

**Safety Data Sheet
ORTHOFAST****Revision nr. 3
Dated 14/04/2023****SECTION 1: Identification of the substance/mixture and of the company/undertaking****1.1. Product identifier**

Mixture identification:
Product Name: ORTHOFAST
Code: B901100, B901096, B901090

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

For professional use only. Alginate for dental impression.

1.3. Details of the supplier of the safety data sheet

Name
Zhermack S.p.a
Via Bovazecchino 100
45021 Badia Polesine (RO)
Italy
tel. +39 0425-597611
fax +39 0425-597689

Competent person responsible for the safety data sheet:
msds@zhermack.com

1.4. Emergency telephone number

UK Emergency number: 999 (24 hours)

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

EC regulation criteria 1272/2008 (CLP)

STOT RE 2, H373 May cause damage to organs (lungs) through prolonged or repeated exposure if inhaled.

Aquatic Chronic 3, H412 Harmful to aquatic life with long lasting effects.

Adverse physicochemical, human health and environmental effects:

No other hazards

2.2. Label elements

The Regulation EC 1272/2008, on classification, labelling and packaging of substances and mixtures (CLP), shall not apply to a medical device in the finished state used in direct physical contact with the human body according to art. 1.5, letter d). Therefore the product is exempted from the CLP labeling requirements.

Hazard pictograms:



Warning

Hazard statements:

H373 May cause damage to organs (lungs) through prolonged or repeated exposure if inhaled.

H412 Harmful to aquatic life with long lasting effects.

Precautionary statements:

P260 Do not breathe dust.

P273 Avoid release to the environment.

P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

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P314 Get medical advice/attention if you feel unwell.

P501 Dispose of contents/container in accordance with applicable regulations.

Special Provisions:

None

Contains

Cristobalite

Special provisions according to Annex XVII of REACH and subsequent amendments:

None

2.3. Other hazards

Classification of the mixture is based on the results of an in vitro assay conducted in accordance with the guidelines provided by OCSE (OECD Test Guideline 437 resp. EU Method B.47 – Bovine Corneal Opacity and Permeability (BCOP) Test Method) and GLP certified - Good Laboratory Practices. For more information refer to section 11.

No PBT, vPvB or endocrine disruptor substances present in concentration $\geq 0.1\%$

Other Hazards:

No other hazards

SECTION 3: Composition/information on ingredients

3.1. Substances

Not Applicable

3.2. Mixtures

Hazardous components within the meaning of the CLP regulation and related classification:

Qty	Name	Ident. Number	Classification
$\geq 5\%$ - $< 8\%$	Cristobalite	CAS: 14464-46-1 EC: 238-455-4	STOT RE 1 H372 Causes damage to organs (lungs) through prolonged or repeated exposure if inhaled.
$\geq 1\%$ - $< 3\%$	Dipotassium exafluorotitanate	CAS: 16919-27-0 EC: 240-969-9 REACH No.: 01-21199782 68-20-XXXX	Acute Tox. 4 H302 Harmful if swallowed. Eye Dam. 1 H318 Causes serious eye damage. Acute Toxicity Estimate: ATE - Oral 324 mg/kg bw
$\geq 0,5\%$ - $< 2,5\%$	zinc oxide	Index number: 030-013-00-7 CAS: 1314-13-2 EC: 215-222-5 REACH No.: 01-21194638 81-32-XXXX	Aquatic Acute 1 H400 Very toxic to aquatic life. M=1. Aquatic Chronic 1 H410 Very toxic to aquatic life with long lasting effects. M=1.
$\geq 0,5\%$ - $< 2,5\%$	Paraffin oil	CAS: 8042-47-5 EC: 232-455-8 REACH No.: 01-21194870 78-27-XXXX	Asp. Tox. 1 H304 May be fatal if swallowed and enters airways.
$< 0,1\%$	ethyl acetate	Index number: 607-022-00-5 CAS: 141-78-6 EC: 205-500-4 REACH No.: 01-21194751 03-46-XXXX	STOT SE 3 H336 May cause drowsiness or dizziness. Flam. Liq. 2 H225 Highly flammable liquid and vapour. Eye Irrit. 2 H319 Causes serious eye irritation.

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			EUH066 Repeated exposure may cause skin dryness or cracking. Specific Concentration Limits: C >= 10%: EUH066
<0,1%	acetic acid	Index number: 607-002-00-6 CAS: 64-19-7 EC: 200-580-7 REACH No.: 01-21194753 28-30-XXXX	Flam. Liq. 3 H226 Flammable liquid and vapour. Skin Corr. 1A H314 Causes severe skin burns and eye damage. Specific Concentration Limits: C >= 90%: Skin Corr. 1A H314 C >= 90%: Skin Corr. 1A H314 25% <= C < 90%: Skin Corr. 1B H314 25% <= C < 90%: Skin Corr. 1C H314 10% <= C < 25%: Skin Irrit. 2 H315 C >= 25%: Eye Dam. 1 H318 10% <= C < 25%: Eye Irrit. 2 H319
<0,1%	formic acid ... %	Index number: 607-001-00-0 CAS: 64-18-6 EC: 200-579-1 REACH No.: 01-21194911 74-37-XXXX	STOT SE 1 H370 Causes damage to organs. Flam. Liq. 3 H226 Flammable liquid and vapour. Acute Tox. 3 H331 Toxic if inhaled. Acute Tox. 4 H302 Harmful if swallowed. Skin Corr. 1A H314 Causes severe skin burns and eye damage. EUH071 Corrosive to the respiratory tract. Specific Concentration Limits: C >= 10%: STOT SE 1 H370 1% <= C < 10%: STOT SE 2 H371 C >= 0,1%: EUH071 C >= 90%: Skin Corr. 1A H314 C >= 90%: Skin Corr. 1A H314 10% <= C < 90%: Skin Corr. 1B H314 10% <= C < 90%: Skin Corr. 1C H314 2% <= C < 10%: Skin Irrit. 2 H315 C >= 10%: Eye Dam. 1 H318 2% <= C < 10%: Eye Irrit. 2 H319 Acute Toxicity Estimate: ATE - Oral 730 mg/kg bw ATE - Inhalation (Vapours) 7,85 mg/l

