

# **Safety Data Sheet**

according to Regulation (EC) No. 1907/2006 (REACH) (This safety data sheet is for information only and does not comply with the official language requirements of article 31 (5) of REACH.)

# VT10 Fasern, B1, B1 Fasern

Version number: 1.0

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First version: 21.02.2024

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

1.1 **Product identifier** 

Trade name

# VT10 Fasern, B1, B1 Fasern

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

Relevant identified uses

# 1.3 Details of the supplier of the safety data sheet

PAGEL Spezial-Beton GmbH & Co. KG Wolfsbankring 9 45355 Essen Germany Building material

Telephone: +49 201/68504-0 Telefax: +49 201/68504-31 e-mail: info@pagel.com Website: www.pagel.com

schempershofe@pagel.de, labor@pagel.de

# 1.4 Emergency telephone number

e-mail (competent person)

Poison centre					
Name	Telephone	Telefax			
Giftnotruf Mainz	+49 (0) 6131-19240	+49 (0) 6131 - 23 2468			

# **SECTION 2: Hazards identification**

# 2.1 Classification of the substance or mixture

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

Classification								
Section	Hazard class	Category	Hazard class and category	Hazard state- ment				
3.2	skin corrosion/irritation	2	Skin Irrit. 2	H315				
3.3	serious eye damage/eye irritation	1	Eye Dam. 1	H318				
3.8R	specific target organ toxicity - single expos- ure (respiratory tract irritation)	3	STOT SE 3	H335				

For full text of abbreviations: see SECTION 16

#### 2.2 Label elements

#### Labelling according to Regulation (EC) No 1272/2008 (CLP)

Signal word danger

Pictograms

GHS05, GHS07



#### **Hazard statements**

H315	Causes skin irritation.
H318	Causes serious eye damage.
H335	May cause respiratory irritation.

#### **Precautionary statements**

P101	If medical advice is needed, have product container or label at hand.				
P102	Keep out of reach of children.				
P261	Avoid breathing dust.				
P280	Wear protective gloves/protective gloveglovegloveglovegloveglovegloveglove	tive clothing/eye protection/face protection.			
P302+P352	IF ON SKIN: Wash with plenty	of soap and water.			
P305+P351+P338	IF IN EYES: Rinse cautiously w	ith water for several minutes. Remove contact			
	lenses, if present and easy to	do. Continue rinsing.			
P310	Immediately call a POISON CENTER.				
P501	Dispose of contents/container	r in accordance with local/regional/national/interna-			
	tional regulations.				
Hazardous ingredio	ents for labelling	portland cement			
		flue dust, portland cement			
		cement, alumina, chemicals			

#### Additional labelling requirements

see section 15 of the safety data sheet

# 2.3 Other hazards

The product develops an alkaline pH value with moisture and can cause irritation. The product contains chromate reducer, which results in a content of water-soluble chrome (VI) of less than 0.0002 %. In case of improper storage (moisture ingress) or storage exceeding the recommended storage time, however, the contained chromate reducer may lose its effect prematurely and a sensitising effect of the cement/binder can occur upon skin contact (H317 and EUH203). The preparation is low in chromium. The content of soluble chromium (VI) compounds has been lowered with agent to below 2 ppm in the cement portion. Proper storage and compliance with the expiration date is a prerequisite for the effectiveness of the chromate reduction.

# Results of PBT and vPvB assessment

Does not contain a PBT-/vPvB-substance in a concentration of  $\ge 0,1\%$ .

# Endocrine disrupting properties

Information on this property is not available.

# **SECTION 3: Composition/information on ingredients**

# 3.1 Substances

Not relevant (mixture).

## 3.2 Mixtures

# Description of the mixture

# Hazardous ingredients

Hazardous ingredients							
Name of substance	Identifier	Wt%	Classification acc. to GHS	Pictograms	Notes		
portland cement	CAS No 65997-15-1 EC No 266-043-4	< 75	Skin Irrit. 2 / H315 Eye Dam. 1 / H318 Skin Sens. 1B / H317 STOT SE 3 / H335		-		
quartz	CAS No 14808-60-7 EC No 238-878-4	< 75	-	-	IOELV		
flue dust, portland cement	CAS No 68475-76-3 EC No 270-659-9	< 5	Skin Irrit. 2 / H315 Eye Dam. 1 / H318 Skin Sens. 1 / H317 STOT SE 3 / H335		-		
cement, alumina, chemicals	CAS No 65997-16-2 EC No 266-045-5	< 5	Skin Irrit. 2 / H315 Eye Dam. 1 / H318		-		

## Notes

IOELV: Substance with a community indicative occupational exposure limit value

for full text of H-phrases: see SECTION 16

# **SECTION 4: First aid measures**

#### 4.1 Description of first aid measures

#### **General notes**

Take off immediately all contaminated clothing.

