



Safety Data Sheet AQUASIL PUTTY SOFT - BASE Revision nr. 3 Dated 04/08/2025

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

1.1. Product identifier

Mixture identification:

Product Name: AQUASIL PUTTY SOFT - BASE

Code: 60578320, 60578321

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

Recommended use: For professional use only. Addition silicone 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

Responsable: msds@zhermack.com

1.4. Emergency telephone number

+39 0425 597611 (office hours)

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Regulation (EC) n. 1272/2008 (CLP)

The product is not classified as hazardous according to Regulation EC 1272/2008 (CLP).

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.

The product is not classified as hazardous according to Regulation EC 1272/2008 (CLP).

Special Provisions:

EUH210 Safety data sheet available on request.

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

None.

2.3. Other hazards

No PBT, vPvB or endocrine disruptor substances present in concentration >=0.1%.

Other Hazards: No other hazards

There is no exposure to breathable free crystalline silica during normal use of this product. For more information see section 11.

SECTION 3: Composition/information on ingredients

3.1. Substances

N.A.

3.2. Mixtures

Mixture identification: AQUASIL PUTTY SOFT - BASE

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

Qty	Name	Ident. Numb.	Classification	Registration Number	Material Properties
15-20 %	Cristobalite	CAS:14464-46-1 EC:238-455-4	STOT RE 1, H372		
< 0.025%	octamethylcyclotetrasiloxane; [D4] CAS:556-67-2 EC:209-136-7 Index:014-018-00-:	Flam. Liq. 3, H226; Repr. 2, H361f; Aquatic Chronic 1, H410, 1 M-Chronic:10		PBT, vPvB

SECTION 4: First aid measures

4.1. Description of first aid measures

In case of skin contact:

Wash with plenty of water and soap.

In case of eyes contact:

Wash immediately with water.

In case of Ingestion:

Do not induce vomiting, get medical attention showing the SDS and label hazardous.

In case of Inhalation:

Remove casualty to fresh air and keep warm and at rest.

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

N.A.

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

N.A.

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.

Remove persons to safety.

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

Date 04/08/2025 Production Name AQUASIL PUTTY SOFT - BASE Page n. 2 of 9

6.3. Methods and material for containment and cleaning up

Suitable material for taking up: absorbing material, organic, sand 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, inhaltion of vapours and mists.

See also section 8 for recommended protective equipment.

Advice on general occupational hygiene:

Do not eat or drink while working.

7.2. Conditions for safe storage, including any incompatibilities

Incompatible materials:

None in particular.

Instructions as regards storage premises:

Adequately ventilated premises.

7.3. Specific end use(s)

None in particular

Industrial sector specific solutions:

None in particular

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Community Occupational Exposure Limits (OEL)

Cristobalite

CAS: 14464-46-1 ACGIH Long Term: 0.025 mg/m3

Notes: (R), A2 - Pulm fibrosis, lung cancer

Long Term: 0.025 mg/m3

Notes: (R), A2 - Pulm fibrosis, lung cancer

EU Long Term: 0.1 mg/m3

Notes: Respirable

TLV Long Term: 0.1 mg/m3

Notes: Respirable

 $octamethyl cyclotetrasiloxane; \ [D4] \\$

CAS: 556-67-2 TWA Long Term: 120 mg/m3 - 10 ppm

8.2. Exposure controls

Eye protection:

Not needed for normal use. Anyway, operate according good working practices.

Protection for skin:

No special precaution must be adopted for normal use.

Protection for hands:

Not needed for normal use.

Respiratory protection:

N.A.

Thermal Hazards:

N.A.

Environmental exposure controls:

N.A.

Hygienic and Technical measures

N.A.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state: Liquid

Colour: blue

Appearance: N.A.

Date 04/08/2025 Production Name AQUASIL PUTTY SOFT - BASE Page n. 3 of 9

Odour: characteristic

pH: N.A.

Kinematic viscosity: N.A.

Melting point/freezing point: N.A.

Boiling point or initial boiling point and

boiling range:

N.A.

Flash point: Not Relevant

Lower and upper explosion limit: N.A.

Relative vapour density: N.A.

Vapour pressure: N.A.

Density and/or relative density: 1.60 g/cm³

Solubility in water: N.A.

