

DD provi P HI

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

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

Dental Direkt polymer milling blanks are intended for the fabrication of fixed or removable restorations as well as dental splints.

Uses advised against

No information available.

1.3. Details of the supplier of the safety data sheet

Company name:	Dental Direkt GmbH	
Street:	Industriezentrum 106-108	
Place:	D-32139 Spenge	
Telephone:	05225 - 8 63 19-0	Telefax: 05225 - 8 63 19-99
e-mail:	info@dentaldirekt.de	
Internet:	www.dentaldirekt.de	
Responsible Department:	info@dentaldirekt.de	

1.4. Emergency telephone number: +49 (0) 761 19240 (VIZ Freiburg) Poisons information Centre of Ireland +353 1 809 21 66; <http://www.poisons.ie/Public>

Further Information

Medical device

SECTION 2: Hazards identification**2.1. Classification of the substance or mixture****Regulation (EC) No 1272/2008**

This mixture is not classified as hazardous in accordance with Regulation (EC) No 1272/2008.

2.2. Label elements**Regulation (EC) No 1272/2008****Special labelling of certain mixtures**

EUH208	Contains 1-hydroxy-4-(p-toluidino)anthraquinone. May produce an allergic reaction.
EUH210	Safety data sheet available on request.

2.3. Other hazards

The substances in the mixture do not meet the PBT/vPvB criteria according to REACH, annex XIII.

Dust can form an explosive mixture with air.

Comb. Dust (Combustible Dust)

SECTION 3: Composition/information on ingredients**3.2. Mixtures****Chemical characterization**

POLYMETHYL METHACRYLATE, Dyes

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Hazardous components

CAS No	Chemical name			Quantity
	EC No	Index No	REACH No	
	Classification (Regulation (EC) No 1272/2008)			
13463-67-7	titanium dioxide			<=0,1 %
	236-675-5	022-006-00-2	01-2119489379-17	
	Carc. 2; H351			
81-48-1	1-hydroxy-4-(p-toluidino)anthraquinone			< 1 %
	201-353-5		01-2120761559-41	
	Skin Sens. 1B, Aquatic Chronic 4; H317 H413			

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

Specific Conc. Limits, M-factors and ATE

CAS No	EC No	Chemical name	Quantity
	Specific Conc. Limits, M-factors and ATE		
13463-67-7	236-675-5	titanium dioxide	<=0,1 %
	oral: LD50 = > 2000 mg/kg		
81-48-1	201-353-5	1-hydroxy-4-(p-toluidino)anthraquinone	< 1 %
	oral: LD50 = >5000 mg/kg		

Further Information

No information available.

SECTION 4: First aid measures
4.1. Description of first aid measures
General information

In case of allergic symptoms, especially in the breathing area, seek medical advice immediately.

Never give anything by mouth to an unconscious person or a person with cramps.

In case of accident or unwellness, seek medical advice immediately (show directions for use or safety data sheet if possible).

After inhalation

Remove person to fresh air and keep comfortable for breathing. In case of respiratory tract irritation, consult a physician.

After contact with skin

After contact with skin, wash immediately with plenty of water and soap. If skin irritation occurs: Get medical advice/attention.

After contact with eyes

Rinse immediately carefully and thoroughly with eye-bath or water. In case of eye irritation consult an ophthalmologist.

After ingestion

IF SWALLOWED: Call a doctor if you feel unwell.

Rinse mouth immediately and drink 1 glass of water.

Never give anything by mouth to an unconscious person or a person with cramps.

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

No information available.

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

First Aid, decontamination, treatment of symptoms.

SECTION 5: Firefighting measures

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5.1. Extinguishing media**Suitable extinguishing media**

Dry extinguishing powder, Carbon dioxide (CO₂), Foam, Extinguishing powder

Unsuitable extinguishing media

Full water jet

5.2. Special hazards arising from the substance or mixture

In case of fire may be liberated: Methyl acrylate, Methyl methacrylate, styrene, butyl acrylate
Do not inhale explosion and combustion gases.