In all cases of doubt, or when symptoms persist, seek medical advice.

In case of unconsciousness place person in the recovery position. Never give anything by mouth.

#### **Following inhalation**

Provide fresh air.

If breathing is irregular or stopped, immediately seek medical assistance and start first aid actions. In case of respiratory tract irritation, consult a physician.

#### Following skin contact

After contact with skin, take off immediately all contaminated clothing, and wash immediately with plenty of water and soap. Brush off loose particles from skin.

If skin irritation or rash occurs: Get medical advice/attention.

# Following eye contact

Rinse immediately carefully and thoroughly with eye shower or water. Remove contact lenses, if present and easy to do. Continue rinsing. Get immediate medical advice/attention.

#### **Following ingestion**

Rinse mouth immediately and drink plenty of water. Do NOT induce vomiting. Get immediate medical advice/attention.

#### Notes for the doctor

None.

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

Cough, pain, choking, and breathing difficulties. Risk of serious damage to eyes.

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

None.

# SECTION 5: Firefighting measures

# 5.1 Extinguishing media

# Suitable extinguishing media

Co-ordinate firefighting measures to the fire surroundings

# Unsuitable extinguishing media

water jet

# 5.2 Special hazards arising from the substance or mixture

Hazardous decomposition products: Section 10.

## 5.3 Advice for firefighters

#### Non-combustible.

In case of fire and/or explosion do not breathe fumes. Co-ordinate firefighting measures to the fire surroundings. Do not allow firefighting water to enter drains or water courses. Collect contaminated firefighting water separately. Fight fire with normal precautions from a reasonable distance.

# Special protective equipment for firefighters

self-contained breathing apparatus (EN 133)

# **SECTION 6: Accidental release measures**

# 6.1 Personal precautions, protective equipment and emergency procedures

#### For non-emergency personnel

Remove persons to safety. Ventilate affected area. Control of dust. Do not breathe dust. Do not get in eyes, on skin, or on clothing. Wearing of 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.

# For emergency responders

Wear breathing apparatus if exposed to vapours/dust/spray/gases.

# 6.2 Environmental precautions

Keep away from drains, surface and ground water. Retain contaminated washing water and dispose of it. If substance has entered a water course or sewer, inform the responsible authority.

# 6.3 Methods and material for containment and cleaning up

#### Advice on how to contain a spill

Take up mechanically.

#### Advice on how to clean up a spill

Take up mechanically. Collect spillage. Vacuuming techniques. Approved industrial vacuum cleaner.

# Other information relating to spills and releases

Place in appropriate containers for disposal. Ventilate affected area.

# 6.4 Reference to other sections

Personal protective equipment: see section 8. Incompatible materials: see section 10. Disposal considerations: see section 13.

#### **SECTION 7: Handling and storage**

# 7.1 Precautions for safe handling

Avoid contact with skin and eyes. Do not breathe dust.

#### Measures to prevent fire as well as aerosol and dust generation

Use local and general ventilation. Removal of dust deposits.

#### Specific notes/details

Dust deposits may accumulate on all deposition surfaces in a technical room. When diluting, always stir the product into standing water.

# Handling of incompatible substances or mixtures

Do not mix with acids.

#### Keep away from

aluminium, ammonium compounds, metals

#### Measures to protect the environment

Avoid release to the environment.

#### Advice on general occupational hygiene

Do not eat, drink and smoke in work areas. Remove contaminated clothing and protective equipment before entering eating areas. Do not breathe dust. Do not get in eyes, on skin, or on clothing. Wash hands after use. Preventive skin protection (barrier creams/ointments) is recommended.

# 7.2 Conditions for safe storage, including any incompatibilities

#### **Flammability hazards**

None.

#### Incompatible substances or mixtures

Incompatible materials: see section 10. Observe hints for combined storage.

# Protect against external exposure, such as

humidity

# Consideration of other advice

Keep away from food, drink and animal feeding stuffs. Store in a dry place. Store in a closed container.

# Ventilation requirements

Provision of sufficient ventilation.

#### Specific designs for storage rooms or vessels

Keep container tightly closed and in a well-ventilated place.

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# **Packaging compatibilities**

Keep only in original container. Unsuitable materials: Aluminium.

# 7.3 Specific end use(s)

No information available.