Solubility in oil: N.A.

Partition coefficient n-octanol/water (log

value):

N.A.

Auto-ignition temperature: Product is not selfigniting

Decomposition temperature: N.A.

Flammability: Non-flammable

Volatile Organic compounds - VOCs = N.A.

Particle characteristics:

Particle size: N.A.

9.2. Other information

Explosive properties: Not explosive

Miscibility: Not miscible

No other relevant information

SECTION 10: Stability and reactivity

10.1. Reactivity

Stable under normal conditions

10.2. Chemical stability

Data not available.

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

'For the purpose of the classification of health hazards (Part 3), route of exposure, information on mechanisms and metabolism studies are useful in determining the significance of an effect on humans. If such information raises doubts as to its relevance to humans, no matter how well-founded and high-quality the data are, a lower classification may be justified. When there is scientific evidence that the mechanism or mode of action is not relevant for humans, the substance or mixture shall not be classified' (Annex I, Section 1.1.1.5, Regulation EC 1272/2008). Monitoring of possible inhalation exposure conducted in-house according to industrial hygiene regulations for paste and fluid products revealed dust exposure levels below the quantification limit of the method, therefore exposure is not expected during the use indicated in section 1.2 for this specific product. However, the actual levels of dust present in the workplace must be obtained by monitoring as required by worker health and safety regulations.

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

a) acute toxicity Not classified

Based on available data, the classification criteria are not met

Based on available data, the classification criteria are not met

c) serious eye damage/irritation Not classified

Based on available data, the classification criteria are not met

d) respiratory or skin sensitisation Not classified

Based on available data, the classification criteria are not met

e) germ cell mutagenicity Not classified

Based on available data, the classification criteria are not met

f) carcinogenicity Not classified

Based on available data, the classification criteria are not met

g) reproductive toxicity Not classified

Based on available data, the classification criteria are not met

h) STOT-single exposure Not classified

Based on available data, the classification criteria are not met

i) STOT-repeated exposure Not classified

Based on available data, the classification criteria are not met

j) aspiration hazard Not classified

Based on available data, the classification criteria are not met

Toxicological information on main components of the mixture:

octamethylcyclotetrasiloxane; [D4]

CAS: 556-67-2 g) reproductive toxicity No Observed Adverse Effect Level 3.64 mg/l

11.2. Information on other hazards

Endocrine disrupting properties:

No endocrine disruptor substances present in concentration >= 0.1%

SECTION 12: Ecological information

12.1. Toxicity

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

Eco-Toxicological Information:

List of Eco-Toxicological properties of the product

Not classified for environmental hazards.

No data available for the product

List of Eco-Toxicological properties of the components

octamethylcyclotetrasiloxane; [D4]

CAS: 556-67-2 a) Aquatic acute toxicity: Algae > 0.0022 mg/L 96h

a) Aquatic acute toxicity: ErC10 Algae > 0.0022 mg/L 96h
 a) Aquatic acute toxicity: EC50 Fish > 10000 mg/L 3h
 a) Aquatic acute toxicity: EC50 Daphnia > 0.015 mg/L 48h
 b) Aquatic chronic toxicity: NOEC Fish > 0.0044 mg/L 93d

b) Aquatic chronic toxicity: NOEC Daphnia > 0.015 mg/L 21d

12.2. Persistence and degradability

Cristobalite

CAS: 14464-46-1 Non-readily biodegradable

octamethylcyclotetrasiloxane; [D4]

CAS: 556-67-2 Non-readily biodegradable Notes: MSDS supplier

12.3. Bioaccumulative potential

Cristobalite

CAS: 14464-46-1 Not bioaccumulative octamethylcyclotetrasiloxane; [D4]

CAS: 556-67-2 Not bioaccumulative Test: BCF - Bioconcentrantion factor; Value: 14900

Notes: (Log Pow, ECHA dossier).

Date 04/08/2025 Production Name AQUASIL PUTTY SOFT - BASE Page n. 5 of 9

12.4. Mobility in soil

N.A.

12.5. Results of PBT and vPvB assessment

List of Eco-Toxicological properties of the components

octamethylcyclotetrasiloxane; [D4]

CAS: 556-67-2 < 0.1% PBT - vPvB

12.6 Endocrine disrupting properties

No endocrine disruptor substances present in concentration >= 0.1%

12.7 Other adverse effects

N.A.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Recover if possible. In so doing, comply with the local and national regulations currently in force.