5.3. Advice for firefighters

In case of fire: Evacuate area.

Move undamaged containers from immediate hazard area if it can be done safely.

Special protective equipment for firefighters: Flame-retardant protective clothing

In case of fire: Wear a self-contained breathing apparatus and chemical protective clothing.

Additional information

Use water spray to cool containers.

Do not allow run-off from fire-fighting to enter drains or water courses.

Residues of fire and contaminated water have to be disposed according to the local regulations.

SECTION 6: Accidental release measures**6.1. Personal precautions, protective equipment and emergency procedures****General advice**

See protective measures under point 7 and 8.

Personal protection equipment: see section 8

Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Remove all sources of ignition. Take precautionary measures against static discharges.

Provide adequate ventilation.

Avoid dust formation. In case of inadequate ventilation wear respiratory protection.

Avoid contact with skin, eyes and clothes.

For non-emergency personnel

Remove persons to safety.

For emergency responders

Knock down dust with water spray jet.

6.2. Environmental precautions

Do not allow to enter into surface water or drains.

Do not allow to enter into soil/subsoil.

6.3. Methods and material for containment and cleaning up**For containment**

Take up mechanically. Use approved industrial vacuum cleaner for removal. Avoid dust formation. Collect in closed and suitable containers for disposal. Dispose of waste according to applicable legislation.

For cleaning up

Cleaning agent: Water

Dust:

Do not use a brush or compressed air for cleaning surfaces or clothing. Do not use a dry brush as dust clouds or static can be created. Use approved industrial vacuum cleaner for removal.

Other information

Provide fresh air.

6.4. Reference to other sections

Safe handling: see section 7

Personal protection equipment: see section 8

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Disposal: see section 13

SECTION 7: Handling and storage**7.1. Precautions for safe handling****Advice on safe handling**

- Wear personal protection equipment (refer to section 8).
- Keep container tightly closed.
- Avoid contact with skin, eyes and clothes.
- Avoid release to the environment.
- Avoid dust formation. Avoid: Dust deposits
- Do not breathe dust. In case of inadequate ventilation wear respiratory protection.
- Provide adequate ventilation as well as local exhaustion at critical locations. To follow: Occupational exposure limit values
- Remove all sources of ignition.

Advice on protection against fire and explosion

- Use explosion-proof machinery, apparatus, ventilation facilities, tools etc.
- Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
- May form combustible dust concentrations in air.
- Take precautionary measures against static discharges.

Advice on general occupational hygiene

- Work in well-ventilated zones or use proper respiratory protection.
- Only wear fitting, comfortable and clean protective clothing.
- Wash hands before breaks and after work.
- Separate storage of work clothes.
- Make available sufficient washing facilities

Further information on handling

- Observe instructions for use.
- Working places should be designed to allow cleaning at any time.

7.2. Conditions for safe storage, including any incompatibilities**Requirements for storage rooms and vessels**

- Store in a dry place. Keep only in the original container in a cool, well-ventilated place.

Hints on joint storage

- Keep away from food, drink and animal feedingstuffs.
- Keep away from: Oxidizing agent

Further information on storage conditions

- Keep away from: Frost, Heat, UV-radiation/sunlight
- Handle with care - avoid bumps, friction and impact.

