions (ADR) : 274, 335, 375, 601

Limited quantities (ADR) : 5kg

Excepted quantities (ADR) : E1

Orange plates :



EAC code : 2Z

Transport by sea

Special provisions (IMDG) : 274, 335, 966, 967, 969

EmS-No. (Fire) : F-A

EmS-No. (Spillage) : S-F

Air transport

PCA Excepted quantities (IATA) : E1

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PCA Limited quantities (IATA)	:	Y956
Special provisions (IATA)	:	A97, A158, A179, A197
Inland waterway transport		
Classification code (ADN)	:	M7
Special provisions (ADN)	:	274, 335, 375, 601
Limited quantities (ADN)	:	5 kg
Excepted quantities (ADN)	:	E1
Rail transport		
Special provisions (RID)	:	274, 335, 375, 601
Excepted quantities (RID)	:	E1
Hazard identification number (RID)	:	90

14.7. Maritime transport in bulk according to IMO instruments

Not applicable

SECTION 15: Regulatory information

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

15.1.1. EU-Regulations

Contains no REACH substances with Annex XVII restrictions
Contains no substance on the REACH candidate list
Contains no REACH Annex XIV substances
Contains no substance subject to Regulation (EU) No 649/2012 of the European Parliament and of the Council of 4 July 2012 concerning the export and import of hazardous chemicals.
Contains no substance subject to Regulation (EU) No 2019/1021 of the European Parliament and of the Council of 20 June 2019 on persistent organic pollutants

15.1.2. National regulations

REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006

15.2. Chemical safety assessment

No chemical safety assessment has been carried out

SECTION 16: Other information

Data sources	:	REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.
Other information	:	None.

Full text of H- and EUH-statements:

Aquatic Acute 1	Hazardous to the aquatic environment – Acute Hazard, Category 1
Aquatic Chronic 1	Hazardous to the aquatic environment – Chronic Hazard, Category 1
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.

The information in this safety data sheet is based on information from the manufacturer/supplier, present european and national legislation, and presupposes that the product is used within the specified area of application.