Substances in nanoform:

>= 1% - < 3% Dipotassium hexafluorotitanate

REACH No.: 01-2119978268-20-XXXX, CAS: 16919-27-0, EC: 240-969-9

>= 0,5% - < 2,5% Trisodium orthophosphate

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REACH No.: 01-2119489800-32-XXXX, CAS: 7601-54-9, EC: 231-509-8

>=0,05% - <0,1% 2-[(4-methyl-2-nitrophenyl)azo]-3-oxo-N-phenylbutyramide
REACH No.: 01-2119958943-22-XXXX, CAS: 2512-29-0, EC: 219-730-8

<0,1% Silicon dioxide, amorphous
REACH No.: 01-2119379499-16-XXXX, CAS: 7631-86-9, EC: 231-545-4

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

In case of skin contact:

Areas of the body that have - or are only even suspected of having - come into contact with the product must be rinsed immediately with plenty of running water and possibly with soap.

Wash with plenty of water and soap.

Wash thoroughly the body (shower or bath).

Remove contaminated clothing immediately and dispose off safely.

In case of eyes contact:

In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

In case of Ingestion:

Do not under any circumstances induce vomiting. OBTAIN A MEDICAL EXAMINATION IMMEDIATELY.

In case of Inhalation:

If breathing is irregular or stopped, administer artificial respiration.

In case of inhalation, consult a doctor immediately and show him packing or label.

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

None

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

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

Treatment:

None

SECTION 5: Firefighting measures**5.1. Extinguishing media**

Suitable extinguishing media:

Water.

Carbon dioxide (CO₂).

Extinguishing media which must not be used for safety reasons:

None in particular.

5.2. Special hazards arising from the substance or mixture

Do not inhale explosion and combustion gases.

Burning produces heavy smoke.

5.3. Advice for firefighters

Use suitable breathing apparatus .

Collect contaminated fire extinguishing water separately. This must not be discharged into drains.

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

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

For non emergency personnel:

Wear personal protection equipment.

Wear breathing apparatus if exposed to vapours/dusts/aerosols.

Provide adequate ventilation.

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Use appropriate respiratory protection.
See protective measures under point 7 and 8.
For emergency responders:
Wear personal protection equipment.

6.2. Environmental precautions

Do not allow to enter into soil/subsoil. Do not allow to enter into surface water or drains.
Retain contaminated washing water and dispose it.
In case of gas escape or of entry into waterways, soil or drains, inform the responsible authorities.

Suitable material for taking up: absorbing material, organic, sand

6.3. Methods and material for containment and cleaning up

Wash with plenty of water.

6.4. Reference to other sections

See also section 8 and 13

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Avoid contact with skin and eyes, inhalation of vapours and mists.
Use localized ventilation system.
Don't use empty container before they have been cleaned.
Before making transfer operations, assure that there aren't any incompatible material residuals in the containers.
See also section 8 for recommended protective equipment.
Advice on general occupational hygiene:
Contaminated clothing should be changed before entering eating areas.
Do not eat or drink while working.

7.2. Conditions for safe storage, including any incompatibilities

Keep away from food, drink and feed.
Incompatible materials:
See section 10.5.
Instructions as regards storage premises:
Adequately ventilated premises.

7.3. Specific end use(s)

See section 1.2.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

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Cristobalite - CAS: 14464-46-1

OEL Type	TWA		Duration	STEL		Duration	Notes	Country
EU	0.1 mg/m ³		8h				Respirable	
TLV	0.1 mg/m ³		8h				Respirable	ITALY
ACGIH	0.025 mg/m ³		8h				(R), A2 - Pulm fibrosis, lung cancer	

Dipotassium hexafluorotitanate - CAS: 16919-27-0

OEL Type	TWA		Duration	STEL		Duration	Notes	Country
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No data available								

zinc oxide - CAS: 1314-13-2

OEL Type	TWA		Duration	STEL		Duration	Notes	Country
VLA	2 mg/m ³		8h	10 mg/m ³		15min		SPAIN
MV	5 mg/m ³		8h	20 mg/m ³		15min	Respirable	SLOVENIA
VME/VLE	3 mg/m ³		8h	3 mg/m ³		15min	Respirable	SWITZERLAND
MAK	2 mg/m ³		8h	4 mg/m ³		15min	Inhalable	GERMANY
MAK	0.1 mg/m ³		8h	0.4 mg/m ³		15min	Respirable	GERMANY
MAK	3 mg/m ³		8h	3 mg/m ³		15min	Respirable	SWITZERLAND
AK	5 mg/m ³		8h	20 mg/m ³		15min	Respirable	HUNGARY
GVI/KGVI	2 mg/m ³		8h	10 mg/m ³		15min	Respirable	CROATIA
HTP	2 mg/m ³		8h	10 mg/m ³		15min		FINLAND
MAK	5 mg/m ³		8h				Respirable	AUSTRIA
NDS/NDSCh	5 mg/m ³		8h	10 mg/m ³		15min	Inhalable	POLAND
NGV/KGV	5 mg/m ³		8h					SWEDEN
NPEL	1 mg/m ³		8h	1 mg/m ³		15min	Respirable	SLOVAKIA (Slovak Republic)
OELV	2 mg/m ³		8h				Respirable	IRELAND
RD	5 mg/m ³		8h					LITHUANIA
RV	0.5 mg/m ³		8h					LATVIA
TLV	5 mg/m ³		8h					ESTONIA
TLV	5 mg/m ³		8h					NORWAY
TLV	5 mg/m ³		8h	10 mg/m ³		15min		ROMANIA
TLV	2 mg/m ³		8h	5 mg/m ³		15min		CZECH REPUBLIC
TLV	4 mg/m ³		8h					DENMARK
TLV	5 mg/m ³		8h	10 mg/m ³		15min		BULGARIA
TLV	5 mg/m ³		8h	10 mg/m ³		15min		GREECE

