

SAFETY DATA SHEET

According to REACH etc. (Amendment etc.) (EU Exit) Regulations 2019

schülke 

gigazyme® X-tra *No Change Service!*

Version
02.08

Revision Date:
06.09.2022

Date of last issue: 16.05.2022

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

1.1 Product identifier

Trade name : gigazyme® X-tra

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

Use of the Sub-
stance/Mixture : Cleaning agent, Disinfectants

Recommended restrictions
on use : Restricted to professional users.

1.3 Details of the supplier of the safety data sheet

Producer : Schülke & Mayr GmbH
Robert-Koch-Str. 2

22851 Norderstedt
Germany
Telephone: +49 (0)40/ 52100-0
Telefax: +49 (0)40/ 52100318
mail@schuelke.com
www.schuelke.com

Supplier : Schülke & Mayr UK Ltd.
Cygnet House
1, Jenkin Road, Meadowhall

Sheffield S9 1AT
United Kingdom
Telephone: +44 114 254 35 00
Telefax: +44 114 254 35 01
mail.uk@schulke.com

E-mail address of person
responsible for the
SDS/Contact person : Application Specialists
+49 (0)40/ 521 00 666
AD@schuelke.com
(Schülke & Mayr UK Ltd.: +44-1142543500)

1.4 Emergency telephone number

Emergency telephone num-
ber : Carechem 24 International: +44 1235 239670

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008) as amended by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019)

SAFETY DATA SHEET

According to REACH etc. (Amendment etc.) (EU Exit) Regulations 2019

schülke 

gigazyme® X-tra **No Change Service!**

Version
02.08

Revision Date:
06.09.2022

Date of last issue: 16.05.2022

Acute toxicity, Category 4	H302: Harmful if swallowed.
Skin corrosion, Sub-category 1B	H314: Causes severe skin burns and eye damage.
Serious eye damage, Category 1	H318: Causes serious eye damage.
Short-term (acute) aquatic hazard, Category 1	H400: Very toxic to aquatic life.
Long-term (chronic) aquatic hazard, Category 2	H411: Toxic to aquatic life with long lasting effects.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008) as amended by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019)

Hazard pictograms

:



Signal word

:

Danger

Hazard statements

:

H302 Harmful if swallowed.
H314 Causes severe skin burns and eye damage.
H410 Very toxic to aquatic life with long lasting effects.

Precautionary statements

:

Prevention:

P273 Avoid release to the environment.
P280 Wear protective gloves/ eye protection/ face protection.

Response:

P301 + P312 IF SWALLOWED: Call a POISON CENTER/ doctor if you feel unwell.
P303 + P361 + P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water or shower.
P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

Disposal:

P501 Dispose of contents/ container to an approved waste disposal plant.

Hazardous components which must be listed on the label:

Poly(oxy-1,2-ethanediyl), .alpha.-tridecyl-.omega.-hydroxy-, branched didecyldimethylammonium chloride

Additional Labelling

The product is classified in accordance with Annex I (2.6.4.5) to Regulation

SAFETY DATA SHEET

According to REACH etc. (Amendment etc.) (EU Exit) Regulations
2019

schülke 

gigazyme® X-tra **No Change Service!**

Version
02.08

Revision Date:
06.09.2022

Date of last issue: 16.05.2022

(EC) 1272/2008.

EUH208 Contains polyhexamethylene biguanide hydrochloride, subtilisin.

May produce an allergic reaction.

2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Chemical nature : Solution of the following substances with harmless additives.

Components

Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
Poly(oxy-1,2-ethanediyl), .alpha.-tridecyl-.omega.-hydroxy-, branched	69011-36-5 500-241-6 - - - - - -	Acute Tox. 4; H302 Eye Dam. 1; H318 Aquatic Chronic 3; H412 specific concentration limit Eye Dam. 1; H318 > 10 % Eye Irrit. 2; H319 > 1 - < 10 %	>= 10 - < 20
didecyldimethylammonium chloride	7173-51-5 230-525-2 612-131-00-6 01-2119945987-15-XXXX	Acute Tox. 3; H301 Skin Corr. 1B; H314 Eye Dam. 1; H318 Aquatic Acute 1; H400 Aquatic Chronic 2; H411 M-Factor (Acute aquatic toxicity): 10 M-Factor (Chronic aquatic toxicity): 1	>= 5 - < 10
propan-2-ol	67-63-0 200-661-7 603-117-00-0 01-2119457558-25-XXXX	Flam. Liq. 2; H225 Eye Irrit. 2; H319 STOT SE 3; H336 (Central nervous system)	>= 1 - < 10
polyhexamethylene biguanide hydro-	27083-27-8	Acute Tox. 4; H302	>= 0.25 - < 1