# **SECTION 8: Exposure controls/personal protection**

# 8.1 Control parameters

Occupational exposure limit values (Workplace Exposure Limits)									
Coun- try	Name of agent	CAS No	Identi- fier	TWA [ppm]	TWA [mg/m³]	STEL [ppm]	STEL [mg/m³]	Nota- tion	Source
DE	dust	-	MAK	-	4	-	-	i	DFG
DE	dust	-	AGW	-	10	-	20	Y, i	TRGS 900
DE	dust	-	AGW	-	1,25	-	2,5	Y, r	TRGS 900
DE	dust	-	MAK	-	0,3	-	2,4	r	DFG
DE	calcium sulfate hemihydrate	10034- 76-1	МАК	-	4	-	-	i	DFG
DE	calcium sulfate dihydrate	10101- 41-4	МАК	-	4	-	-	i	DFG
DE	calcium sulfate hydrate (gypsum)	13397- 24-5	МАК	-	4	-	-	i	DFG
DE	Quarzhaltiger Staub	14808- 60-7	AGW	-	0,05	-	0,4	-	TRGS 559
DE	calcium sulfate	7778-18- 9	AGW	-	6	-	-	r	TRGS 900
DE	calcium sulfate, anhydrous	7778-18- 9	МАК	-	4	-	-	i	DFG
EU	crystalline silica	14808- 60-7	IOELV	-	0,1	-	-	dust, r	2017/2398/ EU

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Notation	
dust	as dust
i	inhalable fraction
r	respirable fraction
STEL	short-term exposure limit: a limit value above which exposure should not occur and which is related to a 15- minute period  (unless otherwise specified)
TWA	time-weighted average (long-term exposure limit): measured or calculated in relation to a reference period of 8 hours time-weighted average (unless otherwise specified)
Y	a risk of developmental toxicity does not need to be expected if the occupational exposure limit value and the

# Human health values

biological limit value (BGW) are adhered to

Relevant DNELs of components								
Name of sub- stance	CAS No	End- point	Threshol d level	Protection goal, route of exposure	Used in	Exposure time		
flue dust, portland cement	68475-76-3	DNEL	0,84 mg/ m³	human, inhalat- ory	worker (industry)	chronic - local ef- fects		
cement, alumina, chemicals	65997-16-2	DNEL	2,5 mg/m³	human, inhalat- ory	worker (industry)	chronic - system- ic effects		

# **Environmental values**

Relevant PNECs of components							
Name of substance	CAS No	Endpoint	Threshold level	Environmental com- partment			
flue dust, portland cement	68475-76-3	PNEC	282 <sup>µg</sup> /I	freshwater			
flue dust, portland cement	68475-76-3	PNEC	28 <sup>µg</sup> / <sub>l</sub>	marine water			
flue dust, portland cement	68475-76-3	PNEC	6 <sup>mg</sup> / <sub>l</sub>	sewage treatment plant (STP)			
flue dust, portland cement	68475-76-3	PNEC	875 <sup>µg</sup> / <sub>kg</sub>	freshwater sediment			
flue dust, portland cement	68475-76-3	PNEC	88 <sup>µg</sup> / <sub>kg</sub>	marine sediment			
flue dust, portland cement	68475-76-3	PNEC	5 <sup>mg</sup> / <sub>kg</sub>	sediments			
cement, alumina, chemicals	65997-16-2	PNEC	260 <sup>mg</sup> / <sub>l</sub>	freshwater			
cement, alumina, chemicals	65997-16-2	PNEC	10 <sup>mg</sup> / <sub>l</sub>	sewage treatment plant (STP)			

# 8.2 Exposure controls

# Appropriate engineering controls

Use local and general ventilation.

## Individual protection measures (personal protective equipment)

#### **Eye/face protection**

Wear eye/face protection. (EN 166).

#### Hand protection

Protective gloves					
Material	Material thickness	Breakthrough times of the glove material			
no information available	no information available	no information available			

Wear suitable gloves.

Chemical protection gloves are suitable, which are tested according to EN 374. Check leak-tightness/impermeability prior to use.

#### Other protection measures

Protective clothing for use against solid particulates.

#### **Body protection**

Protective clothing for use against solid particulates. (EN 13832, EN 340, EN 14605).

#### **Respiratory protection**

In case of inadequate ventilation wear respiratory protection. Particulate filter device (EN 143). P1 (filters at least 80 % of airborne particles, colour code: White).

P2 (filters at least 94 % of airborne particles, colour code: White).

# **Environmental exposure controls**

Use appropriate container to avoid environmental contamination. Keep away from drains, surface and ground water.

