

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

1.1. Product identifier

Product form : Mixture
Trade name : OrthoAlginate, extra fast (1:40min)
Product code : 9003879

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

1.2.1. Relevant identified uses

Main use category : Industrial use
Use of the substance/mixture : Alginate for dental impression.

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

Manufacturer/Supplier

CB Healthcare Consulting GmbH
Tarpen 40
22419 Hamburg
Germany
T +49 (0) 40-65668-180

Email competent person

sds@kft.de

Importer

CB Healthcare Consulting Ltd
Medcare South
Bailey Drive, Gillingham Business Park, Gillingham,
Kent, United Kingdom, ME8 0PZ
Tel No.: 01634 878750

1.4. Emergency telephone number

Emergency number : +49 (0)6132 84463 - GBK GmbH (24h 7d/w - 365d/a)

Country/Area	Organisation/Company	Address	Emergency number	Comment
United Kingdom	National Health Service (NHS) England / Scotland / Wales / Northern Ireland	-	England / Scotland: 111 Wales: 111 or 0845 46 47 Northern Ireland: call your local General Practitioner. For life-threatening emergencies: call 999 for an ambulance.	24 h medical helpline for general public

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to GB CLP (SI 2019:720 as amended)

Specific target organ toxicity – Repeated exposure, Category 2 H373
Full text of H- and EUH-statements: see section 16

Adverse physicochemical, human health and environmental effects

May cause damage to organs (lungs) through prolonged or repeated exposure (inhalation).

2.2. Label elements

Labelling according to GB CLP (SI 2019:720 as amended)

Hazard pictograms (GB CLP)



GHS08

Signal word (GB CLP)

: Warning

OrthoAlginate, extra fast (1:40min)

Safety Data Sheet

According to REACH Regulation (EC) No 1907/2006, as retained and amended in UK law.

Contains	: cristobalite
Hazard statements (GB CLP)	: H373 - May cause damage to organs (lungs) through prolonged or repeated exposure (if inhaled).
Precautionary statements (GB CLP)	: P260 - Do not breathe dust. P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P314 - Get medical advice or attention, if you feel unwell.
Extra phrases (GB CLP)	: The Regulation GB CLP (SI 2019:720 as amended) 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 GB CLP labeling requirements.

2.3. Other hazards

Component	
Substance(s) not meeting the PBT criteria of UK REACH regulation, in accordance with Annex XIII	cristobalite (14464-46-1), Dipotassium hexafluorotitanate (16919-27-0), White mineral oil (8042-47-5)
Substance(s) not meeting the vPvB criteria of UK REACH regulation, in accordance with Annex XIII	cristobalite (14464-46-1), Dipotassium hexafluorotitanate (16919-27-0), White mineral oil (8042-47-5)

The mixture does not contain substance(s) included in the list established in accordance with Article 59(1) of UK REACH for having endocrine disrupting properties, or substance(s) are not identified as having endocrine disrupting properties in accordance with the criteria set out in GB BPR and GB PPP at a concentration equal to or greater than 0,1 %

Component	
Substance(s) not considered as endocrine disrupting. They are not included in the list established in accordance with Article 59(1) of UK REACH for having endocrine disrupting properties, nor identified as having endocrine disrupting properties in accordance with the criteria set out in GB BPR and GB PPP	cristobalite(14464-46-1), Dipotassium hexafluorotitanate(16919-27-0), White mineral oil(8042-47-5)

Other information : 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.

SECTION 3: Composition/information on ingredients

3.1. Substances

Not applicable

3.2. Mixtures

Name	Product identifier	%	Classification according to GB CLP (SI 2019:720 as amended)
cristobalite	CAS-No.: 14464-46-1 EC-No.: 238-455-4	5 – 8	STOT RE 1, H372
Dipotassium hexafluorotitanate (Nanoform)	CAS-No.: 16919-27-0 EC-No.: 240-969-9	1 – 3	Acute Tox. 4 (Oral), H302 (ATE=324 mg/kg bodyweight) Eye Dam. 1, H318
White mineral oil	CAS-No.: 8042-47-5 EC-No.: 232-455-8	0.5 – 2.5	Asp. Tox. 1, H304

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

Components - Nanoform

Dipotassium hexafluorotitanate (16919-27-0)	
Additional information	No additional information available

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According to REACH Regulation (EC) No 1907/2006, as retained and amended in UK law.