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VLEP	5 mg/m3		8h					FRANCE
VLEP	2 mg/m3		8h	10 mg/m3		15min	Respirable	BELGIUM
TLV-ACGIH	2 mg/m3		8h	10 mg/m3		15min	(R) - Metal fume fever	
ACGIH	2 mg/m3		8h	10 mg/m3			(R) - Metal fume fever	

Paraffin oil - CAS: 8042-47-5

OEL Type	TWA		Duration	STEL		Duration	Notes	Country
AGW	5 mg/m3		8h	20 mg/m3		15min	Respirable	GERMANY
MAK	5 mg/m3		8h	20 mg/m3		15min	Respirable	GERMANY
TLV	5 mg/m3		8h	10 mg/m3		15min		ROMANIA
MAK	5 mg/m3		8h				Inhalable	SWITZERLAND

ethyl acetate - CAS: 141-78-6

OEL Type	TWA		Duration	STEL		Duration	Notes	Country
MAK	750 mg/m3	200 ppm	8h	1500 mg/m3	400 ppm	15min		GERMANY
AGW	730 mg/m3	200 ppm	8h	1460 mg/m3	400 ppm	15min		GERMANY
MAK	730 mg/m3	200 ppm	8h	1460 mg/m3	400 ppm	15min		SWITZERLAND
AK	1400 mg/m3		8h	1400 mg/m3		15min		HUNGARY
HTP	730 mg/m3	200 ppm	8h	1470 mg/m3	400 ppm	15min		FINLAND
MAK	734 mg/m3	200 ppm	8h	1468 mg/m3	400 ppm	15min		AUSTRIA
NDS/NDSch	200 mg/m3		8h	600 mg/m3		15min		POLAND
NGV/KGV	550 mg/m3	150 ppm	8h	1100 mg/m3	300 ppm	15min		SWEDEN
OELV		200 ppm	8h		400 ppm	15min		IRELAND
VLEP	734 mg/m3	200 ppm	8h	1468 mg/m3	400 ppm	15min		ITALY
RV	200 mg/m3	54 ppm	8h	1468 mg/m3	400 ppm	15min		LATVIA
TLV	400 mg/m3	111 ppm	8h	500 mg/m3	139 ppm	15min		ROMANIA
TLV	540 mg/m3	150 ppm	8h	1080 mg/m3	300 ppm	15min		DENMARK
VLEP	734 mg/m3	200 ppm	8h	1468 mg/m3	400 ppm	15min		FRANCE

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VLEP	734 mg/m ³	200 ppm	8h	1468 mg/m ³	400 ppm	15min		BELGIUM
WEL	730 mg/m ³	200 ppm	8h	1460 mg/m ³	400 ppm	15min		UNITED KINGDOM
VLA	1460 mg/m ³	400 ppm	8h					SPAIN
EU	734 mg/m ³	200 ppm	8h	1468 mg/m ³	400 ppm			
TLV-ACGIH		400 ppm	8h				URT and eye irr	
ACGIH		400 ppm	8h				URT and eye irr	

acetic acid - CAS: 64-19-7

OEL Type	TWA		Duratio n	STEL		Duratio n	Notes	Country
MAK	25 mg/m ³	10 ppm	8h	50 mg/m ³	20 ppm	15min		GERMANY
AGW	25 mg/m ³	10 ppm	8h	50 mg/m ³	20 ppm	15min		GERMANY
MAK	25 mg/m ³	10 ppm	8h	50 mg/m ³	20 ppm	15min		SWITZERLA ND
VME/VLE	25 mg/m ³	10 ppm	8h	50 mg/m ³	20 ppm	15min		SWITZERLA ND
MV	25 mg/m ³	10 ppm	8h	50 mg/m ³	20 ppm	15min		SLOVENIA
AK	25 mg/m ³		8h	50 mg/m ³		15min		HUNGARY
GVI/KGVI	25 mg/m ³	10 ppm	8h	50 mg/m ³	20 ppm	15min		CROATIA
HTP	13 mg/m ³	5 ppm	8h	25 mg/m ³	10 ppm	15min		FINLAND
MAK	25 mg/m ³	10 ppm	8h	50 mg/m ³	20 ppm	15min		AUSTRIA
NDS/NDSCh	25 mg/m ³		8h	50 mg/m ³		15min		POLAND
NGV/KGV	13 mg/m ³	5 ppm	8h	25 mg/m ³	10 ppm	15min		SWEDEN
NPEL	25 mg/m ³	10 ppm	8h	50 mg/m ³	20 ppm	15min		SLOVAKIA (Slovak Republic)
EU	25 mg/m ³	10 ppm	8h	50 mg/m ³	20 ppm			
OELV	25 mg/m ³	10 ppm	8h	50 mg/m ³	20 ppm	15min		IRELAND
RD	25 mg/m ³	10 ppm	8h	50 mg/m ³	20 ppm	15min		LITHUANIA
RV	25 mg/m ³	10 ppm	8h	50 mg/m ³	20 ppm	15min		LATVIA
TGG	25 mg/m ³		8h	50 mg/m ³		15min		NETHERLAN DS
TLV	25 mg/m ³	10 ppm	8h	25 mg/m ³	10 ppm	15min		ESTONIA