# **SECTION 9: Physical and chemical properties**

# 9.1 Information on basic physical and chemical properties

Physical state	solid
Colour	grey - white
Odour	characteristic
Melting point/freezing point	>770 °C (CAS 68475-76-3)
Boiling point or initial boiling point and boiling range	not determined (melting point)
Flammability	non-combustible

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Lov	wer and upper explosion limit	not applicable (solid)
Fla	ish point	not applicable
Au	to-ignition temperature	not applicable (solid)
De	composition temperature	not relevant
р⊦	ł (value)	alkaline (suspension)
Vis	scosity	not relevant (solid)
Sol	lubility(ies)	
Wa	ater solubility	not determined
Pa	rtition coefficient n-octanol/water (log value)	not determined
Va	pour pressure	not determined
De	nsity and/or relative density	
De	nsity	not determined
Rel	lative vapour density	not applicable
	rticle characteristics	no data available
Ot	her information	
	formation with regard to physical hazard isses	hazard classes acc. to GHS (physical hazards): not relevant
Ot	her safety characteristics	there is no additional information

# **SECTION 10: Stability and reactivity**

# 10.1 Reactivity

9.2

This material is not reactive under normal ambient conditions.

# 10.2 Chemical stability

The material is stable under normal ambient and anticipated storage and handling conditions of temperature and pressure. See below "Conditions to avoid".

# 10.3 Possibility of hazardous reactions

Reactions with light metals to form hydrogen.

#### 10.4 Conditions to avoid

Protect from moisture.

# **10.5** Incompatible materials

acids, aluminium, ammonium compounds, metals

# 10.6 Hazardous decomposition products

Reasonably anticipated hazardous decomposition products produced as a result of use, storage, spill and heating are not known.

#### **SECTION 11: Toxicological information**

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

#### **Classification procedure**

If not otherwise specified the classification is based on: Ingredients of the mixture (additivity formula).

# Classification according to GHS (1272/2008/EC, CLP)

#### Acute toxicity

Test data are not available for the complete mixture.

Acute toxicity of components							
Name of substance	CAS No	Expos- ure route	End- point	Value	Species	Method	Source
flue dust, portland ce- ment	68475-76-3	oral	LD0	>1.848 <sup>mg</sup> / <sub>kg</sub>	rat	OECD Guideline 422	ECHA
flue dust, portland ce- ment	68475-76-3	dermal	LD0	≥2.000 <sup>mg</sup> / <sub>kg</sub>	rat	OECD Guideline 402	ECHA
flue dust, portland ce- ment	68475-76-3	inhala- tion: dust/ mist	LC50	>6,04 <sup>mg</sup> / <sub>l</sub> /4h	rat	OECD Guideline 436	ECHA
cement, alumina, chem- icals	65997-16-2	oral	LD50	>2.000 <sup>mg</sup> / <sub>kg</sub>	rat, fe- male	OECD Guideline 423	ECHA
cement, alumina, chem- icals	65997-16-2	dermal	LD50	>2.000 <sup>mg</sup> / <sub>kg</sub>	rat	OECD Guideline 402	ECHA

# Skin corrosion/irritation

Causes skin irritation.

#### Serious eye damage/eye irritation

Causes serious eye damage.

# Respiratory or skin sensitisation Skin sensitisation

Classification could not be established because: Data are lacking, inconclusive, or conclusive but not sufficient for classification.

#### **Respiratory sensitisation**

Classification could not be established because: Data are lacking, inconclusive, or conclusive but not sufficient for classification.

#### Germ cell mutagenicity

Classification could not be established because: Data are lacking, inconclusive, or conclusive but not sufficient for classification.

#### Carcinogenicity

Classification could not be established because: Data are lacking, inconclusive, or conclusive but not sufficient for classification.

## **Reproductive toxicity**

Classification could not be established because: Data are lacking, inconclusive, or conclusive but not sufficient for classification.

# Specific target organ toxicity - single exposure

May cause respiratory irritation.

# Specific target organ toxicity - repeated exposure

Classification could not be established because: Data are lacking, inconclusive, or conclusive but not sufficient for classification.

#### **Aspiration hazard**

Shall not be classified as presenting an aspiration hazard.

# **11.2** Information on other hazards

#### **Endocrine disrupting properties**

Information on this property is not available.

#### **SECTION 12: Ecological information**

# 12.1 Toxicity

#### Aquatic toxicity (acute)

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

# Aquatic toxicity (acute) of components

Name of sub- stance	CAS No	Endpoint	Expos- ure time	Value	Species	Method	Source
flue dust, port- land cement	68475-76-3	ErC50	72 h	28,2 <sup>mg</sup> / <sub>l</sub>	algae (Desmod- esmus sub- spicatus)	OECD Guideline 201	ECHA
flue dust, port- land cement	68475-76-3	ErC50	72 h	22,4 <sup>mg</sup> / <sub>l</sub>	algae (Desmod- esmus sub- spicatus)	OECD Guideline 201	ECHA
cement, alu- mina, chemic- als	65997-16-2	LC50	96 h	>100 <sup>mg</sup> / <sub>l</sub>	Danio rerio	OECD Guideline 203	ECHA
cement, alu- mina, chemic- als	65997-16-2	EC50	24 h	6,4 <sup>mg</sup> / <sub>l</sub>	daphnia magna	OECD Guideline 202	ECHA
cement, alu- mina, chemic- als	65997-16-2	ErC50	72 h	3,6 <sup>mg</sup> / <sub>l</sub>	algae (Desmod- esmus sub- spicatus)	OECD Guideline 201	ECHA

