

Safety Data Sheet

ZA 8 LT - BASE

Revision nr. 4
Dated 21/06/2023

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

1.1. Product identifier

Mixture identification:

Product Name: ZA 8 LT - BASE

Code: DT23051, DT23052, DT23053, DT23054

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

For industrial/ professional use only. Addition silicone for mold making.

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

+39 0425 597611 (office hours)

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

EC regulation criteria 1272/2008 (CLP)

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

Adverse physicochemical, human health and environmental effects:

No other hazards

2.2. Label elements

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

Hazard pictograms:

None

Hazard statements:

None

Precautionary statements:

None

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 $\geq 0.1\%$

Other Hazards:

No other hazards

Safety Data Sheet

ZA 8 LT - BASE

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
<0,04%	octamethylcyclotetrasiloxane; [D4]	Index number: 014-018-00-1 CAS: 556-67-2 EC: 209-136-7 REACH No.: 01-21195292 38-36-XXXX	Flam. Liq. 3 H226 Flammable liquid and vapour. Repr. 2 H361f Suspected of damaging fertility. Aquatic Chronic 1 H410 Very toxic to aquatic life with long lasting effects. M=10.
<0,04%	octamethylcyclotetrasiloxane; [D4]	Index number: 014-018-00-1 CAS: 556-67-2 EC: 209-136-7	Flam. Liq. 3 H226 Flammable liquid and vapour. Repr. 2 H361f Suspected of damaging fertility. Aquatic Chronic 1 H410 Very toxic to aquatic life with long lasting effects. M=10.

Substances in nanoform:

>= 13% - < 20% Silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis products with silica - Nanoform

CAS: 68909-20-6, EC: 272-697-1

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:

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:

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

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

None

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

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

Safety Data Sheet

ZA 8 LT - BASE

DNEL Exposure Limit Values

octamethylcyclotetrasiloxane; [D4] - CAS: 556-67-2

Consumer: 13 mg/m³ - Exposure: Human Inhalation - Frequency: Long Term, local effects

Worker Professional: 73 mg/m³ - Exposure: Human Inhalation - Frequency: Long Term, local effects

Consumer: 3.7 mg/kg bw/d - Exposure: Human Oral - Frequency: Long Term, systemic effects

Consumer: 13 mg/m³ - Exposure: Human Inhalation - Frequency: Long Term, systemic effects

Worker Professional: 73 mg/m³ - Exposure: Human Inhalation - Frequency: Long Term, systemic effects

PNEC Exposure Limit Values

octamethylcyclotetrasiloxane; [D4] - CAS: 556-67-2

Target: Fresh Water - Value: 0.0015 mg/l

Target: Marine water - Value: 1.5E-5 mg/l

Target: Freshwater sediments - Value: 0.64 mg/kg

Target: Marine water sediments - Value: 0.064 mg/kg

Target: Microorganisms in sewage treatments - Value: 10 mg/l

Target: Food chain - Value: 41 mg/kg

Target: Soil (agricultural) - Value: 0.48 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:

Use respiratory protection where ventilation is insufficient or exposure is prolonged.

Respiratory protection devices must be used if the technical measures adopted are not suitable for restricting the worker's exposure to the threshold values considered (e.g. TLV-TWA).

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:	Liquid	--	--
Colour:	White	--	--
Odour:	Odourless	--	--
Melting point/freezing	Not available	--	--

Safety Data Sheet

ZA 8 LT - BASE

point:			
Boiling point or initial boiling point and boiling range:	Not available	--	--
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:	Insoluble	--	--
Solubility in oil:	Not available	--	--
Partition coefficient n-octanol/water (log value):	Not available	--	--
Vapour pressure:	Not available	--	--
Density and/or relative density:	Not available	--	--
Relative vapour density:	Not available	--	--
Particle characteristics:			
Particle size:	Not available	--	--

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:

ZA 8 LT - BASE

a) acute toxicity

Not classified

b) skin corrosion/irritation

Not classified

Safety Data Sheet
ZA 8 LT - BASE

- c) serious eye damage/irritation
Not classified
- 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
Not classified
- j) aspiration hazard
Not classified

Toxicological information of the main substances found in the product:

octamethylcyclotetrasiloxane; [D4] - CAS: 556-67-2

a) acute toxicity:

Test: LC50 - Route: Inhalation - Species: Rat 36 mg/l - Duration: 4h - Source: (OECD 403, GLP, ECHA dossier).