SAFETY DATA SHEET

According to REACH etc. (Amendment etc.) (EU Exit) Regulations
2019

schülke 

gigazyme® X-tra **No Change Service!**

Version
02.08

Revision Date:
06.09.2022

Date of last issue: 16.05.2022

chloride	--- 616-207-00-X ---	Acute Tox. 2; H330 Skin Irrit. 2; H315 Eye Dam. 1; H318 Skin Sens. 1B; H317 Carc. 2; H351 STOT RE 1; H372 (Respiratory Tract) Aquatic Acute 1; H400 Aquatic Chronic 1; H410 M-Factor (Acute aquatic toxicity): 10 M-Factor (Chronic aquatic toxicity): 10	
subtilisin	9014-01-1 232-752-2 647-012-00-8 01-2119480434-38- XXXX	Acute Tox. 4; H302 Skin Irrit. 2; H315 Eye Dam. 1; H318 Resp. Sens. 1; H334 STOT SE 3; H335 (Respiratory sys- tem) Aquatic Acute 1; H400 Aquatic Chronic 2; H411 M-Factor (Acute aquatic toxicity): 1 M-Factor (Chronic aquatic toxicity): 1	>= 0.1 - < 0.25
Substances with a workplace exposure limit :			
glycerol	56-81-5 200-289-5 --- ---		>= 30 - < 50

For explanation of abbreviations see section 16.

SECTION 4: First aid measures

4.1 Description of first aid measures

General advice : Take off all contaminated clothing immediately.

If inhaled : If symptoms persist, call a physician.

In case of skin contact : Wash off immediately with plenty of water for at least 15 minutes.

SAFETY DATA SHEET

According to REACH etc. (Amendment etc.) (EU Exit) Regulations
2019

schülke 

gigazyme® X-tra **No Change Service!**

Version
02.08

Revision Date:
06.09.2022

Date of last issue: 16.05.2022

- In case of eye contact : In case of eye contact, remove contact lens and rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes.
If eye irritation persists, consult a specialist.
- If swallowed : Do NOT induce vomiting.
Clean mouth with water and drink afterwards plenty of water.
Obtain medical attention.

4.2 Most important symptoms and effects, both acute and delayed

- Symptoms : Treat symptomatically.
- Risks : Harmful if swallowed.
Causes serious eye damage.
Causes severe burns.

4.3 Indication of any immediate medical attention and special treatment needed

- Treatment : For specialist advice physicians should contact the Poisons Information Service.

SECTION 5: Firefighting measures

5.1 Extinguishing media

- Suitable extinguishing media : Dry powder
Foam
Water spray jet
Carbon dioxide (CO₂)
- Unsuitable extinguishing media : Do NOT use water jet.

5.2 Special hazards arising from the substance or mixture

- Specific hazards during fire-fighting : Do not allow run-off from fire fighting to enter drains or water courses.
- Hazardous combustion products : No hazardous combustion products are known

5.3 Advice for firefighters

- Special protective equipment for firefighters : In the event of fire, wear self-contained breathing apparatus.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

- Personal precautions : Increased risk of slipping in the presence of leaked / spilled product.
Use personal protective equipment.

SAFETY DATA SHEET

According to REACH etc. (Amendment etc.) (EU Exit) Regulations
2019

schülke 

gigazyme® X-tra *No Change Service!*

Version
02.08

Revision Date:
06.09.2022

Date of last issue: 16.05.2022

6.2 Environmental precautions

Environmental precautions : Do not flush into surface water or sanitary sewer system.
Avoid subsoil penetration.

6.3 Methods and material for containment and cleaning up

Methods for cleaning up : Wipe up with absorbent material (e.g. cloth, fleece).
Soak up with inert absorbent material (e.g. sand, silica gel,
acid binder, universal binder, sawdust).

6.4 Reference to other sections

see Section 8 + 13

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Advice on safe handling : Prepare the working solution as given on the label(s) and/or
the user instructions.

Advice on protection against fire and explosion : Normal measures for preventive fire protection.