# Aquatic toxicity (chronic)

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

# Aquatic toxicity (chronic) of components

Name of sub- stance	CAS No	Endpoint	Expos- ure time	Value	Species	Method	Source
flue dust, port- land cement	68475-76-3	EL10	21 d	68,2 <sup>mg</sup> / <sub>l</sub>	daphnia magna	OECD Guideline 211	ECHA
cement, alu- mina, chemic- als	65997-16-2	EC50	3 h	>1.000 <sup>mg</sup> / <sub>l</sub>	microorgan- isms	OECD Guideline 209	ECHA
cement, alu- mina, chemic- als	65997-16-2	NOEC	72 h	2,6 <sup>mg</sup> / <sub>l</sub>	algae (Desmod- esmus sub- spicatus)	OECD Guideline 201	ECHA
cement, alu- mina, chemic- als	65997-16-2	LOEC	72 h	5,3 <sup>mg</sup> / <sub>l</sub>	algae (Desmod- esmus sub- spicatus)	OECD Guideline 201	ECHA
cement, alu- mina, chemic- als	65997-16-2	growth (Eb- Cx) 20%	3 h	>1.000 <sup>mg</sup> / <sub>l</sub>	microorgan- isms	OECD Guideline 209	ECHA

# 12.2 Persistence and degradability

#### **Biodegradation**

The study does not need to be conducted, the relevant substances in the mixture are inorganic.

## Persistence

No data available.

# 12.3 Bioaccumulative potential

No data available.

# 12.4 Mobility in soil

No data available.

# 12.5 Results of PBT and vPvB assessment

Does not contain a PBT-/vPvB-substance in a concentration of  $\ge 0,1\%$ .

# 12.6 Endocrine disrupting properties

Information on this property is not available.

#### 12.7 Other adverse effects

Data are not available.

#### Remarks

Wassergefährdungsklasse, WGK (water hazard class): 1.

#### **SECTION 13: Disposal considerations**

## 13.1 Waste treatment methods

This material and its container must be disposed of as hazardous waste.

#### Sewage disposal-relevant information

Do not empty into drains.

#### Waste treatment of containers/packagings

Completely emptied packages can be recycled. Handle contaminated packages in the same way as the substance itself.

## Remarks

Please consider the relevant national or regional provisions.

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#### Version number: 1.0

First version: 21.02.2024

SECTION 14	Transport information
SECTION 14	: Transport information

14.1UN number or ID numbernot assigned14.2UN proper shipping name-14.3Transport hazard class(es)-14.4Packing group-14.5Environmental hazards-14.6Special precautions for user-14.7Maritime transport in bulk according to IM-			
14.3Transport hazard class(es)-14.4Packing group-14.5Environmental hazards-14.6Special precautions for user-	14.1	UN number or ID number	not assigned
14.4Packing group14.5Environmental hazards14.6Special precautions for user	14.2	UN proper shipping name	-
14.5Environmental hazards-14.6Special precautions for user-	14.3	Transport hazard class(es)	-
14.6 Special precautions for user -	14.4	Packing group	-
	14.5	Environmental hazards	-
14.7 Maritime transport in bulk according to IMO -	14.6	Special precautions for user	-
	14.7	Maritime transport in bulk according to IMO	-

# SECTION 15: Regulatory information

instruments

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

**Relevant provisions of the European Union (EU)** 

#### **Restrictions according to REACH, Annex XVII**

Name	Name acc. to inventory	CAS No	Restriction
flue dust, portland cement	chromium(VI) compounds	-	R47
flue dust, portland cement	substances in tattoo inks and perman- ent make-up	-	R75
cement, alumina, chemicals	substances in tattoo inks and perman- ent make-up	-	R75

#### Legend

R47 1. Cement and cement-containing mixtures shall not be placed on the market, or used, if they contain, when hydrated, more than 2 mg/kg (0,0002 %) soluble chromium VI of the total dry weight of the cement.

2. If reducing agents are used, then without prejudice to the application of other Community provisions on the classification, packaging and labelling of substances and mixtures, suppliers shall ensure before the placing on the market that the packaging of cement or cement-containing mixtures is visibly, legibly and indelibly marked with information on the packing date, as well as on the storage conditions and the storage period appropriate to maintaining the activity of the reducing agent and to keeping the content of soluble chromium VI below the limit indicated in paragraph 1.