SECTION 14: Transport information

Not classified as dangerous in the meaning of transport regulations.

14.1. UN number or ID number

N.A.

14.2. UN proper shipping name

N.A.

14.3. Transport hazard class(es)

ADR-Class: NA IATA-Class: NA IMDG-Class: NA

14.4. Packing group

N.A.

14.5. Environmental hazards

N.A.

14.6. Special precautions for user

N.A

Road and Rail (ADR-RID):

N.A.

Air (IATA):

N.A.

Sea (IMDG):

N.A.

14.7. Maritime transport in bulk according to IMO instruments

N.A.

SECTION 15: Regulatory information

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

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. 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)

Date 04/08/2025 Production Name AQUASIL PUTTY SOFT - BASE Page n. 6 of 9

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)

Regulation (EU) n. 2021/849 (ATP 17 CLP)

Regulation (EU) n. 2022/692 (ATP 18 CLP)

Regulation (EU) n. 2023/707

Regulation (EU) n. 2023/1434 (ATP 19 CLP)

Regulation (EU) n. 2023/1435 (ATP 20 CLP)

Regulation (EU) n. 2024/197 (ATP 21 CLP)

Regulation (EU) n. 2020/878

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: 3

Restrictions related to the substances contained: 40, 70, 75

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

None

Regulation (EU) No 649/2012 (PIC regulation)

No substances listed

SVHC Substances:

Codo

Substances in candidate list (Art. 59 Reg. 1907/2006, REACH):

Component Ident. Numb. Quantity Material Properties

octamethylcyclotetrasiloxane; [D4] CAS: 556-67-2 < 0.1% SVHC - PBT - vPvB

EINECS: 209-136-7 Index: 014-018-00-1

15.2. Chemical safety assessment

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

SECTION 16: Other information

Code	Description		
H226	Flammable liquid and vapour.		
H361f	Suspected of damaging fertility.		
H372	Causes damage to organs (lungs) through prolonged or repeated exposure if inhaled.		
H410	Very toxic to aquatic life with long lasting effects.		
Code	Hazard class and hazard category	Description	
2.6/2			
2.6/3	Flam. Liq. 3	Flammable liquid, Category 3	
2.6/3 3.7/2	Flam. Liq. 3 Repr. 2	Flammable liquid, Category 3 Reproductive toxicity, Category 2	
•	•	, , , ,	

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

Main bibliographic sources:

ECDIN - Environmental Chemicals Data and Information Network - Joint Research Centre, Commission of the European Communities

SAX's DANGEROUS PROPERTIES OF INDUSTRIAL MATERIALS - Eight Edition - Van Nostrand Reinold

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.

Legend to abbreviations and acronyms used in the safety data sheet:

ACGIH: American Conference of Governmental Industrial Hygienists

ADR: European Agreement concerning the International Carriage of Dangerous Goods by Road.

AND: European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways

ATE: Acute Toxicity Estimate

ATEmix: Acute toxicity Estimate (Mixtures) BCF: Biological Concentration Factor

Date 04/08/2025 Production Name AQUASIL PUTTY SOFT - BASE Page n. 7 of 9

BEI: Biological Exposure Index

BOD: Biochemical Oxygen Demand

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

CAV: Poison Center

CE: European Community

CLP: Classification, Labeling, Packaging.

CMR: Carcinogenic, Mutagenic and Reprotoxic

COD: Chemical Oxygen Demand

COV: Volatile Organic Compound

CSA: Chemical Safety Assessment

CSR: Chemical Safety Report

DMEL: Derived Minimal Effect Level

DNEL: Derived No Effect Level.

DPD: Dangerous Preparations Directive

DSD: Dangerous Substances Directive EC50: Half Maximal Effective Concentration

ECHA: European Chemicals Agency

EINECS: European Inventory of Existing Commercial Chemical Substances.

ES: Exposure Scenario

GefStoffVO: Ordinance on Hazardous Substances, Germany.

GHS: Globally Harmonized System of Classification and Labeling of Chemicals.

