

**Safety Data Sheet
SEPARATOR FOR GINGIFAST****Revision nr. 6
Dated 04/11/2022****SECTION 1: Identification of the substance/mixture and of the company/undertaking****1.1. Product identifier**

Mixture identification:

Product Name: SEPARATOR FOR GINGIFAST

Code: C400888, C203227, C203232, C401500, C401520

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

For professional use only. Isolator between two surfaces.

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)

Flam. Liq. 2, H225 Highly flammable liquid and vapour.

Eye Irrit. 2, H319 Causes serious eye irritation.

STOT SE 3, H336 May cause drowsiness or dizziness.

EUH066 Repeated exposure may cause skin dryness or cracking.

Adverse physicochemical, human health and environmental effects:

No other hazards

2.2. Label elements

Hazard pictograms:



Danger

Hazard statements:

H225 Highly flammable liquid and vapour.

H319 Causes serious eye irritation.

H336 May cause drowsiness or dizziness.

Precautionary statements:

P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.

P233 Keep container tightly closed.

P264 Wash hands thoroughly after handling.

P280 Wear protective gloves and eye/face protection.

P304+P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing.

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P312 Call a POISON CENTER if you feel unwell.

Special Provisions:

EUH066 Repeated exposure may cause skin dryness or cracking.

Contains

ethyl acetate

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

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
$\geq 80\%$ - $< 90\%$	ethyl acetate	Index number: 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. EUH066 Repeated exposure may cause skin dryness or cracking. Specific Concentration Limits: C $\geq 10\%$: EUH066

SECTION 4: First aid measures

4.1. Description of first aid measures

In case of skin contact:

Immediately take off all contaminated clothing.

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 thoroughly the body (shower or bath).

Remove contaminated clothing immediately and dispose off safely.

After contact with skin, wash immediately with soap and plenty of water.

In case of eyes contact:

After contact with the eyes, rinse with water with the eyelids open for a sufficient length of time, then consult an ophthalmologist immediately.

Protect uninjured eye.

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

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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:

CO₂ or Dry chemical fire extinguisher.

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 all sources of ignition.

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

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.

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

Store at below 20 °C. Keep away from unguarded flame and heat sources. Avoid direct exposure to sunlight.

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Keep away from unguarded flame, sparks, and heat sources. Avoid direct exposure to sunlight.

Keep away from food, drink and feed.

Incompatible materials:

See section 10.5.

Instructions as regards storage premises:

Cool and adequately ventilated.

7.3. Specific end use(s)

See section 1.2.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

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ethyl acetate - CAS: 141-78-6

OEL Type	TWA		Duration	STEL		Duration	Notes	Country
MAK	750 mg/m ³	200 ppm	8h	1500 mg/m ³	400 ppm	15min		GERMANY
AGW	730 mg/m ³	200 ppm	8h	1460 mg/m ³	400 ppm	15min		GERMANY
MAK	730 mg/m ³	200 ppm	8h	1460 mg/m ³	400 ppm	15min		SWITZERLAND
AK	1400 mg/m ³		8h	1400 mg/m ³		15min		HUNGARY
HTP	730 mg/m ³	200 ppm	8h	1470 mg/m ³	400 ppm	15min		FINLAND
MAK	734 mg/m ³	200 ppm	8h	1468 mg/m ³	400 ppm	15min		AUSTRIA
NDS/NDSch	200 mg/m ³		8h	600 mg/m ³		15min		POLAND
NGV/KGV	550 mg/m ³	150 ppm	8h	1100 mg/m ³	300 ppm	15min		SWEDEN
OELV		200 ppm	8h		400 ppm	15min		IRELAND
VLEP	734 mg/m ³	200 ppm	8h	1468 mg/m ³	400 ppm	15min		ITALY
RV	200 mg/m ³	54 ppm	8h	1468 mg/m ³	400 ppm	15min		LATVIA
TLV	400 mg/m ³	111 ppm	8h	500 mg/m ³	139 ppm	15min		ROMANIA
TLV	540 mg/m ³	150 ppm	8h	1080 mg/m ³	300 ppm	15min		DENMARK
VLEP	734 mg/m ³	200 ppm	8h	1468 mg/m ³	400 ppm	15min		FRANCE
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	8h				URT and	

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		ppm					eye irr	
ACGIH		400	8h				URT and	
		ppm					eye irr	

DNEL Exposure Limit Values

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

PNEC Exposure Limit Values

ethyl acetate - CAS: 141-78-6

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

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:

Suitable material:

NBR (nitrile rubber - 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 "A" , brown colour

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	--	--

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Colour:	Opaque	--	--
Odour:	Typical of solvent	--	--
Melting point/freezing point:	Not available	--	--
Boiling point or initial boiling point and boiling range:	76	ASTM D 1120	--
Flammability:	Flam. Liq. 2, H225	--	--
Lower and upper explosion limit:	Not available	--	--
Flash point:	-1 ° C	ASTM D93-19	--
Auto-ignition temperature:	Not available	--	--
Decomposition temperature:	Not available	--	--
pH:	Not Relevant	--	--
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:	0.93 g/cm ³ (calculated)	--	--
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

The vapours may also form explosive mixtures with the air.