3. By way of derogation, paragraphs 1 and 2 shall not apply to the placing on the market for, and use in, controlled closed and totally automated processes in which cement and cement-containing mixtures are handled solely by machines and in which there is no possibility of contact with the skin.

4. The standard adopted by the European Committee for Standardization (CEN) for testing the water-soluble chromium (VI) content of cement and cement-containing mixtures shall be used as the test method for demonstrating conformity with paragraph 1.

5. Leather articles coming into contact with the skin shall not be placed on the market where they contain chromium VI in concentrations equal to or greater than 3 mg/kg (0,0003 % by weight) of the total dry weight of the leather.

6. Articles containing leather parts coming into contact with the skin shall not be placed on the market where any of those leather parts contains chromium VI in concentrations equal to or greater than 3 mg/kg (0,0003 % by

#### Legend

weight) of the total dry weight of that leather part.

7. Paragraphs 5 and 6 shall not apply to the placing on the market of second-hand articles which were in enduse in the Union before 1 May 2015.

#### Legend

R75 1. Shall not be placed on the market in mixtures for use for tattooing purposes, and mixtures containing any such substances shall not be used for tattooing purposes, after 4 January 2022 if the substance or substances in question is or are present in the following circumstances:

(a) in the case of a substance classified in Part 3 of Annex VI to Regulation (EC) No 1272/2008 as carcinogen category 1A, 1B or 2, or germ cell mutagen category 1A, 1B or 2, the substance is present in the mixture in a concentration equal to or greater than 0,00005 % by weight;

(b) in the case of a substance classified in Part 3 of Annex VI to Regulation (EC) No 1272/2008 as reproductive toxicant category 1A, 1B or 2, the substance is present in the mixture in a concentration equal to or greater than 0,001 % by weight;

(c) in the case of a substance classified in Part 3 of Annex VI to Regulation (EC) No 1272/2008 as skin sensitiser category 1, 1A or 1B, the substance is present in the mixture in a concentration equal to or greater than 0,001 % by weight;

(d) in the case of a substance classified in Part 3 of Annex VI to Regulation (EC) No 1272/2008 as skin corrosive category 1, 1A, 1B or 1C or skin irritant category 2, or as serious eye damage category 1 or eye irritant category 2, the substance is present in the mixture in a concentration equal to or greater than:

(i) 0,1 % by weight, if the substance is used solely as a pH regulator;

(ii) 0,01 % by weight, in all other cases;

(e) in the case of a substance listed in Annex II to Regulation (EC) No 1223/2009 (\*1), the substance is present in the mixture in a concentration equal to or greater than 0,00005 % by weight;

(f) in the case of a substance for which a condition of one or more of the following kinds is specified in column g (Product type, Body parts) of the table in Annex IV to Regulation (EC) No 1223/2009, the substance is present in the mixture in a concentration equal to or greater than 0,00005 % by weight:

(i) "Rinse-off products";

(ii) "Not to be used in products applied on mucous membranes";

(iii) "Not to be used in eye products";

(g) in the case of a substance for which a condition is specified in column h (Maximum concentration in ready for use preparation) or column i (Other) of the table in Annex IV to Regulation (EC) No 1223/2009, the substance is present in the mixture in a concentration, or in some other way, that does not accord with the condition specified in that column;

(h) in the case of a substance listed in Appendix 13 to this Annex, the substance is present in the mixture in a concentration equal to or greater than the concentration limit specified for that substance in that Appendix.
2. For the purposes of this entry use of a mixture "for tattooing purposes" means injection or introduction of the mixture into a person's skin, mucous membrane or eyeball, by any process or procedure (including procedures commonly referred to as permanent make-up, cosmetic tattooing, micro-blading and micro-pigmentation), with the aim of making a mark or design on his or her body.

3. If a substance not listed in Appendix 13 falls within more than one of points (a) to (g) of paragraph 1, the strictest concentration limit laid down in the points in question shall apply to that substance. If a substance listed in Appendix 13 also falls within one or more of points (a) to (g) of paragraph 1, the concentration limit laid down in point (h) of paragraph 1 shall apply to that substance.

4. By way of derogation, paragraph 1 shall not apply to the following substances until 4 January 2023:

(a) Pigment Blue 15:3 (CI 74160, EC No 205-685-1, CAS No 147-14-8);

(b) Pigment Green 7 (CI 74260, EC No 215-524-7, CAS No 1328-53-6).

5. If Part 3 of Annex VI to Regulation (EC) No 1272/2008 is amended after 4 January 2021 to classify or re-classify a substance such that the substance then becomes caught by point (a), (b), (c) or (d) of paragraph 1 of this entry, or such that it then falls within a different one of those points from the one within which it fell previously, and the date of application of that new or revised classification is after the date referred to in paragraph 1 or, as the case may be, paragraph 4 of this entry, that amendment shall, for the purposes of applying this entry to that substance, be treated as taking effect on the date of application of that new or revised classification of that new or revised classification.