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TLV	25 mg/m ³	10 ppm	8h	50 mg/m ³	20 ppm	15min		MALTA
TLV	25 mg/m ³	10 ppm	8h	50 mg/m ³	20 ppm	15min		NORWAY
TLV	25 mg/m ³	10 ppm	8h	50 mg/m ³	20 ppm	15min		ROMANIA
TLV	25 mg/m ³	10.2 ppm	8h	50 mg/m ³	20.4 ppm	15min		CZECH REPUBLIC
TLV	25 mg/m ³	10 ppm	8h					DENMARK
TLV	25 mg/m ³	10 ppm	8h	50 mg/m ³	20 ppm	15min		CYPRUS
TLV	25 mg/m ³	10 ppm	8h	37 mg/m ³	15 ppm	15min		GREECE
VL	25 mg/m ³	10 ppm	8h	50 mg/m ³	20 ppm	15min		LUXEMBOURG
VLE	25 mg/m ³	10 ppm	8h	50 mg/m ³	20 ppm	15min		PORTUGAL
VLEP				25 mg/m ³	10 ppm	15min		FRANCE
VLEP	25 mg/m ³	10 ppm	8h	50 mg/m ³	20 ppm	15min		ITALY
VLEP	25 mg/m ³	10 ppm	8h	38 mg/m ³	15 ppm	15min		BELGIUM
WEL	25 mg/m ³	10 ppm	8h	50 mg/m ³	20 ppm	15min		UNITED KINGDOM
VLA	25 mg/m ³	10 ppm	8h	50 mg/m ³	20 ppm	15min		SPAIN
ACGIH		10 ppm	8h		15 ppm		URT and eye irr, pulm func	

formic acid ... % - CAS: 64-18-6

OEL Type	TWA		Duration	STEL		Duration	Notes	Country
TLV	9 mg/m ³	5 ppm	8h	18 mg/m ³	10 ppm	15min		DENMARK
MAK	9.5 mg/m ³	5 ppm	8h	19 mg/m ³	10 ppm	15min		GERMANY
AGW	9.5 mg/m ³	5 ppm	8h	19 mg/m ³	10 ppm	15min		GERMANY
MAK	95 mg/m ³	5 ppm	8h	19 mg/m ³	10 ppm	15min		SWITZERLAND
VME/VLE	95 mg/m ³	5 ppm	8h	19 mg/m ³	10 ppm	15min		SWITZERLAND
AK	9 mg/m ³		8h					HUNGARY
HTP	5 mg/m ³	3 ppm	8h	19 mg/m ³	10 ppm	15min		FINLAND
MAK	9 mg/m ³	5 ppm	8h	9 mg/m ³	5 ppm	15min		AUSTRIA
NDS/NDSCh	5 mg/m ³		8h	15 mg/m ³		15min		POLAND

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NGV/KGV	5 mg/m ³	3 ppm	8h	9 mg/m ³	5 ppm	15min		SWEDEN
OELV	9 mg/m ³	5 ppm	8h					IRELAND
RV	9 mg/m ³	5 ppm	8h					LATVIA
TGG				5 mg/m ³		15min		NETHERLANDS
TLV	9 mg/m ³	5 ppm	8h					ROMANIA
TLV-ACGIH		5 ppm	8h		10 ppm	15min	URT, eye, & skin irr	
VLEP	9 mg/m ³	5 ppm	8h					FRANCE
VLEP	9 mg/m ³	5 ppm	8h					ITALY
VLEP	9.5 mg/m ³	5 ppm	8h	19 mg/m ³	10 ppm	15min		BELGIUM
WEL	9.6 mg/m ³	5 ppm	8h					UNITED KINGDOM
VLA	9 mg/m ³	5 ppm	8h	18 mg/m ³	10 ppm	15min		SPAIN
EU	9 mg/m ³	5 ppm	8h					
ACGIH		5 ppm	8h		10 ppm		URT, eye, and skin irr	

DNEL Exposure Limit Values

Dipotassium exafluorotitanate - CAS: 16919-27-0

Worker Professional: 5.2 mg/m³ - Exposure: Human Inhalation - Frequency: Long Term, local effects

Worker Professional: 5.2 mg/m³ - Exposure: Human Inhalation - Frequency: Long Term, systemic effects

Worker Professional: 5.2 mg/m³ - Exposure: Human Inhalation - Frequency: Short Term, systemic effects

Worker Professional: 75 mg/kg bw/d - Exposure: Human Dermal - Frequency: Long Term, systemic effects

Worker Professional: 75 mg/kg bw/d - Exposure: Human Dermal - Frequency: Short Term, systemic effects

Consumer: 37.5 mg/kg bw/d - Exposure: Human Dermal - Frequency: Short Term, systemic effects

Consumer: 37.5 mg/kg bw/d - Exposure: Human Dermal - Frequency: Long Term, systemic effects

zinc oxide - CAS: 1314-13-2

Consumer: 0.83 mg/kg/d - Exposure: Human Oral - Frequency: Long Term, systemic effects

Consumer: 2.5 mg/m³ - Exposure: Human Inhalation - Frequency: Long Term, systemic effects

Worker Professional: 5 mg/m³ - Exposure: Human Inhalation - Frequency: Long Term, systemic effects

Consumer: 87 mg/kg/d - Exposure: Human Dermal - Frequency: Long Term, systemic effects

Worker Professional: 87 mg/kg/d - Exposure: Human Dermal - Frequency: Long Term, systemic effects

Paraffin oil - CAS: 8042-47-5

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Consumer: 93 mg/kg/d - Exposure: Human Dermal - Frequency: Long Term, systemic effects

Consumer: 35 mg/m³ - Exposure: Human Inhalation - Frequency: Long Term, systemic effects

Consumer: 40 mg/kg/d - Exposure: Human Oral - Frequency: Long Term, systemic effects

Worker Professional: 220 mg/kg/d - Exposure: Human Dermal - Frequency: Long Term, systemic effects

Worker Professional: 160 mg/m³ - Exposure: Human Inhalation - Frequency: Long Term, systemic effects

ethyl acetate - CAS: 141-78-6

Worker Professional: 1468 mg/m³ - Exposure: Human Inhalation - Frequency: Short Term, local effects

Worker Professional: 734 mg/m³ - Exposure: Human Inhalation - Frequency: Long Term, local effects