Test: LD50 - Route: Skin - Species: Rat > 2375 mg/kg - Source: (similar to OECD 402, ECHA dossier).

Test: LD50 - Route: Oral - Species: Rat 4800 mg/kg - Source: (similar to OECD 401, ECHA dossier)

b) skin corrosion/irritation:

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

c) serious eye damage/irritation:

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

d) respiratory or skin sensitisation:

Test: Skin Sensitization - Based on available data, the classification criteria are not met - Source: (OECD 406, ECHA dossier).

e) germ cell mutagenicity:

Test: In vitro - Negative - Source: (OECD 476, OECD 471, OECD 473; ECHA dossier).

Test: In vivo - Species: Rat - Negative - Source: (OECD 474; OECD 478, ECHA dossier).

f) carcinogenicity:

Test: 18201_NOAEC - Route: Inhalation - Species: Rat > 700 ppm - Notes: male rat - Source: (OECD 453, ECHA dossier).

Test: 18201_NOAEC - Route: Inhalation Vapour - Species: Rat = 150 ppm - Notes: female rat - Source: OECD 453, MSDS supplier

g) reproductive toxicity:

Test: NOAEL - Route: Inhalation Vapour - Species: Rat = 300 ppm - Source: EPA OPPTS 870.3800, MSDS supplier

Test: 18201_NOAEC - Route: Inhalation Vapour - Species: Rabbit > 6.1 mg/l - Notes:

Safety Data Sheet

ZA 8 LT - BASE

developmental - Source: OECD 414, MSDS supplier

Test: 18201_NOAEC - Route: Inhalation Vapour - Species: Rabbit > 3.6 mg/l - Notes:

maternal - Source: OECD 414, MSDS supplier

Test: 18201_NOAEC - Route: Inhalation Vapour - Species: Rat > 6.1 mg/l - Notes:

developmental - Source: OECD 414, MSDS supplier

Test: 18201_NOAEC - Route: Inhalation Vapour - Species: Rat = 3.6 mg/l - Notes: maternal -

Source: OECD 414, MSDS supplier

i) STOT-repeated exposure:

Test: 18201_NOAEC - Route: Inhalation Vapour - Species: Rat 1.8 mg/l - Notes: Systemic effect, chronic nephropathy - Source: OECD 453, MSDS supplier

Test: LOAEC - Route: Inhalation Vapour - Species: Rat = 8.5 mg/l - Notes: Systemic effect, chronic nephropathy - Source: OECD 453, MSDS supplier

Test: 18201_NOAEC - Route: Inhalation Vapour - Species: Rat = 1.8 mg/l - Notes: local effects, inflammatory processes of the lungs - Source: OECD 453, MSDS supplier

Test: LOAEC - Route: Inhalation Vapour - Species: Rat = 8.5 mg/l - Notes: local effects, inflammatory processes of the lungs - Source: OECD 453, MSDS supplier

octamethylcyclotetrasiloxane; [D4] - CAS: 556-67-2

a) acute toxicity:

Test: LC50 - Species: Rat 36 mg/l - Source: (OECD 403, GLP, rat, 4 h, ECHA dossier).

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

Test: LD50 - Route: Oral - Species: Rat 4800 mg/kg - Source: (similar to OECD 401, rat, 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

The product is not classified for chronic aquatic hazard: a test based on the bioavailability / release of D4 by the polymer silicone was performed with the OECD 29 method. It was found that the quantity of D4 released by 100mg of polymer is at least below the quantification limit of the method (i.e. 4.4 ppb), a value significantly lower than the limit that would result in the classification for chronic aquatic toxicity, i.e. NOEC of 0.0044 mg / L for fish and 0.0079 mg / L for aquatic invertebrates. Therefore, the product is not classified for this hazard class..