6. If Annex II or Annex IV to Regulation (EC) No 1223/2009 is amended after 4 January 2021 to list or change the listing of a substance such that the substance then becomes caught by point (e), (f) or (g) of paragraph 1 of this entry, or such that it then falls within a different one of those points from the one within which it fell previously, and the amendment takes effect after the date referred to in paragraph 1 or, as the case may be, paragraph 4 of this entry, that amendment shall, for the purposes of applying this entry to that substance, be treated as taking effect from the date falling 18 months after entry into force of the act by which that amendment was made. 7. Suppliers placing a mixture on the market for use for tattooing purposes shall ensure that, after 4 January 2022, the mixture is marked with the following information:

#### Legend

(a) the statement "Mixture for use in tattoos or permanent make-up";

(b) a reference number to uniquely identify the batch;

(c) the list of ingredients in accordance with the nomenclature established in the glossary of common ingredient names pursuant to Article 33 of Regulation (EC) No 1223/2009, or in the absence of a common ingredient name, the IUPAC name. In the absence of a common ingredient name or IUPAC name, the CAS and EC number. Ingredients shall be listed in descending order by weight or volume of the ingredients at the time of formulation. "Ingredient" means any substance added during the process of formulation and present in the mixture for use for tattooing purposes. Impurities shall not be regarded as ingredients. If the name of a substance, used as ingredient within the meaning of this entry, is already required to be stated on the label in accordance with Regulation (EC) No 1272/2008, that ingredient does not need to be marked in accordance with this Regulation;

(d) the additional statement "pH regulator" for substances falling under point (d)(i) of paragraph 1;

(e) the statement "Contains nickel. Can cause allergic reactions." if the mixture contains nickel below the concentration limit specified in Appendix 13;

(f) the statement "Contains chromium (VI). Can cause allergic reactions." if the mixture contains chromium (VI) below the concentration limit specified in Appendix 13;

(g) safety instructions for use insofar as they are not already required to be stated on the label by Regulation (EC) No 1272/2008.

The information shall be clearly visible, easily legible and marked in a way that is indelible.

The information shall be written in the official language(s) of the Member State(s) where the mixture is placed on the market, unless the Member State(s) concerned provide(s) otherwise.

Where necessary because of the size of the package, the information listed in the first subparagraph, except for point (a), shall be included instead in the instructions for use.

Before using a mixture for tattooing purposes, the person using the mixture shall provide the person undergoing the procedure with the information marked on the package or included in the instructions for use pursuant to this paragraph.

8. Mixtures that do not contain the statement "Mixture for use in tattoos or permanent make-up" shall not be used for tattooing purposes.

9. This entry does not apply to substances that are gases at temperature of 20 °C and pressure of 101,3 kPa, or generate a vapour pressure of more than 300 kPa at temperature of 50 °C, with the exception of formaldehyde (CAS No 50-00-0, EC No 200-001-8).

10. This entry does not apply to the placing on the market of a mixture for use for tattooing purposes, or to the use of a mixture for tattooing purposes, when placed on the market exclusively as a medical device or an accessory to a medical device, within the meaning of Regulation (EU) 2017/745, or when used exclusively as a medical device or an accessory to a medical device, within the same meaning. Where the placing on the market or use may not be exclusively as a medical device or an accessory to a medical device or an accessory to a medical device or an accessory to a medical device. (EU) 2017/745, and of this Regulation shall apply cumulatively.

#### List of substances subject to authorisation (REACH, Annex XIV) / SVHC - candidate list

None of the ingredients are listed.

#### **Seveso Directive**

Not assigned.

# Directive on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS)

None of the ingredients are listed.

#### Regulation on the marketing and use of explosives precursors

None of the ingredients are listed.

#### **Regulation on drug precursors**

None of the ingredients are listed.

# Regulation on substances that deplete the ozone layer (ODS)

None of the ingredients are listed.

# Regulation concerning the export and import of hazardous chemicals (PIC)

None of the ingredients are listed.

## **Regulation on persistent organic pollutants (POP)**

None of the ingredients are listed.

#### National regulations (Germany)

# Verordnung über Anlagen zum Umgang mit wassergefährdenden Stoffen (Ordinance on facilities for handling substances hazardous to water) (AwSV)

Wassergefährdungsklasse, WGK 1 (water hazard class) - classificatio

- classification acc. to annex 1 (AwSV)

# Technical instructions on air quality control (Germany)

Not assigned.