10.4. Conditions to avoid

Heat, direct sunlight.
Avoid bunching of electrostatic charges.
Avoid all sources of ignition.

10.5. Incompatible materials

Avoid contact with combustible materials. The product could catch fire.

10.6. Hazardous decomposition products

flammable gases / vapors
acetic acid

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
The product is classified: Eye Irrit. 2 H319
- 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
The product is classified: STOT SE 3 H336
- i) STOT-repeated exposure
Not classified
- j) aspiration hazard
Not classified

Toxicological information of the main substances found in the product:

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).

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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Not classified for environmental hazards

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

12.2. Persistence and degradability

ethyl acetate - CAS: 141-78-6

Biodegradability: Readily biodegradable

12.3. Bioaccumulative potential

Not available

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

ADR-UN Number: 1173

IATA-UN Number: 1173

IMDG-UN Number: 1173

14.2. UN proper shipping name

ADR-Shipping Name: ETHYL ACETATE

IATA-Shipping Name: ETHYL ACETATE

IMDG-Shipping Name: ETHYL ACETATE

14.3. Transport hazard class(es)

ADR-Class: 3

IATA-Class: 3

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IATA-Label:	3
IMDG-Class:	3
14.4. Packing group	
ADR-Packing Group:	II
IATA-Packing group:	II
IMDG-Packing group:	II
14.5. Environmental hazards	
ADR-Environmental Pollutant:	No
IMDG-Marine pollutant:	No
IMDG-EmS:	F-E , S-D
14.6. Special precautions for user	
ADR-Subsidiary hazards:	-
ADR-S.P.:	-
ADR-Transport category (Tunnel restriction code):	2 (D/E)
ADR - Hazard identification number:	33
IATA-Passenger Aircraft:	353
IATA-Subsidiary hazards:	-
IATA-Cargo Aircraft:	364
IATA-S.P.:	-
IATA-ERG:	3L
IMDG-Subsidiary hazards:	-
IMDG-Stowage and handling:	Category B
IMDG-Segregation:	-
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)
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:

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Restriction 75

Provisions related to directive EU 2012/18 (Seveso III):
 Seveso III category according to Annex 1, part 1
 Product belongs to category: P5c

WGK Classification (Water hazard class - Verwaltungsvorschrift wassergefährdende Stoffe)
 WGK1 - Slightly hazardous for water

Lagerklasse according to TRGS 510:
 LGK 3: Flammable 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:
 None

SECTION 16: Other information

Full text of phrases referred to in Section 3:
 EUH066 Repeated exposure may cause skin dryness or cracking.

Hazard class and hazard category	Code	Description
Flam. Liq. 2	2.6/2	Flammable liquid, Category 2
Eye Irrit. 2	3.3/2	Eye irritation, Category 2
STOT SE 3	3.8/3	Specific target organ toxicity - single exposure, Category 3

This safety data sheet has been completely updated in compliance to Regulation 2020/878. 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
Flam. Liq. 2, H225	On basis of test data
Eye Irrit. 2, H319	Calculation method
STOT SE 3, H336	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
 PubChem - open chemistry database at the National Institutes of Health (NIH)

**Safety Data Sheet
SEPARATOR FOR GINGIFAST**

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.

Safety Data Sheet

GINGIFAST RIGID - BASE

Revision nr. 4
Dated 09/08/2023

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

1.1. Product identifier

Mixture identification:

Product Name: GINGIFAST RIGID - BASE
Code: C401520, C430001, C203230

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

For professional use only. Addition silicone for the reproduction of gingival masks.

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

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

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

Other Hazards:

No other hazards

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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
>= 20% - < 25%	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.

Substances in nanoform:

>= 3% - < 5% Silicon dioxide, amorphous

REACH No.: 01-2119379499-16-XXXX, CAS: 7631-86-9, EC: 231-545-4

>= 0,1% - < 0,3% Trisodium

1-(1-naphthylazo)-2-hydroxynaphthalene-4',6,8-trisulphonate

CAS: 2611-82-7, EC: 220-036-2

<0,1% Aluminium,

4,5-dihydro-5-oxo-1-(4-sulfophenyl)-4-[(4-sulfophenyl)azo]-1H-pyrazole-3-carboxylic acid complex - Nanoform

CAS: 12225-21-7, EC: 235-428-9

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

Do not inhale explosion and combustion gases.

Burning produces heavy smoke.

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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

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.

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

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

GINGIFAST RIGID - BASE

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	

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							cancer	
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DNEL Exposure Limit Values
Not available

PNEC Exposure Limit Values
Not available

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:	Pink	--	--
Odour:	Odourless	--	--
Melting point/freezing point:	Not available	--	--
Boiling point or initial boiling point and boiling range:	Not available	--	--
Flammability:	Non-flammable	--	--
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	--	--

Safety Data Sheet

GINGIFAST RIGID - BASE

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

"For the purposes of classification of health hazards (part 3), the route of exposure, information on mechanisms and metabolism studies are useful for determining the relevance of effects in humans. If this information raises doubts as to their relevance in humans, in spite of the indisputable data legitimacy and quality, a lower classification may be justified. When there is scientific evidence that the mechanism or mode of action is not relevant to humans, the substance or mixture should not be classified" (annex I, section 1.1.1.5, EC Regulation 1272/2008).