Hygiene measures : Keep away from food and drink.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers : Store at room temperature in the original container.

Further information on storage conditions : Keep away from direct sunlight. Keep container tightly closed.
Keep away from heat. Recommended storage temperature: 5
- 25°C

Advice on common storage : No materials to be especially mentioned.

7.3 Specific end use(s)

Specific use(s) : none

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational Exposure Limits

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
glycerol	56-81-5	TWA (Mist)	10 mg/m ³	GB EH40
propan-2-ol	67-63-0	TWA	400 ppm 999 mg/m ³	GB EH40
		STEL	500 ppm	GB EH40

SAFETY DATA SHEET

According to REACH etc. (Amendment etc.) (EU Exit) Regulations 2019

schülke 

gigazyme® X-tra **No Change Service!**

Version
02.08

Revision Date:
06.09.2022

Date of last issue: 16.05.2022

			1,250 mg/m3	
subtilisin	9014-01-1	TWA	0.00004 mg/m3	GB EH40
Further information: One of the suitable measurement methods is the fluorescence polarisation technique developed by the Health and Safety Laboratory (HSL). The previous limit for subtilisin was based on high-volume static sampling to achieve sufficient sensitivity. However, improvements in the analytical methodology have improved the sensitivity and the WEL for subtilisin reflects this. The limit is based on standard personal sampling (MDHS14/4).4 Short-term reference period (15 minute) sampling is not appropriate., Substances that can cause occupational asthma (also known as asthmagens and respiratory sensitisers) can induce a state of specific airway hyper-responsiveness via an immunological irritant or other mechanism. Once the airways have become hyper-responsive, further exposure to the substance, sometimes even in tiny quantities, may cause respiratory symptoms. These symptoms can range in severity from a runny nose to asthma. Not all workers who are exposed to a sensitiser will become hyper-responsive and it is impossible to identify in advance those who are likely to become hyper-responsive. Substances that can cause occupational asthma should be distinguished from substances which may trigger the symptoms of asthma in people with pre-existing airway hyper-responsiveness, but which do not include the disease themselves. The latter substances are not classified as asthmagens or respiratory sensitisers. Further information can be found in the HSE publication Asthmagen? Critical assessments of the evidence for agents implicated in occupational asthma., Wherever it is reasonably practicable, exposure to substances that can cause occupational asthma should be prevented. Where this is not possible, the primary aim is to apply adequate standards of control to prevent workers from becoming hyper-responsive. For substances that can cause occupational asthma, COSHH requires that exposure be reduced to as low as is reasonably practicable. Activities giving rise to short-term peak concentrations should receive particular attention when risk management is being considered. Health surveillance is appropriate for all employees exposed or liable to be exposed to a substance which may cause occupational asthma and there should be appropriate consultation with an occupational health professional over the degree of risk and level of surveillance., Subtilisins are proteolytic enzymes derived from <i>Bacillus subtilis</i>. They are used in biological washing powders, animal feedstuffs etc. The enzyme preparation contains active enzyme, inactive enzyme and protein residues., Capable of causing occupational asthma., Where no specific short-term exposure limit is listed, a figure three times the long-term exposure limit should be used., The 'Sen' notation in the list of WELs has been assigned only to those substances which may cause occupational asthma in the categories shown in Table 1. It should be remembered that other substances not in these tables may cause occupational asthma. HSE's asthma web pages (www.hse.gov.uk/asthma) provide further information.				

Derived No Effect Level (DNEL):

Substance name	End Use	Exposure routes	Potential health effects	Value
Poly(oxy-1,2-ethanediyl), .alpha.-tridecyl-.omega.-hydroxy-, branched	Workers	Inhalation	Long-term systemic effects	294 mg/m3
didecyl-dimethylammonium chloride	Workers	Inhalation	Acute systemic effects, Long-term systemic effects	5.39 mg/m3

SAFETY DATA SHEET

According to REACH etc. (Amendment etc.) (EU Exit) Regulations 2019

schülke 

gigazyme® X-tra **No Change Service!**

Version
02.08

Revision Date:
06.09.2022

Date of last issue: 16.05.2022

	Workers	Dermal	Acute systemic effects, Long-term systemic effects	1.55 mg/kg
propan-2-ol	Workers	Skin contact	Long-term systemic effects	888 mg/kg
	Workers	Inhalation	Long-term systemic effects	500 mg/m3
subtilisin	Workers	Skin contact	Acute local effects, Long-term local effects	2000 ppm
	Workers	Inhalation	Long-term local effects	0.00006 mg/m3