IARC: International Agency for Research on Cancer

IATA: International Air Transport Association.

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

IC50: half maximal inhibitory concentration

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.

IRCCS: Scientific Institute for Research, Hospitalization and Health Care

KAFH: Keep Away From Heat KSt: Explosion coefficient.

LC50: Lethal concentration, for 50 percent of test population.

LD50: Lethal dose, for 50 percent of test population.

LDLo: Leathal Dose Low N.A.: Not Applicable N/A: Not Applicable

N/D: Not defined/ Not available

NA: Not available

NIOSH: National Institute for Occupational Safety and Health

NOAEL: No Observed Adverse Effect Level

OSHA: Occupational Safety and Health Administration

PBT: Persistent, Bioaccumulative and Toxic

PGK: Packaging Instruction

PNEC: Predicted No Effect Concentration.

PSG: Passengers

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.

TWATLV: Threshold Limit Value for the Time Weighted Average 8 hour day. (ACGIH Standard).

vPvB: Very Persistent, Very Bioaccumulative.

WGK: German Water Hazard Class.

Paragraphs modified from the previous revision:

- Safety Data Sheet
- SECTION 1: Identification of the substance/mixture and of the company/undertaking
- SECTION 2: Hazards identification
- SECTION 3: Composition/information on ingredients
- SECTION 4: First aid measures
- SECTION 5: Firefighting measures
- SECTION 6: Accidental release measures
- SECTION 7: Handling and storage

Date 04/08/2025 Production Name AQUASIL PUTTY SOFT - BASE Page n. 8 of 9

- SECTION 8: Exposure controls/personal protection
- SECTION 9: Physical and chemical properties
- SECTION 10: Stability and reactivity
- SECTION 11: Toxicological information
- SECTION 12: Ecological information
- SECTION 13: Disposal considerations
- SECTION 14: Transport information
- SECTION 15: Regulatory information
- SECTION 16: Other information

Date 04/08/2025 Production Name AQUASIL PUTTY SOFT - BASE Page n. 9 of 9





Safety Data Sheet AQUASIL PUTTY SOFT - CATALYST Revision nr. 3 Dated 04/08/2025

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

1.1. Product identifier

Mixture identification:

Product Name: AQUASIL PUTTY SOFT - CATALYST

Code: 60578320, 60578321

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

Recommended use: For professional use only. Addition silicone 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

Responsable: msds@zhermack.com

1.4. Emergency telephone number

+39 0425 597611 (office hours)

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Regulation (EC) n. 1272/2008 (CLP)

The product is not classified as hazardous according to Regulation EC 1272/2008 (CLP).

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.

The product is not classified as hazardous according to Regulation EC 1272/2008 (CLP).

Special Provisions:

EUH210 Safety data sheet available on request.

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

None.

2.3. Other hazards

No PBT, vPvB or endocrine disruptor substances present in concentration >=0.1%.

Other Hazards: No other hazards

There is no exposure to breathable free crystalline silica during normal use of this product. For more information see section 11.

SECTION 3: Composition/information on ingredients

3.1. Substances

N.A.

3.2. Mixtures

Mixture identification: AQUASIL PUTTY SOFT - CATALYST

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

Qty	Name	Ident. Numb.	Classification	Registration Number	Material Properties
15-20 %	Cristobalite	CAS:14464-46-1 EC:238-455-4	STOT RE 1, H372		
0.1-0.25 %	1,1,3,3-tetramethyl-1,3- divinyldisiloxane	CAS:2627-95-4 EC:220-099-6	Flam. Liq. 2, H225; Repr. 2, H361		
< 0.025%	octamethylcyclotetrasiloxane; [D4] CAS:556-67-2 EC:209-136-7 Index:014-018-00-1	Flam. Liq. 3, H226; Repr. 2, H361f; Aquatic Chronic 1, H410, M-Chronic:10		PBT, vPvB

SECTION 4: First aid measures

4.1. Description of first aid measures

In case of skin contact:

Wash with plenty of water and soap.

In case of eyes contact:

Wash immediately with water.

In case of Ingestion:

Do not induce vomiting, get medical attention showing the SDS and label hazardous.

In case of Inhalation:

Remove casualty to fresh air and keep warm and at rest.

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

N.A.

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

N.A.

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.