7.3. Specific end use(s)

- Reference to other sections: 1.2

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

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Occupational exposure limits

CAS No	Substance	ppm	mg/m ³	fib/cm ³	Category	Origin
-	Dusts non-specific, respirable	-	4		TWA (8 h)	
-	Dusts non-specific, total inhalable	-	10		TWA (8 h)	
96-33-3	Methyl acrylate	2	7		TWA (8 h)	
80-62-6	Methyl methacrylate	50	-		TWA (8 h)	
		100	-		STEL (15 min)	
141-32-2	n-Butyl acrylate	2	11		TWA (8 h)	
		10	53		STEL (15 min)	
100-42-5	Styrene	20	85		TWA (8 h)	
		40	170		STEL (15 min)	
13463-67-7	Titanium dioxide, total inhalable dust	-	10		TWA (8 h)	

Biological limit values

CAS No	Substance	Parameter	Value	Test material	Sampling time
100-42-5	Styrene	Mandelic acid plus phenylglyoxylic acid	400 mg/g	Creatinine	End of shift

DNEL/DMEL values

CAS No	Substance	Exposure route	Effect	Value
13463-67-7	titanium dioxide			
	Worker DNEL, long-term	inhalation	local	1,25 mg/m ³
	Consumer DNEL, long-term	oral	systemic	700 mg/kg bw/day
81-48-1	1-hydroxy-4-(p-toluidino)anthraquinone			
	Worker DNEL, long-term	inhalation	systemic	11,27 mg/m ³
	Worker DNEL, long-term	dermal	systemic	6,392 mg/kg bw/day
	Consumer DNEL, long-term	inhalation	systemic	2,779 mg/m ³
	Consumer DNEL, long-term	dermal	systemic	3,196 mg/kg bw/day
	Consumer DNEL, long-term	oral	systemic	1,598 mg/kg bw/day

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PNEC values

CAS No	Substance	
Environmental compartment		Value
13463-67-7	titanium dioxide	
Freshwater		0,184 mg/l
Freshwater (intermittent releases)		0,193 mg/l
Marine water		0,018 mg/l
Freshwater sediment		1000 mg/kg
Marine sediment		100 mg/kg
Micro-organisms in sewage treatment plants (STP)		100 mg/l
Soil		100 mg/kg
81-48-1	1-hydroxy-4-(p-toluidino)anthraquinone	
Freshwater		0,002 mg/l
Freshwater (intermittent releases)		0,018 mg/l
Marine water		0,0002 mg/l
Freshwater sediment		149429,35 mg/kg
Marine sediment		149429,35 mg/kg
Micro-organisms in sewage treatment plants (STP)		9,489 mg/l
Soil		71615,54 mg/kg

Additional advice on limit values

When processing this product, especially in the thermal process, the regulations for the substances listed below must be observed. By using effective devices for ventilation and extraction at the discharge points, the limit values of any vapours that may be generated can be complied with.

- methyl 2-methylprop-2-enoate; methyl 2-methylpropenoate; methyl methacrylate
- butyl acrylate
- styrene
- methyl acrylate; methyl propenoate

8.2. Exposure controls

Appropriate engineering controls

Provide adequate ventilation as well as local exhaust at critical locations.
dust formation: Provide earthing of containers, equipment, pumps and ventilation facilities.

Individual protection measures, such as personal protective equipment

Eye/face protection

IF exposed or concerned: Suitable eye protection: EN 166
Eye glasses with side protection
goggles

Hand protection

Suitable gloves type EN ISO 374
The quality of the protective gloves resistant to chemicals must be chosen as a function of the specific working place concentration and quantity of hazardous substances.

Suitable material: PVC (polyvinyl chloride)
Thickness of the glove material: $\geq 0,5$ mm

Breakthrough times and swelling properties of the material must be taken into consideration. Observe the wear time limits as specified by the manufacturer.

For special purposes, it is recommended to check the resistance to chemicals of the protective gloves mentioned above together with the supplier of these gloves.

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Wear cotton undermitten if possible.

Skin protection

antistatic Protective clothing.

Respiratory protection

Respiratory protection necessary at: exceeding exposure limit values, Formation of: dust/mist/vapour
If technical exhaust or ventilation measures are not possible or insufficient, respiratory protection must be worn. The filter class must be suitable for the maximum contaminant concentration (gas/vapour/aerosol/particulates) that may arise when handling the product. If the concentration is exceeded, self-contained breathing apparatus must be used. Particle filter device (EN 143)

Formation of: vapour

Type A2, Self-contained respirator (breathing apparatus)

Thermal hazards

Formation of organic vapours

Do not breathe mist/vapours/spray.