Worker Professional: 1468 mg/m³ - Exposure: Human Inhalation - Frequency: Short Term, systemic effects

Worker Professional: 734 mg/m³ - Exposure: Human Inhalation - Frequency: Long Term, systemic effects

Worker Professional: 63 mg/kg bw/d - Exposure: Human Dermal - Frequency: Long Term, systemic effects

acetic acid - CAS: 64-19-7

Consumer: 25 mg/m³ - Exposure: Human Inhalation - Frequency: Short Term, systemic effects

Consumer: 25 mg/m³ - Exposure: Human Inhalation - Frequency: Long Term, systemic effects

Worker Professional: 25 mg/m³ - Exposure: Human Inhalation - Frequency: Short Term, systemic effects

Worker Professional: 25 mg/m³ - Exposure: Human Inhalation - Frequency: Long Term, systemic effects

formic acid ... % - CAS: 64-18-6

Worker Industry: 9.5 mg/m³ - Worker Professional: 9.5 mg/m³ - Exposure: Human Inhalation - Frequency: Long Term, systemic effects

Worker Industry: 9.5 mg/m³ - Worker Professional: 9.5 mg/m³ - Exposure: Human Inhalation - Frequency: Long Term, local effects

Consumer: 3 mg/m³ - Exposure: Human Inhalation - Frequency: Long Term, systemic effects

Consumer: 3 mg/m³ - Exposure: Human Inhalation - Frequency: Long Term, local effects

PNEC Exposure Limit Values

Dipotassium exafluorotitanate - CAS: 16919-27-0

Target: Fresh Water - Value: 0.131 mg/l

Target: Marine water - Value: 0.131 mg/l

Target: Freshwater sediments - Value: 24.45 03

Target: Marine water sediments - Value: 4.89 03

Target: Microorganisms in sewage treatments - Value: 1.5 mg/l

Target: Soil (agricultural) - Value: 19.1 mg/kg

Target: intermittent release - Value: 0.108 mg/l

zinc oxide - CAS: 1314-13-2

Target: Fresh Water - Value: 117 mg/l

Target: Marine water - Value: 0.0061 mg/l

Target: Freshwater sediments - Value: 117 mg/kg

Target: Marine water sediments - Value: 56.5 mg/kg

Target: Microorganisms in sewage treatments - Value: 0.052 mg/l

Target: Soil (agricultural) - Value: 35.6 mg/kg

ethyl acetate - CAS: 141-78-6

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Target: Fresh Water - Value: 0.26 mg/l
 Target: Marine water - Value: 0.026 mg/l
 Target: Soil (agricultural) - Value: 0.24 mg/kg
 Target: Marine water sediments - Value: 0.125 mg/kg
 Target: Freshwater sediments - Value: 1.25 mg/kg
 acetic acid - CAS: 64-19-7
 Target: Soil (agricultural) - Value: 0.478 mg/kg
 Target: Fresh Water - Value: 3.058 mg/l
 Target: intermittent release - Value: 3.058 mg/l
 Target: Marine water - Value: 0.3058 mg/l
 Target: Freshwater sediments - Value: 11.36 mg/kg
 Target: Marine water sediments - Value: 1.136 mg/kg
 Target: Microorganisms in sewage treatments - Value: 85 mg/l
 formic acid ... % - CAS: 64-18-6
 Target: Marine water - Value: 0.2 mg/l
 Target: Fresh Water - Value: 2 mg/l
 Target: Microorganisms in sewage treatments - Value: 7.2 mg/l
 Target: Marine water sediments - Value: 1.34 mg/kg
 Target: Freshwater sediments - Value: 13.4 mg/kg
 Target: Soil (agricultural) - Value: 1.5 mg/kg

8.2. Exposure controls

Precautionary measures:

Give adequate ventilation to the premises where the product is stored and/or handled.

Eye protection:

Wear airtight protective goggles (EN 166).

Protection for skin:

Wear professional overalls and safety footwear (EN 14605).

Protection for hands:

Protect hands with work gloves (EN 374).

The following should be considered when choosing work glove material (EN 374): compatibility, degradation, failure time and permeability.

The work gloves' resistance to chemical agents should be checked before use, as it can be unpredictable. The gloves' wear time depends on the duration and type of use.

Respiratory protection:

Mask with filter "P2 or P3".

Thermal Hazards:

None

Environmental exposure controls:

None

Appropriate engineering controls:

None

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Properties	Value	Method:	Notes
Physical state:	Dust	--	--
Colour:	Orange	--	--
Odour:	apricot	--	--
Melting point/freezing point:	Not available	--	--
Boiling point or initial boiling point and boiling range:	Not available	--	--

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Flammability:	Not available	--	--
Lower and upper explosion limit:	Not available	--	--
Flash point:	Not available	--	--
Auto-ignition temperature:	Not available	--	--
Decomposition temperature:	Not available	--	--
pH:	Not available	--	--
Kinematic viscosity:	Not available	--	--
Solubility in water:	Partially soluble	--	--
Solubility in oil:	Not available	--	--
Partition coefficient n-octanol/water (log value):	Not available	--	--
Vapour pressure:	Not available	--	--
Density and/or relative density:	0.2-0.5 g/cm ³	--	--
Relative vapour density:	Not available	--	--
Particle characteristics:			
Particle size:	Not available	--	--
Nanoforms:	See Nanoform information in Section 3.	--	--

9.2. Other information

No other relevant information

SECTION 10: Stability and reactivity

10.1. Reactivity

Stable under normal conditions

10.2. Chemical stability

Stable under normal conditions

10.3. Possibility of hazardous reactions

None

10.4. Conditions to avoid

Stable under normal conditions.

10.5. Incompatible materials

None in particular.

10.6. Hazardous decomposition products

None.