Remove persons to safety.

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

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

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, inhaltion of vapours and mists.

See also section 8 for recommended protective equipment.

Advice on general occupational hygiene:

Do not eat or drink while working.

7.2. Conditions for safe storage, including any incompatibilities

Incompatible materials:

None in particular.

Instructions as regards storage premises:

Adequately ventilated premises.

7.3. Specific end use(s)

None in particular

Industrial sector specific solutions:

None in particular

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Community Occupational Exposure Limits (OEL)

Cristobalite

CAS: 14464-46-1 ACGIH Long Term: 0.025 mg/m3

Notes: (R), A2 - Pulm fibrosis, lung cancer

Long Term: 0.025 mg/m3

Notes: (R), A2 - Pulm fibrosis, lung cancer

EU Long Term: 0.1 mg/m3

Notes: Respirable

TLV Long Term: 0.1 mg/m3

Notes: Respirable

 $octamethyl cyclotetrasiloxane; \ [D4] \\$

CAS: 556-67-2 TWA Long Term: 120 mg/m3 - 10 ppm

8.2. Exposure controls

Eye protection:

Not needed for normal use. Anyway, operate according good working practices.

Protection for skin:

No special precaution must be adopted for normal use.

Protection for hands:

Not needed for normal use.

Respiratory protection:

N.A.

Thermal Hazards:

N.A

Environmental exposure controls:

N.A.

Hygienic and Technical measures

N.A.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state: Liquid

Date 04/08/2025 Production Name AQUASIL PUTTY SOFT - CATALYST Page n. 3 of 9

Colour: white

Appearance: Viscous fluid

Odour: characteristic

pH: N.A.

Kinematic viscosity: N.A.

Melting point/freezing point: N.A.

Boiling point or initial boiling point and

boiling range:

Not Relevant

N.A. Flash point:

Lower and upper explosion limit: N.A.

Relative vapour density: N.A.

Vapour pressure: N.A.

Density and/or relative density: 1.60 g/cm3

Solubility in water: Insoluble

Solubility in oil: N.A.

Partition coefficient n-octanol/water (log

value):

N A

Auto-ignition temperature: Product is not selfigniting

Decomposition temperature: N.A.

Flammability: Flammable

Volatile Organic compounds - VOCs = N.A.

Particle characteristics:

Particle size: N.A.

9.2. Other information

Explosive properties: Not explosive

No other relevant information

SECTION 10: Stability and reactivity

10.1. Reactivity

Stable under normal conditions

10.2. Chemical stability

Data not available.

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

'For the purpose of the classification of health hazards (Part 3), route of exposure, information on mechanisms and metabolism studies are useful in determining the significance of an effect on humans. If such information raises doubts as to its relevance to humans, no matter how well-founded and high-quality the data are, a lower classification may be justified. When there is scientific evidence that the mechanism or mode of action is not relevant for humans, the substance or mixture shall not be classified' (Annex I, Section 1.1.1.5, Regulation EC 1272/2008). Monitoring of possible inhalation exposure conducted in-house according to industrial hygiene regulations for paste and fluid products revealed dust exposure levels below the quantification limit of the method, therefore exposure is not expected during the use indicated in section 1.2 for this specific product. However, the actual levels of dust present in the workplace must be obtained by monitoring as required by worker health and safety regulations.

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

Toxicological Information of the Preparation

a) acute toxicity Not classified

Based on available data, the classification criteria are not met

Based on available data, the classification criteria are not met

c) serious eye damage/irritation Not classified

Based on available data, the classification criteria are not met

d) respiratory or skin sensitisation Not classified

Based on available data, the classification criteria are not met

e) germ cell mutagenicity Not classified

Based on available data, the classification criteria are not met

f) carcinogenicity Not classified

Based on available data, the classification criteria are not met

g) reproductive toxicity Not classified

Based on available data, the classification criteria are not met

h) STOT-single exposure Not classified

Based on available data, the classification criteria are not met

i) STOT-repeated exposure Not classified

Based on available data, the classification criteria are not met

j) aspiration hazard Not classified

Based on available data, the classification criteria are not met

Toxicological information on main components of the mixture:

octamethylcyclotetrasiloxane; [D4]

CAS: 556-67-2 g) reproductive toxicity No Observed Adverse Effect Level 3.64 mg/l

11.2. Information on other hazards

Endocrine disrupting properties:

No endocrine disruptor substances present in concentration >= 0.1%

SECTION 12: Ecological information

12.1. Toxicity

Adopt good working practices, so that the product is not released into the environment. Eco-Toxicological Information:

List of Eco-Toxicological properties of the product

Not classified for environmental hazards.