Environmental exposure controls

Dust must be exhausted directly at the point of origin.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state:	solid
Colour:	various
Odour:	odourless

	Test method
Melting point/freezing point:	No data available
Boiling point or initial boiling point and boiling range:	No data available
Flammability	
Solid/liquid:	>300 °C
Gas:	No data available
Lower explosion limits:	No data available
Upper explosion limits:	No data available
Flash point:	No data available
Decomposition temperature:	>350 °C
pH-Value:	No data available
Water solubility:	The study does not need to be conducted because the substance is known to be insoluble in water.
Solubility in other solvents	
miscible with most organic solvents	
Partition coefficient n-octanol/water:	No data available
Vapour pressure:	No data available
Density:	~1,17 g/cm ³
Relative vapour density:	not determined

9.2. Other information

Information with regard to physical hazard classes

Explosive properties

 May form combustible dust concentrations in air.

Sustaining combustion: No data available

Self-ignition temperature

 Solid:

No data available

 Gas:

No data available

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Oxidizing properties
Not oxidising.

Other safety characteristics

Evaporation rate:	No data available
Solid content:	100%
Sublimation point:	No data available
Softening point:	>90°C °C ISO 306
Pour point:	No data available
Viscosity / dynamic:	No data available

Further Information

No information available.

SECTION 10: Stability and reactivity

10.1. Reactivity

This material is considered to be non-reactive under normal use conditions.

10.2. Chemical stability

The product is stable under storage at normal ambient temperatures.

10.3. Possibility of hazardous reactions

May form combustible dust concentrations in air.

10.4. Conditions to avoid

Heat

Generation/formation of dust: Avoid dust formation.

Take precautionary measures against static discharges. Take action to prevent static discharges.

Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.

10.5. Incompatible materials

Oxidizing agent

10.6. Hazardous decomposition products

Carbon dioxide (CO₂), Carbon monoxide, Monomers

Further information

No data available

SECTION 11: Toxicological information

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

Toxicokinetics, metabolism and distribution

No information available.

Acute toxicity

Based on available data, the classification criteria are not met.

CAS No	Chemical name				
	Exposure route	Dose	Species	Source	Method
13463-67-7	titanium dioxide				
	oral	LD50 > 2000 mg/kg	Rat	Study report (1996)	OECD Guideline 401
81-48-1	1-hydroxy-4-(p-toluidino)anthraquinone				
	oral	LD50 >5000 mg/kg	Rat		OECD 401

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Irritation and corrosivity

Based on available data, the classification criteria are not met.

Sensitising effects

Contains 1-hydroxy-4-(p-toluidino)anthraquinone. May produce an allergic reaction.

Carcinogenic/mutagenic/toxic effects for reproduction

Based on available data, the classification criteria are not met.

STOT-single exposure

Based on available data, the classification criteria are not met.

STOT-repeated exposure

Based on available data, the classification criteria are not met.

Aspiration hazard

Based on available data, the classification criteria are not met.

11.2. Information on other hazards**Endocrine disrupting properties**

No data available

Further information

Calculation method.

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

No further relevant information available.