SECTION 11: Toxicological information

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

Toxicological information of the product:

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a) acute toxicity

Not classified

b) skin corrosion/irritation

Not classified

c) serious eye damage/irritation

Not classified

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Test: In vitro - Based on available data, the classification criteria are not met - Source: Bridging principle, OECD 437 resp. EU Method B.47, GLP, study report 2019

- d) respiratory or skin sensitisation
Not classified
- e) germ cell mutagenicity
Not classified
- f) carcinogenicity
Not classified
- g) reproductive toxicity
Not classified
- h) STOT-single exposure
Not classified
- i) STOT-repeated exposure
The product is classified: STOT RE 2 H373
- j) aspiration hazard
Not classified

Toxicological information of the main substances found in the product:

Cristobalite - CAS: 14464-46-1

- i) STOT-repeated exposure:
Route: Inhalation - Notes: Silicosis, pulmonary fibrosis; Target organ: lungs - Source: (MSDS supplier).

Dipotassium hexafluorotitanate - CAS: 16919-27-0

- a) acute toxicity
ATE - Oral 324 mg/kg bw
Test: LD50 - Route: Oral - Species: Rat 324 mg/kg - Source: (OECD 401, ECHA dossier).
- b) skin corrosion/irritation:
Species: Rabbit - Based on available data, the classification criteria are not met - Source: (OECD 404, MSDS supplier).
- c) serious eye damage/irritation:
Species: Rabbit - Eye Corrosive - Source: (OECD 405, MSDS supplier).
- d) respiratory or skin sensitisation:
Test: Skin Sensitization - Species: Guinea pig - Based on available data, the classification criteria are not met - Source: (OECD 406, MSDS supplier).
- e) germ cell mutagenicity:
Test: In vitro - Species: Salmonella Typhimurium - Negative - Source: (OECD 471, MSDS supplier).
Test: In vitro - Positive - Source: (OECD 487, MSDS supplier).
Test: In vitro - Negative - Source: (OECD 476, MSDS supplier).
Test: In vivo - Species: Rat - Negative - Source: (OECD 474, MSDS supplier).

zinc oxide - CAS: 1314-13-2

- a) acute toxicity:
Test: LD50 - Route: Skin - Species: Rat > 2000 mg/kg - Source: (OECD 402, GLP, ECHA dossier).
Test: LC50 - Route: Inhalation - Species: Rat > 5.7 mg/l - Source: (OECD 403, ECHA dossier).
Test: LD50 - Route: Oral - Species: Rat > 5000 mg/kg - Source: (OECD 401, ECHA dossier).
- b) skin corrosion/irritation:

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Species: Rabbit - Based on available data, the classification criteria are not met -
Source: (ECHA dossier).

c) serious eye damage/irritation:

Species: Rabbit - Based on available data, the classification criteria are not met -
Source: (ECHA dossier).

d) respiratory or skin sensitisation:

Test: Skin Sensitization - Species: Guinea pig - Based on available data, the
classification criteria are not met - Source: (ECHA dossier).

e) germ cell mutagenicity:

Test: In vitro - Negative - Source: (OCDE 471, ECHA dossier).

Test: In vivo - Species: Mouse - Negative - Source: (OCDE 474, GLP, ECHA dossier).

Paraffin oil - CAS: 8042-47-5

a) acute toxicity:

Test: LC50 - Route: Inhalation - Species: Rat > 5 mg/l - Duration: 4h - Source: (OECD
403, ECHA dossier).

Test: LD50 - Route: Skin - Species: Rabbit > 2000 mg/kg - Source: (similar or
equivalent to OECD 402, ECHA dossier).

Test: LD50 - Route: Oral - Species: Rat > 5000 mg/kg - Source: (similar or equivalent
to OECD 401, ECHA dossier).

j) aspiration hazard:

Positive - Source: (MSDS supplier).

ethyl acetate - CAS: 141-78-6

a) acute toxicity:

Test: LD50 - Route: Oral - Species: Rat 4934 mg/kg - Source: (OECD 401, MSDS
supplier).

Test: LD50 - Route: Skin - Species: Rabbit > 18000 mg/kg - Source: (MSDS supplier).

Test: LC50 - Route: Inhalation - Species: Rat 56 mg/l - Duration: 4h - Source: (SDS
supplier).

b) skin corrosion/irritation:

Species: Rabbit - Based on available data, the classification criteria are not met -
Source: (OECD TG 404, MSDS supplier).

c) serious eye damage/irritation:

Species: Rabbit - Based on available data, the classification criteria are not met -
Source: (OECD TG 405, MSDS supplier).

d) respiratory or skin sensitisation:

Species: Guinea pig - Based on available data, the classification criteria are not met -
Source: (OECD TG 406, MSDS supplier).

acetic acid - CAS: 64-19-7

a) acute toxicity:

Test: LC50 - Route: Inhalation - Species: Rat > 16000 ppm - Duration: 4h - Source:
(MSDS supplier).

Test: LD50 - Route: Oral - Species: Rat 3310 mg/kg - Source: (MSDS supplier).

b) skin corrosion/irritation:

Species: Rabbit - Skin Corrosive - Source: (OECD 404, MSDS supplier).

c) serious eye damage/irritation:

Species: Rabbit - Eye Corrosive - Source: (OECD 405, MSDS supplier).

e) germ cell mutagenicity:

Test: In vitro - Negative - Source: (MSDS supplier).

Test: In vivo - Negative - Source: (MSDS supplier).

g) reproductive toxicity:

Negative - Source: (MSDS supplier).

formic acid ... % - CAS: 64-18-6

a) acute toxicity

ATE - Oral 730 mg/kg bw

ATE - Inhalation (Vapours) 7,85 mg/l

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Test: LD50 - Route: Oral - Species: Rat 730 mg/kg - Source: (OECD 401, ECHA dossier).

Test: LD50 - Route: Skin - Species: Rat > 2000 mg/kg - Source: (OECD 402, ECHA dossier).