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures general	: In all cases of doubt, or when symptoms persist, seek medical attention.
First-aid measures after inhalation	: Remove person to fresh air and keep comfortable for breathing.
First-aid measures after skin contact	: After contact with skin, take off immediately all contaminated clothing, and wash immediately with plenty of water.
First-aid measures after eye contact	: In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
First-aid measures after ingestion	: Do not induce vomiting. Call a poison center or a doctor if you feel unwell.

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

No additional information available

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

Treat symptomatically.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media	: Use extinguishing media appropriate for surrounding fire. Water spray. Carbon dioxide. Dry powder. Foam.
Unsuitable extinguishing media	: Strong water jet.

5.2. Special hazards arising from the substance or mixture

Hazardous decomposition products in case of fire	: Toxic fumes may be released. Carbon dioxide. Carbon monoxide.
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5.3. Advice for firefighters

Protection during firefighting	: Do not attempt to take action without suitable protective equipment. Self-contained breathing apparatus. Complete protective clothing.
Other information	: Do not allow run-off from fire fighting to enter drains or water courses. Disposal must be done according to official regulations.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

Emergency procedures	: Ventilate spillage area. Do not breathe dust.
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6.1.2. For emergency responders

Protective equipment	: Do not attempt to take action without suitable protective equipment. For further information refer to section 8: "Exposure controls/personal protection".
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6.2. Environmental precautions

Avoid sub-soil penetration. Prevent entry to sewers and public waters.

6.3. Methods and material for containment and cleaning up

Other information	: Disposal must be done according to official regulations.
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6.4. Reference to other sections

Information for safe handling. See section 7. Concerning personal protective equipment to use, see section 8. For further information refer to section 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling	: Ensure good ventilation of the work station. Wear personal protective equipment. Do not breathe dust.
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According to REACH Regulation (EC) No 1907/2006, as retained and amended in UK law.

Hygiene measures : Do not eat, drink or smoke when using this product. Always wash hands after handling the product.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Store in a well-ventilated place. Keep cool.

Information about storage in one common storage facility : Keep away from food, drink and animal feeding stuffs.

7.3. Specific end use(s)

No additional information available

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

8.1.1 National occupational exposure and biological limit values

No additional information available

8.1.2. Recommended monitoring procedures

No additional information available

8.1.3. Air contaminants formed

No additional information available

8.1.4. DNEL and PNEC

Dipotassium hexafluorotitanate (16919-27-0)	
DNEL/DMEL (Workers)	
Acute - systemic effects, inhalation	5.2 mg/m ³
Acute - local effects, dermal	75 mg/kg bodyweight/day
Acute - local effects, inhalation	5.2
Long-term - systemic effects, dermal	75 mg/kg bodyweight/day
Long-term - systemic effects, inhalation	5.2 mg/m ³
DNEL/DMEL (General population)	
Acute - local effects, inhalation	37.5 mg/m ³
Long-term - systemic effects, inhalation	37.5 mg/m ³
PNEC (Water)	
PNEC aqua (freshwater)	0.02 mg/l
PNEC aqua (marine water)	0.002 mg/l
PNEC aqua (intermittent, freshwater)	0.1 mg/l
PNEC (Sediment)	
PNEC sediment (freshwater)	24.45 mg/kg dwt
PNEC sediment (marine water)	4.89 mg/kg dwt
PNEC (Soil)	
PNEC soil	19.1 mg/kg dwt
PNEC (STP)	
PNEC sewage treatment plant	1.5 mg/l
White mineral oil (8042-47-5)	
DNEL/DMEL (Workers)	
Long-term - systemic effects, dermal	217.05 mg/kg bodyweight/day

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Long-term - systemic effects, inhalation	164.56 mg/m ³
DNEL/DMEL (General population)	
Long-term - systemic effects, oral	25 mg/kg bodyweight/day
Long-term - systemic effects, inhalation	34.78 mg/m ³
Long-term - systemic effects, dermal	93.02 mg/kg bodyweight/day

8.1.5. Control banding

No additional information available

8.2. Exposure controls

8.2.1. Appropriate engineering controls

Appropriate engineering controls:

Ensure good ventilation of the work station.