12.1. Toxicity

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

ZA 8 LT - BASE

The product is classified: -

octamethylcyclotetrasiloxane; [D4] - CAS: 556-67-2

a) Aquatic acute toxicity:

Endpoint: EC50 - Species: Daphnia > 0.015 mg/l - Duration h: 48h (publication, GLP, Daphnia magna, ECHA dossier).

Endpoint: IC50 - Species: Algae > 0.022 mg/l - Duration h: 72h (EPA OTS 797.1050, Selenastrum capricornutum, freshwater, ECHA dossier).

Endpoint: LC50 - Species: Fish > 0.022 mg/l (publication, Oncorhynchus mykiss, ECHA dossier).

Endpoint: NOEC - Species: Fish > 0.044 mg/l (publication, Oncorhynchus mykiss, GLP, ECHA dossier).

octamethylcyclotetrasiloxane; [D4] - CAS: 556-67-2

a) Aquatic acute toxicity:

Endpoint: IC50 - Species: Algae > 0.0022 mg/l - Duration h: 72h (EPA OTS 797.1050, Selenastrum capricornutum, freshwater, ECHA dossier).

Endpoint: LC50 - Species: Fish > 0.0022 mg/l (Oncorhynchus mykiss, GLP, ECHA dossier).

Endpoint: NOEC - Species: Fish > 0.0044 mg/l (publication, Oncorhynchus mykiss, GLP,

Safety Data Sheet

ZA 8 LT - BASE

ECHA dossier).

Long-term toxicity to aquatic invertebrates:

Endpoint: NOEC - Species: Daphnia = 7.9 µg/L - Duration h: 21d EPA OTS 797.1330, Daphnia magna, ECHA dossier

12.2. Persistence and degradability

octamethylcyclotetrasiloxane; [D4] - CAS: 556-67-2

Biodegradability: Non-readily biodegradable

12.3. Bioaccumulative potential

octamethylcyclotetrasiloxane; [D4] - CAS: 556-67-2

Test: Kow - Partition coefficient 6.49 - Notes:)

(Log Pow, ECHA dossier).

octamethylcyclotetrasiloxane; [D4] - CAS: 556-67-2

Test: Kow - Partition coefficient 6.49 - Notes: (Log Pow, ECHA dossier).

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. 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

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. 2020/878

Regulation (EU) n. 286/2011 (ATP 2 CLP)

Safety Data Sheet

ZA 8 LT - BASE

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 3
 Restriction 40

Restrictions related to the substances contained:

Restriction 70
 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 10: Combustible liquids

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

None.

California Proposition 65

Substance(s) listed under California Proposition 65:
 None.

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:
 octamethylcyclotetrasiloxane; [D4]

SECTION 16: Other information

Hazard class and hazard category	Code	Description
Flam. Liq. 3	2.6/3	Flammable liquid, Category 3
Repr. 2	3.7/2	Reproductive toxicity, Category 2
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

**Safety Data Sheet
ZA 8 LT - BASE**

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
Aquatic Chronic	According to Article 12 of the CLP Regulation, "Where, as a result of the evaluation carried out pursuant to Article 9, the following properties or effects are identified, manufacturers, importers and downstream users shall take them into account for the purposes of classification: [...] (b) conclusive scientific experimental data show that the substance or mixture is not biologically available and those data have been ascertained to be adequate and reliable." Following a release study of D4 through the OECD 29 test on polymeric products representative for quantity of D4, the limit that would result in the classification for chronic aquatic toxicity (NOEC of 0.0044 mg / L for fish and 0.0079 mg / L for invertebrates aquatic) is not reached.

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
- PubChem - open chemistry database at the National Institutes of Health (NIH)

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).

Safety Data Sheet

ZA 8 LT - BASE

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.