Test: LC50 - Route: Inhalation Vapour - Species: Rat 7.85 mg/l - Duration: 4h - Source: (OECD 403, ECHA dossier).

b) skin corrosion/irritation:

Skin Corrosive - Source: (ECHA dossier).

c) serious eye damage/irritation:

Eye Corrosive - Source: (ECHA dossier).

11.2. Information on other hazards

Endocrine disrupting properties:

No endocrine disruptor substances present in concentration \geq 0.1%

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

Adopt good working practices, so that the product is not released into the environment.

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The product is classified: Aquatic Chronic 3 - H412

Dipotassium exafluorotitanate - CAS: 16919-27-0

a) Aquatic acute toxicity:

Endpoint: LC50 - Species: Fish 172 mg/l - Duration h: 96h (OECD 203, Danio rerio, ECHA dossier).

Endpoint: EC50 - Species: Daphnia 48.2 mg/l - Duration h: 48h (OECD 203, Daphnia magna, ECHA dossier).

Endpoint: IC50 - Species: Algae 10.81 mg/l - Duration h: 72h (OECD 201, Pseudokirchneriella subcapitata, ECHA dossier).

Endpoint: NOEC - Species: Algae 1.31 mg/l (OECD 201, Pseudokirchneriella subcapitata, ECHA dossier).

zinc oxide - CAS: 1314-13-2

a) Aquatic acute toxicity:

Endpoint: IC50 - Species: Algae 0.17 mg/l - Duration h: 72h (Pseudokirchnerella subcapitata, MSDS supplier).

Endpoint: LC50 - Species: Fish 320 mg/l - Duration h: 96h (Lepomis macrochirus, MSDS supplier).

b) Aquatic chronic toxicity:

Endpoint: NOEC - Species: Algae 0.017 mg/l (Pseudokirchnerella subcapitata, MSDS supplier).

ethyl acetate - CAS: 141-78-6

a) Aquatic acute toxicity:

Endpoint: LC50 - Species: Fish 230 mg/l - Duration h: 96h (Salmo gairdneri, MSDS supplier).

Endpoint: EC50 - Species: Daphnia 3090 mg/l - Duration h: 24h (Daphnia magna, DIN 38412, MSDS supplier).

Endpoint: EC50 - Species: Algae 3300 mg/l - Duration h: 48h (Scenedesmus subspicatus, MSDS supplier).

Endpoint: NOEC - Species: Algae > 100 mg/l - Duration h: 72h (Desmodesmus subspicatus, MSDS supplier).

b) Aquatic chronic toxicity:

Endpoint: NOEC - Species: Daphnia 2.4 mg/l - Duration h: 21d (Daphnia magna, MSDS supplier).

acetic acid - CAS: 64-19-7

a) Aquatic acute toxicity:

Endpoint: EC50 - Species: Daphnia > 301 mg/l - Duration h: 48h (OECD 202, Daphnia magna, MSDS supplier).

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Endpoint: LC50 - Species: Fish > 301 mg/l - Duration h: 96h (similar to OECD 203, Oncorhynchus mykiss, MSDS supplier).

Endpoint: LC50 - Species: Algae > 301 - Duration h: 72h (MSDS supplier).

formic acid ... % - CAS: 64-18-6

a) Aquatic acute toxicity:

Endpoint: LC50 - Species: Fish 130 mg/l (ECHA dossier).

Endpoint: LC50 - Species: Daphnia 365 mg/l (ECHA dossier).

Endpoint: EC50 - Species: Algae 1000 mg/l (ECHA dossier).

12.2. Persistence and degradability

Cristobalite - CAS: 14464-46-1

Biodegradability: Non-readily biodegradable

Dipotassium exafluorotitanate - CAS: 16919-27-0

Biodegradability: Non-readily biodegradable

zinc oxide - CAS: 1314-13-2

Biodegradability: Non-readily biodegradable

Paraffin oil - CAS: 8042-47-5

Biodegradability: Persistent and Biodegradable

ethyl acetate - CAS: 141-78-6

Biodegradability: Readily biodegradable

formic acid ... % - CAS: 64-18-6

Biodegradability: Readily biodegradable

12.3. Bioaccumulative potential

Cristobalite - CAS: 14464-46-1

Not bioaccumulative

12.4. Mobility in soil

Not available

12.5. Results of PBT and vPvB assessment

vPvB Substances: None - PBT Substances: None

12.6. Endocrine disrupting properties

No endocrine disruptor substances present in concentration \geq 0.1%

12.7. Other adverse effects

None

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

Recover, if possible. Send to authorised disposal plants or for incineration under controlled conditions. In so doing, comply with the local and national regulations currently in force.

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

Not classified as dangerous in the meaning of transport regulations.

14.2. UN proper shipping name

Not available

14.3. Transport hazard class(es)

Not available

14.4. Packing group

Not available

14.5. Environmental hazards

ADR-Environmental Pollutant: No

IMDG-Marine pollutant: No

14.6. Special precautions for user

Not available

14.7. Maritime transport in bulk according to IMO instruments

Not Applicable

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Dir. 98/24/EC (Risks related to chemical agents at work)
Dir. 2000/39/EC (Occupational exposure limit values)
Regulation (EC) n. 1907/2006 (REACH)
Regulation (EC) n. 1272/2008 (CLP)
Regulation (EC) n. 790/2009 (ATP 1 CLP) and (EU) n. 758/2013
Regulation (EU) n. 2020/878
Regulation (EU) n. 286/2011 (ATP 2 CLP)
Regulation (EU) n. 618/2012 (ATP 3 CLP)
Regulation (EU) n. 487/2013 (ATP 4 CLP)
Regulation (EU) n. 944/2013 (ATP 5 CLP)
Regulation (EU) n. 605/2014 (ATP 6 CLP)
Regulation (EU) n. 2015/1221 (ATP 7 CLP)
Regulation (EU) n. 2016/918 (ATP 8 CLP)
Regulation (EU) n. 2016/1179 (ATP 9 CLP)
Regulation (EU) n. 2017/776 (ATP 10 CLP)
Regulation (EU) n. 2018/669 (ATP 11 CLP)
Regulation (EU) n. 2018/1480 (ATP 13 CLP)
Regulation (EU) n. 2019/521 (ATP 12 CLP)
Regulation (EU) n. 2020/217 (ATP 14 CLP)
Regulation (EU) n. 2020/1182 (ATP 15 CLP)
Regulation (EU) n. 2021/643 (ATP 16 CLP)