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CAS No	Chemical name					
	Aquatic toxicity	Dose	[h] [d]	Species	Source	Method
13463-67-7	titanium dioxide					
	Acute fish toxicity	LC50 > 100 mg/l	96 h	Carassius auratus	REACH Registration Dossier	OECD Guideline 203
	Acute algae toxicity	ErC50 > 50 mg/l	72 h	Raphidocelis subcapitata	REACH Registration Dossier	OECD Guideline 201
	Acute crustacea toxicity	EC50 > 100 mg/l	48 h	Artemia salina	REACH Registration Dossier	OECD Guideline 202
	Fish toxicity	NOEC >= 80 mg/l	6 d	Danio rerio	REACH Registration Dossier	OECD TG 210
	Algae toxicity	NOEC >= 1 mg/l	32 d	Synedra ulna, Scenedesmus quadricauda, Stigeocloni	Environ. Tox. Chem. 31, 2414-2422 (2012)	In this study, the authors report the re
	Crustacea toxicity	NOEC > 1 mg/l	10 d	Chironomus riparius	REACH Registration Dossier	other: OECD Guideline 219
	Acute bacteria toxicity	(EC50 > 1000 mg/l)	3 h	activated sludge, domestic	REACH Registration Dossier	OECD Guideline 209
81-48-1	1-hydroxy-4-(p-toluidino)anthraquinone					
	Acute fish toxicity	LC50 >500 mg/l	96 h	Oncorhynchus mykiss (Rainbow trout)		OECD 203
	Acute crustacea toxicity	EC50 >100 mg/l	48 h	Daphnia magna (Big water flea)		OECD 202
	Algae toxicity	NOEC =>1,1 mg/l	3 d	Desmodesmus subspicatus		(EC) Nr. 440/2008, Anhang, C.3
	Acute bacteria toxicity	(EC50 >320 mg/l)		Activated sludge		OECD 209

12.2. Persistence and degradability

The product is: Not readily biodegradable (according to OECD criteria)

CAS No	Chemical name				
	Method	Value	d	Source	
	Evaluation				
81-48-1	1-hydroxy-4-(p-toluidino)anthraquinone				
	(EC) Nr. 440/2008, Anhang, C.4-D	0%	28		

12.3. Bioaccumulative potential

No further relevant information available.

Partition coefficient n-octanol/water

CAS No	Chemical name	Log Pow
81-48-1	1-hydroxy-4-(p-toluidino)anthraquinone	4,2

BCF

CAS No	Chemical name	BCF	Species	Source
13463-67-7	titanium dioxide	> 0,47 - < 3,19	Artemia salina	REACH Registration D

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12.4. Mobility in soil

No information available.

12.5. Results of PBT and vPvB assessment

The substances in the mixture do not meet the PBT/vPvB criteria according to REACH, annex XIII.

12.6. Endocrine disrupting properties

This product does not contain a substance that has endocrine disrupting properties with respect to non-target organisms as no components meets the criteria.

12.7. Other adverse effects

No information available.

Further information

water hazard class: nwg

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

Dispose of waste according to applicable legislation. The allocation of waste identity numbers/waste descriptions must be carried out according to the EEC, specific to the industry and process. (AVV 120105, 160306)

Non hazardous waste according to Directive 2008/98/EC (waste framework directive).

flue-gas dust / Dust

place in a designated, labeled waste container

Put lids on containers immediately after use.

List of Wastes Code - residues/unused products

160306 WASTES NOT OTHERWISE SPECIFIED IN THE LIST; off-specification batches and unused products; organic wastes other than those mentioned in 16 03 05

Contaminated packaging

Dispose of waste according to applicable legislation.

Completely emptied packages can be recycled.

Collect the waste separately.

SECTION 14: Transport information**Land transport (ADR/RID)****14.1. UN number or ID number:** No dangerous good in sense of this transport regulation.**14.2. UN proper shipping name:** No dangerous good in sense of this transport regulation.**14.3. Transport hazard class(es):** No dangerous good in sense of this transport regulation.**14.4. Packing group:** No dangerous good in sense of this transport regulation.**Inland waterways transport (ADN)****14.1. UN number or ID number:** No dangerous good in sense of this transport regulation.**14.2. UN proper shipping name:** No dangerous good in sense of this transport regulation.**14.3. Transport hazard class(es):** No dangerous good in sense of this transport regulation.**14.4. Packing group:** No dangerous good in sense of this transport regulation.**Marine transport (IMDG)****14.1. UN number or ID number:** No dangerous good in sense of this transport regulation.**14.2. UN proper shipping name:** No dangerous good in sense of this transport regulation.**14.3. Transport hazard class(es):** No dangerous good in sense of this transport regulation.**14.4. Packing group:** No dangerous good in sense of this transport regulation.**Air transport (ICAO-TI/IATA-DGR)****14.1. UN number or ID number:** No dangerous good in sense of this transport regulation.**14.2. UN proper shipping name:** No dangerous good in sense of this transport regulation.