8.2.2. Personal protection equipment

8.2.2.1. Eye and face protection

Eye protection:

Use eye protection according to EN 166, designed to protect against liquid splashes. ISO 16321-1

8.2.2.2. Skin protection

Skin and body protection:

Wear suitable protective clothing. EN 14605. EN ISO 13688

Hand protection:

In case of repeated or prolonged contact wear gloves. Nitrile rubber. ISO 374-1. Choosing the proper glove is a decision that depends not only on the type of material, but also on other quality features, which differ for each manufacturer. Please follow the instructions related to the permeability and the penetration time provided by the manufacturer. Gloves must be replaced after each use and whenever signs of wear or perforation appear

8.2.2.3. Respiratory protection

Respiratory protection:

In case of insufficient ventilation, wear suitable respiratory equipment. Dust formation: dust mask. A-P2. EN 143.

8.2.2.4. Thermal hazards

No additional information available

8.2.3. Environmental exposure controls

Environmental exposure controls:

Avoid release to the environment.

Other information:

Do not eat, drink or smoke when using this product. Avoid contact with skin and eyes. Always wash hands after handling the product.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Solid
Appearance	: Dust.
Colour	: light blue.
Odour	: mint.
Odour threshold	: Not available
pH	: Not available
pH solution	: Not available
Melting point	: Not available
Freezing point	: Not applicable
Boiling point	: Not available
Flash point	: Not applicable
Relative evaporation rate (butylacetate=1)	: Not applicable
Explosive limits	: Not applicable

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According to REACH Regulation (EC) No 1907/2006, as retained and amended in UK law.

Vapour pressure	: Not applicable
Vapour pressure at 50°C	: Not available
Relative vapour density at 20°C	: Not applicable
Relative density	: Not available
Density	: 0.2 – 0.5 g/cm ³
Solubility	: partly soluble.
Partition coefficient n-octanol/water (Log Kow)	: Not available
Auto-ignition temperature	: Not applicable
Decomposition temperature	: Not available
Viscosity, kinematic	: Not applicable
Explosive properties	: Product is not explosive
Oxidising properties	: Non oxidizing.

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

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

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use.

10.4. Conditions to avoid

No additional information available

10.5. Incompatible materials

No additional information available

10.6. Hazardous decomposition products

Under normal conditions of storage and use, hazardous decomposition products should not be produced.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity (oral)	: Not classified (Based on available data, the classification criteria are not met)
Acute toxicity (dermal)	: Not classified (Based on available data, the classification criteria are not met)
Acute toxicity (inhalation)	: Not classified (Based on available data, the classification criteria are not met)
Skin corrosion/irritation	: Not classified (Based on available data, the classification criteria are not met)
Serious eye damage/irritation	: Not classified (Based on available data, the classification criteria are not met).
Additional information	: Bridging principle "Substantially similar mixtures" (OECD 437 method) B.47 GLP
Respiratory or skin sensitisation	: Not classified (Based on available data, the classification criteria are not met)
Germ cell mutagenicity	: Not classified (Based on available data, the classification criteria are not met)
Carcinogenicity	: Not classified (Based on available data, the classification criteria are not met)
Reproductive toxicity	: Not classified (Based on available data, the classification criteria are not met)
STOT-single exposure	: Not classified (Based on available data, the classification criteria are not met)
STOT-repeated exposure	: May cause damage to organs (lungs) through prolonged or repeated exposure (if inhaled).

cristobalite (14464-46-1)

STOT-repeated exposure	Causes damage to organs through prolonged or repeated exposure.
Aspiration hazard	: Not classified (Based on available data, the classification criteria are not met)

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According to REACH Regulation (EC) No 1907/2006, as retained and amended in UK law.