Restrictions related to the product or the substances contained according to Annex XVII Regulation (EC) 1907/2006 (REACH) and subsequent modifications:

Restrictions related to the product:

Restriction 40

Restrictions related to the substances contained:

Restriction 75

Provisions related to directive EU 2012/18 (Seveso III):

Seveso III category according to Annex 1, part 1

None

WGK Classification (Water hazard class - Verwaltungsvorschrift wassergefährdende Stoffe)

Lagerklasse according to TRGS 510:

LGK 11: Combustible solids

Substances subject to exportation reporting pursuant to (EC) Reg. 649/2012:

None.

California Proposition 65

Substance(s) listed under California Proposition 65:

Cristobalite - Listed as carcinogen.

15.2. Chemical safety assessment

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

Substances for which a Chemical Safety Assessment has been carried out:

Dipotassium hexafluorotitanate

zinc oxide

acetic acid

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SECTION 16: Other information

Full text of phrases referred to in Section 3:

EUH066 Repeated exposure may cause skin dryness or cracking.

H314 Causes severe skin burns and eye damage.

H315 Causes skin irritation.

H318 Causes serious eye damage.

H319 Causes serious eye irritation.

H370 Causes damage to organs.

H371 May cause damage to organs.

EUH071 Corrosive to the respiratory tract.

Hazard class and hazard category	Code	Description
Flam. Liq. 2	2.6/2	Flammable liquid, Category 2
Flam. Liq. 3	2.6/3	Flammable liquid, Category 3
Acute Tox. 3	3.1/3/Inhal	Acute toxicity (inhalation), Category 3
Acute Tox. 4	3.1/4/Oral	Acute toxicity (oral), Category 4
Asp. Tox. 1	3.10/1	Aspiration hazard, Category 1
Skin Corr. 1A	3.2/1A	Skin corrosion, Category 1A
Skin Corr. 1B	3.2/1B	Skin corrosion, Category 1B
Skin Corr. 1C	3.2/1C	Skin corrosion, Category 1C
Skin Irrit. 2	3.2/2	Skin irritation, Category 2
Eye Dam. 1	3.3/1	Serious eye damage, Category 1
Eye Irrit. 2	3.3/2	Eye irritation, Category 2
STOT SE 1	3.8/1	Specific target organ toxicity - single exposure, Category 1
STOT SE 2	3.8/2	Specific target organ toxicity - single exposure, Category 2
STOT SE 3	3.8/3	Specific target organ toxicity - single exposure, Category 3
STOT RE 1	3.9/1	Specific target organ toxicity - repeated exposure, Category 1
STOT RE 2	3.9/2	Specific target organ toxicity - repeated exposure, Category 2
Aquatic Acute 1	4.1/A1	Acute aquatic hazard, category 1
Aquatic Chronic 1	4.1/C1	Chronic (long term) aquatic hazard, category 1
Aquatic Chronic 3	4.1/C3	Chronic (long term) aquatic hazard, category 3

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

Classification according to Regulation (EC) Nr. 1272/2008	Classification procedure
STOT RE 2, H373	Calculation method
Aquatic Chronic 3, H412	Calculation method

This document was prepared by a competent person who has received appropriate training.

Main bibliographic sources:

ECHA – European Chemical Agency

GESTIS - Information system on hazardous substances of the German Social Accident Insurance

IARC – International Agency for Research on Cancer

IPCS INCHEM – International Programme on Chemical Safety

ISS – Istituto Superiore di Sanità

**Safety Data Sheet
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PubChem - open chemistry database at the National Institutes of Health (NIH)

A safety data sheet is not required for this product under article 31 of Regulation 1907/2006/EC. This safety data sheet has been created on a voluntary basis.

The information contained herein is based on our state of knowledge at the above-specified date. It refers solely to the product indicated and constitutes no guarantee of particular quality.

It is the duty of the user to ensure that this information is appropriate and complete with respect to the specific use intended.

This MSDS cancels and replaces any preceding release.

ADR:	European Agreement concerning the International Carriage of Dangerous Goods by Road.
ATE:	Acute Toxicity Estimate
ATEmix:	Acute toxicity Estimate (Mixtures)
CAS:	Chemical Abstracts Service (division of the American Chemical Society).
CLP:	Classification, Labeling, Packaging.
DNEL:	Derived No Effect Level.
EINECS:	European Inventory of Existing Commercial Chemical Substances.
GefStoffVO:	Ordinance on Hazardous Substances, Germany.
GHS:	Globally Harmonized System of Classification and Labeling of Chemicals.
IATA:	International Air Transport Association.
IATA-DGR:	Dangerous Goods Regulation by the "International Air Transport Association" (IATA).
ICAO:	International Civil Aviation Organization.
ICAO-TI:	Technical Instructions by the "International Civil Aviation Organization" (ICAO).
IMDG:	International Maritime Code for Dangerous Goods.
INCI:	International Nomenclature of Cosmetic Ingredients.
KSt:	Explosion coefficient.
LC50:	Lethal concentration, for 50 percent of test population.
LD50:	Lethal dose, for 50 percent of test population.
PNEC:	Predicted No Effect Concentration.
RID:	Regulation Concerning the International Transport of Dangerous Goods by Rail.
STEL:	Short Term Exposure limit.
STOT:	Specific Target Organ Toxicity.
TLV:	Threshold Limiting Value.
TWA:	Time-weighted average
WGK:	German Water Hazard Class.