No data available for the product

List of Eco-Toxicological properties of the components

octamethylcyclotetrasiloxane; [D4]

CAS: 556-67-2 a) Aquatic acute toxicity: Algae > 0.0022 mg/L 96h

a) Aquatic acute toxicity: ErC10 Algae > 0.0022 mg/L 96h
a) Aquatic acute toxicity: EC50 Fish > 10000 mg/L 3h
a) Aquatic acute toxicity: EC50 Daphnia > 0.015 mg/L 48h
b) Aquatic chronic toxicity: NOEC Fish > 0.0044 mg/L 93d
b) Aquatic chronic toxicity: NOEC Daphnia > 0.015 mg/L 21d

12.2. Persistence and degradability

Cristobalite

CAS: 14464-46-1 Non-readily biodegradable

 $octamethyl cyclotetrasiloxane; \ [D4] \\$

CAS: 556-67-2 Non-readily biodegradable Notes: MSDS supplier

12.3. Bioaccumulative potential

Cristobalite

CAS: 14464-46-1 Not bioaccumulative

octamethylcyclotetrasiloxane; [D4]

Date 04/08/2025 Production Name AQUASIL PUTTY SOFT - CATALYST Page n. 5 of 9

CAS: 556-67-2 Not bioaccumulative Test: BCF - Bioconcentrantion factor; Value: 14900

Notes: (Log Pow, ECHA dossier).

12.4. Mobility in soil

N.A.

12.5. Results of PBT and vPvB assessment

List of Eco-Toxicological properties of the components

octamethylcyclotetrasiloxane; [D4]

CAS: 556-67-2 < 0.1% PBT - vPvB

12.6 Endocrine disrupting properties

No endocrine disruptor substances present in concentration >= 0.1%

12.7 Other adverse effects

N.A.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Recover if possible. In so doing, comply with the local and national regulations currently in force.

SECTION 14: Transport information

Not classified as dangerous in the meaning of transport regulations.

14.1. UN number or ID number

N.A.

14.2. UN proper shipping name

N.A.

14.3. Transport hazard class(es)

ADR-Class: NA IATA-Class: NA IMDG-Class: NA

14.4. Packing group

N.A.

14.5. Environmental hazards

N.A.

14.6. Special precautions for user

N.A.

Road and Rail (ADR-RID):

N.A.

Air (IATA):

N.A.

Sea (IMDG):

N.A.

14.7. Maritime transport in bulk according to IMO instruments

N.A.

SECTION 15: Regulatory information

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

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. 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)

Date 04/08/2025 Production Name AQUASIL PUTTY SOFT - CATALYST Page n. 6 of 9

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)

Regulation (EU) n. 2021/849 (ATP 17 CLP)

Regulation (EU) n. 2022/692 (ATP 18 CLP)

Regulation (EU) n. 2023/707

Regulation (EU) n. 2023/1434 (ATP 19 CLP)

Regulation (EU) n. 2023/1435 (ATP 20 CLP)

Regulation (EU) n. 2024/197 (ATP 21 CLP)

Regulation (EU) n. 2020/878

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: 3

Restrictions related to the substances contained: 40, 70, 75

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

None

Regulation (EU) No 649/2012 (PIC regulation)

No substances listed

SVHC Substances:

Substances in candidate list (Art. 59 Reg. 1907/2006, REACH):