Other information

No additional information available

SECTION 12: Ecological information

12.1. Toxicity

Hazardous to the aquatic environment, short-term (acute) : Not classified (Based on available data, the classification criteria are not met)

Hazardous to the aquatic environment, long-term (chronic) : Not classified (Based on available data, the classification criteria are not met)

12.2. Persistence and degradability

OrthoAlginate, extra fast (1:40min)	
Persistence and degradability	No additional information available.
cristobalite (14464-46-1)	
Persistence and degradability	Not applicable.
Dipotassium hexafluorotitanate (16919-27-0)	
Persistence and degradability	Not applicable for inorganic substances.
White mineral oil (8042-47-5)	
Persistence and degradability	Inherently biodegradable.
Biodegradation	31 % (28 d; (OECD 301F method))

12.3. Bioaccumulative potential

OrthoAlginate, extra fast (1:40min)	
Bioaccumulative potential	No additional information available.
cristobalite (14464-46-1)	
Bioaccumulative potential	Not applicable.
White mineral oil (8042-47-5)	
Partition coefficient n-octanol/water (Log Kow)	> 6

12.4. Mobility in soil

OrthoAlginate, extra fast (1:40min)	
Mobility in soil	No additional information available
White mineral oil (8042-47-5)	
Ecology - soil	No additional information available.

12.5. Results of PBT and vPvB assessment

Component	
cristobalite (14464-46-1)	This product does not contain substances at $\geq 0.1\%$ that meet the PBT criteria of UK REACH regulation, annex XIII This product does not contain substances at $\geq 0.1\%$ that meet the vPvB criteria of UK REACH regulation, annex XIII
Dipotassium hexafluorotitanate (16919-27-0)	This product does not contain substances at $\geq 0.1\%$ that meet the PBT criteria of UK REACH regulation, annex XIII This product does not contain substances at $\geq 0.1\%$ that meet the vPvB criteria of UK REACH regulation, annex XIII

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Safety Data Sheet

According to REACH Regulation (EC) No 1907/2006, as retained and amended in UK law.

White mineral oil (8042-47-5)	This product does not contain substances at $\geq 0.1\%$ that meet the PBT criteria of UK REACH regulation, annex XIII This product does not contain substances at $\geq 0.1\%$ that meet the vPvB criteria of UK REACH regulation, annex XIII
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12.6. Other adverse effects

No additional information available

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste treatment methods	: Disposal must be done according to official regulations. European waste catalogue. Do not discharge into drains or the environment. Do not dispose of with domestic waste.
Product/Packaging disposal recommendations	: Recycle or dispose of in compliance with current legislation.
HP Code	: HP5 - "Specific Target Organ Toxicity (STOT)/Aspiration Toxicity:" waste which can cause specific target organ toxicity either from a single or repeated exposure, or which cause acute toxic effects following aspiration.

SECTION 14: Transport information

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

ADR	IMDG	IATA	ADN	RID
14.1. UN number				
Not regulated for transport				
14.2. UN proper shipping name				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
Transport document description				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
14.3. Transport hazard class(es)				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
14.4. Packing group				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
14.5. Environmental hazards				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
No supplementary information available				

14.6. Special precautions for user

Overland transport

Not regulated

Transport by sea

Not regulated

Air transport

Not regulated

Inland waterway transport

Not regulated

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According to REACH Regulation (EC) No 1907/2006, as retained and amended in UK law.

Rail transport

Not regulated

14.7. Transport in bulk according to Annex II of Marpol and the IBC Code

Not applicable

SECTION 15: Regulatory information

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

15.1.1. EU-Regulations

UK REACH Annex XVII (Restriction List)

UK restriction list (REACH Annex XVII)		
Reference code	Applicable on	Entry title or description
3(b)	White mineral oil	Substances or mixtures fulfilling the criteria for any of the following hazard classes or categories set out in Annex I to Regulation (EC) No 1272/2008: Hazard classes 3.1 to 3.6, 3.7 adverse effects on sexual function and fertility or on development, 3.8 effects other than narcotic effects, 3.9 and 3.10
40.	OrthoAlginate, extra fast (1:40min)	Substances classified as flammable gases category 1 or 2, flammable liquids categories 1, 2 or 3, flammable solids category 1 or 2, substances and mixtures which, in contact with water, emit flammable gases, category 1, 2 or 3, pyrophoric liquids category 1 or pyrophoric solids category 1, regardless of whether they appear in the GB classification and labelling list or not.