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14.3. Transport hazard class(es): No dangerous good in sense of this transport regulation.

14.4. Packing group: No dangerous good in sense of this transport regulation.

14.5. Environmental hazards

ENVIRONMENTALLY HAZARDOUS: No

14.6. Special precautions for user

No dangerous good in sense of this transport regulation.

14.7. Maritime transport in bulk according to IMO instruments

No dangerous good in sense of this transport regulation.

SECTION 15: Regulatory information**15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture****EU regulatory information**

Restrictions on use (REACH, annex XVII):

Entry 3, Entry 75

Information according to 2012/18/EU (SEVESO III): Not subject to 2012/18/EU (SEVESO III)

Additional information

Safety Data Sheet according to Regulation (EC) No. 1907/2006 (REACH)

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

Directive (EU) 2018/851 of the European Parliament and of the Council of 30 May 2018 amending Directive 2008/98/EC on waste

Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste and repealing certain Directives

National regulatory information

Water hazard class (D): -- non-hazardous to water

Additional information

Germany To follow:

<https://sicheres-dentallabor.bgetem.de/dentallabor>

DGUV Regel 113-606 "Teil 1: Spritzgießen"

Dust fires and dust explosions - Hazards - assessment - safety measures

Verordnung über Anlagen zum Umgang mit wassergefährdenden Stoffen (AwSV)

TRGS 220, TRGS 400ff., TRGS 500, TRGS 722-724, TRGS 800, TRGS 900

15.2. Chemical safety assessment

For the following substances of this mixture a chemical safety assessment has been carried out:
titanium dioxide

SECTION 16: Other information**Abbreviations and acronyms**

ADR: Accord européen sur le transport des marchandises dangereuses par Route

(European Agreement concerning the International Carriage of Dangerous Goods by Road)

RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer

(Regulations Concerning the International Transport of Dangerous Goods by Rail)

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

IATA-DGR: Dangerous Goods Regulations by the "International Air Transport Association" (IATA)

ICAO: International Civil Aviation Organization

ICAO-TI: Technical Instructions by the "International Civil Aviation Organization" (ICAO)

CAS: Chemical Abstracts Service (division of the American Chemical Society)

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GHS: Globally Harmonized System of Classification and Labelling of Chemicals
CLP: Regulation on Classification, Labelling and Packaging of Substances and Mixtures,
LC50: Lethal concentration, 50 percent
LD50: Lethal dose, 50 percent
EC50: Effectice concentration, 50 percent
DNEL: Derived No Effect Level
PNEC: Predicted No Effect Concentration
PBT: Persistent, Bioaccumulative and Toxic
vPvB: very Persistent and very Bioaccumulative

Relevant H and EUH statements (number and full text)

H317	May cause an allergic skin reaction.
H351	Suspected of causing cancer.
H413	May cause long lasting harmful effects to aquatic life.
EUH208	Contains 1-hydroxy-4-(p-toluidino)anthraquinone. May produce an allergic reaction.
EUH210	Safety data sheet available on request.

Further Information

The above information describes exclusively the safety requirements of the product and is based on our present-day knowledge. The information is intended to give you advice about the safe handling of the product named in this safety data sheet, for storage, processing, transport and disposal. The information cannot be transferred to other products. In the case of mixing the product with other products or in the case of processing, the information on this safety data sheet is not necessarily valid for the new made-up material.

(The data for the hazardous ingredients were taken respectively from the last version of the sub-contractor's safety data sheet.)