Component Ident. Numb. Quantity **Material Properties**

octamethylcyclotetrasiloxane; [D4] CAS: 556-67-2 < 0.1% SVHC - PBT - vPvB

> EINECS: 209-136-7 Index: 014-018-00-1

15.2. Chemical safety assessment

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

SECTION 16: Other information

Code	Description		
H225	Highly flammable liquid and vapour.		
H226	Flammable liquid and vapour.		
H361	Suspected of damaging fertility or the unborn child.		
H361f	Suspected of damaging fertility.		
H372	Causes damage to organs (lungs) through prolonged or repeated exposure if inhaled.		
H410	Very toxic to aquatic life with long lasting effects.		
Code	Hazard class and hazard category	Description	
2.6/2	Flam. Liq. 2	Flammable liquid, Category 2	
2.6/3	Flam. Liq. 3	Flammable liquid, Category 3	
3.7/2	Repr. 2	Reproductive toxicity, Category 2	
		,	
3.9/1	STOT RE 1	Specific target organ toxicity — repeated exposure, Category 1	

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

Main bibliographic sources:

ECDIN - Environmental Chemicals Data and Information Network - Joint Research Centre, Commission of the European Communities

SAX'S DANGEROUS PROPERTIES OF INDUSTRIAL MATERIALS - Eight Edition - Van Nostrand Reinold

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.

Legend to abbreviations and acronyms used in the safety data sheet:

Date 04/08/2025 AQUASIL PUTTY SOFT - CATALYST Production Name Page n. 7 of 9 ACGIH: American Conference of Governmental Industrial Hygienists

ADR: European Agreement concerning the International Carriage of Dangerous Goods by Road.

AND: European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways

ATE: Acute Toxicity Estimate

ATEmix: Acute toxicity Estimate (Mixtures)

BCF: Biological Concentration Factor

BEI: Biological Exposure Index

BOD: Biochemical Oxygen Demand

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

CAV: Poison Center

CE: European Community

CLP: Classification, Labeling, Packaging.

CMR: Carcinogenic, Mutagenic and Reprotoxic

COD: Chemical Oxygen Demand

COV: Volatile Organic Compound

CSA: Chemical Safety Assessment

CSR: Chemical Safety Report

DMEL: Derived Minimal Effect Level

DNEL: Derived No Effect Level.

DPD: Dangerous Preparations Directive

DSD: Dangerous Substances Directive

EC50: Half Maximal Effective Concentration

ECHA: European Chemicals Agency

EINECS: European Inventory of Existing Commercial Chemical Substances.

ES: Exposure Scenario

GefStoffVO: Ordinance on Hazardous Substances, Germany.

GHS: Globally Harmonized System of Classification and Labeling of Chemicals.

IARC: International Agency for Research on Cancer

IATA: International Air Transport Association.

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

IC50: half maximal inhibitory concentration

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.

IRCCS: Scientific Institute for Research, Hospitalization and Health Care

KAFH: Keep Away From Heat

KSt: Explosion coefficient.

LC50: Lethal concentration, for 50 percent of test population.

LD50: Lethal dose, for 50 percent of test population.

LDLo: Leathal Dose Low N.A.: Not Applicable N/A: Not Applicable

N/D: Not defined/ Not available

NA: Not available

NIOSH: National Institute for Occupational Safety and Health

NOAEL: No Observed Adverse Effect Level

OSHA: Occupational Safety and Health Administration

PBT: Persistent, Bioaccumulative and Toxic

PGK: Packaging Instruction

PNEC: Predicted No Effect Concentration.

PSG: Passengers

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.

TWATLV: Threshold Limit Value for the Time Weighted Average 8 hour day. (ACGIH Standard).

vPvB: Very Persistent, Very Bioaccumulative.

WGK: German Water Hazard Class.

Paragraphs modified from the previous revision:

- Safety Data Sheet
- SECTION 1: Identification of the substance/mixture and of the company/undertaking

Date 04/08/2025 Production Name AQUASIL PUTTY SOFT - CATALYST Page n. 8 of 9

- SECTION 2: Hazards identification
- SECTION 3: Composition/information on ingredients
- SECTION 4: First aid measures
- SECTION 5: Firefighting measures
- SECTION 6: Accidental release measures
- SECTION 7: Handling and storage
- SECTION 8: Exposure controls/personal protection
- SECTION 9: Physical and chemical properties
- SECTION 10: Stability and reactivity
- SECTION 11: Toxicological information
- SECTION 12: Ecological information
- SECTION 13: Disposal considerations
- SECTION 14: Transport information
- SECTION 15: Regulatory information
- SECTION 16: Other information

Date 04/08/2025 Production Name AQUASIL PUTTY SOFT - CATALYST Page n. 9 of 9