UK REACH Annex XIV (Authorisation List)

This product contains no substance(s) listed on UK REACH Annex XIV (Authorisation List) equal to or above the 0.1% level of disclosure

UK REACH Candidate List (SVHC)

This product contains no substance(s) listed on the UK REACH Candidate List (SVHC) above the 0.1% level of disclosure

GB PIC regulation (Prior Informed Consent)

This product contains no substance(s) listed on the GB PIC List equal to or above the level of SDS disclosure

POP Regulation (Persistent Organic Pollutants)

This product contains no substance(s) listed on the GB POP List equal to or above the level of SDS disclosure

Ozone Regulation (S.I. No. 168 of 2015)

This product contains no substance(s) listed on the GB Ozone Depletion List equal to or above the level of SDS disclosure

Control of Poisons and Explosives Precursors Act

This product contains no substance(s) listed as a reportable poison on the Control of Poisons and Explosives Precursors Regulations equal to or above the level of SDS disclosure

This product contains no substance(s) listed as a regulated poison on the Control of Poisons and Explosives Precursors Regulations equal to or above the level of SDS disclosure

This product contains no substance(s) listed as a reportable explosive precursor on the Control of Poisons and Explosives Precursors Regulations equal to or above the level of SDS disclosure

This substance is not listed as a regulated poison on the Control of Poisons and Explosives Precursors Regulations

Drug Precursors Regulation (EC 273/2004)

This product contains no substance(s) listed on the GB Drug Precursors List equal to or above the level of SDS disclosure

15.1.2. Other Information

National regulations : Take note of Directive 94/33/EC on the protection of young people at work.

15.2. Chemical safety assessment

No additional information available

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Safety Data Sheet

According to REACH Regulation (EC) No 1907/2006, as retained and amended in UK law.

SECTION 16: Other information

Abbreviations and acronyms:	
ADN	European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road
ATE	Acute Toxicity Estimate
BCF	Bioconcentration factor
CAS-No.	Chemical Abstract Service number
CLP	Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008
DMEL	Derived Minimal Effect level
DNEL	Derived-No Effect Level
EC50	Median effective concentration
EC-No.	European Community number
IARC	International Agency for Research on Cancer
IATA	International Air Transport Association
IMDG	International Maritime Dangerous Goods
LC50	Median lethal concentration
LD50	Median lethal dose
LOAEL	Lowest Observed Adverse Effect Level
NOAEC	No-Observed Adverse Effect Concentration
NOAEL	No-Observed Adverse Effect Level
NOEC	No-Observed Effect Concentration
OECD	Organisation for Economic Co-operation and Development
OEL	Occupational Exposure Limit
PBT	Persistent Bioaccumulative Toxic
PNEC	Predicted No-Effect Concentration
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) No 1907/2006
RID	Regulations concerning the International Carriage of Dangerous Goods by Rail
SDS	Safety Data Sheet
STP	Sewage treatment plant
TLM	Median Tolerance Limit
vPvB	Very Persistent and Very Bioaccumulative

Data sources : MSDSs of the suppliers.
Department issuing data specification sheet: : KFT Chemieservice GmbH
Im Leuschnerpark 3
D-64347 Griesheim

Phone: +49 69 305 34 700
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SDS Service: +49 69 305 34 740

Contact person : Saskia Vetter

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Safety Data Sheet

According to REACH Regulation (EC) No 1907/2006, as retained and amended in UK law.

Full text of H- and EUH-statements:	
Acute Tox. 4 (Oral)	Acute toxicity (oral), Category 4
Asp. Tox. 1	Aspiration hazard, Category 1
Eye Dam. 1	Serious eye damage/eye irritation, Category 1
STOT RE 1	Specific target organ toxicity – Repeated exposure, Category 1
STOT RE 2	Specific target organ toxicity – Repeated exposure, Category 2
H302	Harmful if swallowed.
H304	May be fatal if swallowed and enters airways.
H318	Causes serious eye damage.
H372	Causes damage to organs through prolonged or repeated exposure.
H373	May cause damage to organs (lungs) through prolonged or repeated exposure (if inhaled).

Classification and procedure used to derive the classification for mixtures according to Regulation (EC) 1272/2008 [CLP]:		
STOT RE 2	H373	Calculation method

KFT SDS UK 06 - Version 24.2

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.