# Storage of hazardous substances in non-stationary containers (TRGS 510) (Germany)

Storage class (LGK)	13
	(non-combustible solids)

#### Other information

Observe employment restrictions for young people according to § 22 JArbSchG. Observe occupational restrictions for mothers acc. to § 11 MuSchG!

# 15.2 Chemical Safety Assessment

No Chemical Safety Assessment has been carried out for this mixture by the supplier.

# **SECTION 16: Other information**

#### Abbreviations and acronyms

Abbr.	Descriptions of used abbreviations	
2017/2398/EU	Directive of the European Parliament and of the Council amending Directive 2004/37/EC on the pro- tection of workers from the risks related to exposure to carcinogens or mutagens at work	
ADN	Accord européen relatif au transport international des marchandises dangereuses par voies de nav- igation intérieures (European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways)	
ADR	Accord relatif au transport international des marchandises dangereuses par route (Agreement con- cerning the International Carriage of Dangerous Goods by Road)	
AGW	Workplace exposure limit	
CAS	Chemical Abstracts Service (service that maintains the most comprehensive list of chemical sub- stances)	
CLP	Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures	

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Abbr.	Descriptions of used abbreviations
DFG	Deutsche Forschungsgemeinschaft MAK-und BAT-Werte-Liste, Senatskommission zur Prüfung gesundheitsschädlicher Arbeitsstoffe, Wiley-VCH, Weinheim
DGR	Dangerous Goods Regulations (see IATA/DGR)
DNEL	Derived No-Effect Level
EC50	Effective Concentration 50 %. The EC50 corresponds to the concentration of a tested substance caus- ing 50 % changes in response (e.g. on growth) during a specified time interval
EC No	The EC Inventory (EINECS, ELINCS and the NLP-list) is the source for the seven-digit EC number, an identifier of substances commercially available within the EU (European Union)
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINCS	European List of Notified Chemical Substances
ErC50	≡ EC50: in this method, that concentration of test substance which results in a 50 % reduction in either growth (EbC50) or growth rate (ErC50) relative to the control
Eye Dam.	Seriously damaging to the eye
Eye Irrit.	Irritant to the eye
GHS	"Globally Harmonized System of Classification and Labelling of Chemicals" developed by the United Nations
IATA	International Air Transport Association
IATA/DGR	Dangerous Goods Regulations (DGR) for the air transport (IATA)
IMDG	International Maritime Dangerous Goods Code
index No	The Index number is the identification code given to the substance in Part 3 of Annex VI to Regula- tion (EC) No 1272/2008
IOELV	Indicative occupational exposure limit value
LC50	Lethal Concentration 50%: the LC50 corresponds to the concentration of a tested substance causing 50 % lethality during a specified time interval
LD50	Lethal Dose 50 %: the LD50 corresponds to the dose of a tested substance causing 50 % lethality dur- ing a specified time interval
LGK	Lagerklasse (storage class according to TRGS 510, Germany)
LOEC	Lowest Observed Effect Concentration
NLP	No-Longer Polymer
NOEC	No Observed Effect Concentration
РВТ	Persistent, Bioaccumulative and Toxic
PNEC	Predicted No-Effect Concentration
ppm	Parts per million
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals

# VT10 Fasern, B1, B1 Fasern

Abbr.	Descriptions of used abbreviations
RID	Règlement concernant le transport International ferroviaire des marchandises Dangereuses (Regula- tions concerning the International carriage of Dangerous goods by Rail)
Skin Corr.	Corrosive to skin
Skin Irrit.	Irritant to skin
Skin Sens.	Skin sensitisation
STEL	Short-term exposure limit
STOT SE	Specific target organ toxicity - single exposure
SVHC	Substance of Very High Concern
TRGS	Technische Regeln für Gefahrstoffe (technical rules for hazardous substances, Germany)
TRGS 900	Arbeitsplatzgrenzwerte (TRGS 900)
TWA	Time-weighted average
vPvB	Very Persistent and very Bioaccumulative

# Key literature references and sources for data

Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures. Regulation (EC) No. 1907/2006 (REACH), amended by 2020/878/EU.

Transport of dangerous goods by road, rail and inland waterway (ADR/RID/ADN). International Maritime Dangerous Goods Code (IMDG). Dangerous Goods Regulations (DGR) for the air transport (IATA).

# **Classification procedure**

Physical and chemical properties.

Health hazards.

Environmental hazards.

The method for classification of the mixture is based on ingredients of the mixture (additivity formula).

# List of relevant phrases (code and full text as stated in section 2 and 3)

Code	Text
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H318	Causes serious eye damage.
H335	May cause respiratory irritation.

# Responsible for the safety data sheet

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## Disclaimer

This information is based upon the present state of our knowledge. This SDS has been compiled and is solely intended for this product.