Monitoring activities conducted at the company related to possible inhalation exposure, in accordance with industrial hygiene standards for paste and fluid products, showed levels of exposure to free crystalline silica (breathable part) below the limit of quantification 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 free crystalline silica (breathable part) present in the workplace must be obtained through monitoring as required by regulations for the safety and health of workers.

Toxicological information of the product:

GINGIFAST RIGID - BASE

a) acute toxicity

Not classified

b) skin corrosion/irritation

Not classified

c) serious eye damage/irritation

Not classified

d) respiratory or skin sensitisation

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GINGIFAST RIGID - BASE**

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:

Cristobalite - CAS: 14464-46-1

i) STOT-repeated exposure:

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

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.

GINGIFAST RIGID - BASE

Not classified for environmental hazards

Based on available data, the classification criteria are not met

12.2. Persistence and degradability

Cristobalite - CAS: 14464-46-1

Biodegradability: Non-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. In so doing, comply with the local and national regulations currently in force.

**Safety Data Sheet
GINGIFAST RIGID - BASE****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)

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 70

Restriction 75

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

Seveso III category according to Annex 1, part 1

None

**Safety Data Sheet
GINGIFAST RIGID - BASE**

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:
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:
None

SECTION 16: Other information

Hazard class and hazard category	Code	Description
STOT RE 1	3.9/1	Specific target organ toxicity - repeated exposure, Category 1

This document was prepared by a competent person who has received appropriate training.
Main bibliographic sources:

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.

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GINGIFAST RIGID - BASE

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.

Safety Data Sheet

GINGIFAST RIGID - CATALYST

Revision nr. 4
Dated 09/08/2023

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

1.1. Product identifier

Mixture identification:
Product Name: GINGIFAST RIGID - CATALYST
Code: C401520, C430001, C203230

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

For professional use only. Addition silicone for the reproduction of gingival masks.

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

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

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

Other Hazards:

No other hazards

Safety Data Sheet

GINGIFAST RIGID - CATALYST

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
>= 10% - < 12,5%	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.
<0,09%	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:

>= 3% - < 5% 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:

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

Do not inhale explosion and combustion gases.

Burning produces heavy smoke.

5.3. Advice for firefighters

Use suitable breathing apparatus .

Safety Data Sheet

GINGIFAST RIGID - CATALYST

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

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.

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

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

GINGIFAST RIGID - CATALYST

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	

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GINGIFAST RIGID - CATALYST

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

OEL Type	TWA		Duration	STEL		Duration	Notes	Country
No data available								

DNEL Exposure Limit Values

Not available

PNEC Exposure Limit Values

Not available

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

Safety Data Sheet

GINGIFAST RIGID - CATALYST

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

"For the purposes of classification of health hazards (part 3), the route of exposure, information on mechanisms and metabolism studies are useful for determining the relevance of effects in humans. If this information raises doubts as to their relevance in humans, in spite of the indisputable data legitimacy and quality, a lower classification may be justified. When there is scientific evidence that the mechanism or mode of action is not relevant to humans, the substance or mixture should not be classified" (annex I, section 1.1.1.5, EC Regulation 1272/2008).

Monitoring activities conducted at the company related to possible inhalation exposure, in accordance with industrial hygiene standards for paste and fluid products, showed levels of exposure to free crystalline silica (breathable part) below the limit of quantification 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 free crystalline silica (breathable part) present in the workplace must be obtained through monitoring as required by regulations for the safety and health of workers.

Toxicological information of the product:

GINGIFAST RIGID - CATALYST

a) acute toxicity

Not classified

b) skin corrosion/irritation

Not classified

Safety Data Sheet

GINGIFAST RIGID - CATALYST

- 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:

Cristobalite - CAS: 14464-46-1

i) STOT-repeated exposure:

Route: Inhalation - Notes: Silicosis, pulmonary fibrosis; Target organ: lungs - Source: (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.

GINGIFAST RIGID - CATALYST

The product is classified: -

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).

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GINGIFAST RIGID - CATALYST

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, 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

Cristobalite - CAS: 14464-46-1

Biodegradability: Non-readily biodegradable

12.3. Bioaccumulative potential

Cristobalite - CAS: 14464-46-1

Not bioaccumulative

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 >= 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)

Safety Data Sheet

GINGIFAST RIGID - CATALYST

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)
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 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:
 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:

None

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
STOT RE 1	3.9/1	Specific target organ toxicity - repeated

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GINGIFAST RIGID - CATALYST

		exposure, 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
Aquatic Chronic	<p>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."</p> <p>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.</p>

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)

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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.

Safety Data Sheet

GINGIFAST RIGID - CATALYST

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.