Predicted No Effect Concentration (PNEC):

Substance name	Environmental Compartment	Value
Poly(oxy-1,2-ethanediyl), .alpha.-tridecyl-.omega.-hydroxy-, branched	Fresh water	0.074 mg/l
	Marine water	0.0074 mg/l
	Intermittent use/release	0.015 mg/l
	Sewage treatment plant	1.4 mg/l
	Soil	0.1 mg/kg
	Fresh water sediment	0.604 mg/kg
didecyldimethylammonium chloride	Marine sediment	0.0604 mg/kg
	Fresh water	0.002 mg/l
	Marine water	0.0002 mg/l
	Fresh water sediment	2.83 mg/kg
	Marine sediment	0.28 mg/kg
	Sewage treatment plant	0.595 mg/l
propan-2-ol	Soil	1.4 mg/kg
	Fresh water	140.9 mg/l
	Marine water	140.9 mg/l
	Fresh water sediment	552 mg/kg
	Marine sediment	552 mg/kg
	Soil	28 mg/kg
subtilisin	Intermittent use/release	140.9 mg/l
	Effects on waste water treatment plants	2251 mg/l
	Oral	160 mg/kg food
	Fresh water	0.00006 mg/l
	Marine water	0.000006 mg/l
	Effects on waste water treatment plants	65 mg/l

8.2 Exposure controls

Personal protective equipment

Eye/face protection : Safety glasses with side-shields conforming to EN166

Hand protection
Directive : The selected protective gloves have to satisfy the specifications of Regulation (EU) 2016/425 and the standard EN 374 derived from it.

Remarks : Splash protection: disposable nitrile rubber gloves e.g.

SAFETY DATA SHEET

According to REACH etc. (Amendment etc.) (EU Exit) Regulations
2019

schülke 

gigazyme® X-tra **No Change Service!**

Version
02.08

Revision Date:
06.09.2022

Date of last issue: 16.05.2022

Dermatril (layer thickness: 0.11 mm) made by KCL or gloves from other manufacturers offering the same protection. Prolonged contact: Nitrile rubber gloves e.g. Camatril (>480 Min., layer thickness: 0,40 mm) or butyl rubber gloves e.g. Butoject (>480 Min., layer thickness: 0,70 mm) made by KCL or gloves from other manufacturers offering the same protection.

- Skin and body protection : Work uniform or laboratory coat.
- Respiratory protection : No personal respiratory protective equipment normally required.
- Protective measures : Avoid contact with skin and eyes.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

- Appearance : liquid
- Colour : green
- Odour : odourized
-
- Odour Threshold : not determined
- pH : 7.5 (20 °C)
Concentration: 100 %
- Melting point/freezing point : < -5 °C
- Decomposition temperature : Not applicable
- Boiling point/boiling range : not determined
- Flash point : ca. 52 °C
Method: DIN 53213, Part 1
- Evaporation rate : No data available
- Upper explosion limit / Upper flammability limit : Not applicable
- Lower explosion limit / Lower flammability limit : Not applicable
- Vapour pressure : not determined
- Relative vapour density : No data available
- Density : ca. 1.08 g/cm³ (20 °C)

SAFETY DATA SHEET

According to REACH etc. (Amendment etc.) (EU Exit) Regulations
2019

schülke 

gigazyme® X-tra *No Change Service!*

Version
02.08

Revision Date:
06.09.2022

Date of last issue: 16.05.2022

Solubility(ies)	
Water solubility	: completely soluble (20 °C)
Partition coefficient: n-octanol/water	: Not applicable
Auto-ignition temperature	: No data available
Viscosity	
Viscosity, dynamic	: ca. 53 mPa*s
Explosive properties	: No data available
 Oxidizing properties	: The substance or mixture is not classified as oxidizing.

9.2 Other information

 Flammability (liquids)	: Does not sustain combustion.
Metal corrosion rate	: Not corrosive to metals

SECTION 10: Stability and reactivity

10.1 Reactivity

No dangerous reaction known under conditions of normal use.

10.2 Chemical stability

None reasonably foreseeable.

10.3 Possibility of hazardous reactions

Hazardous reactions : No dangerous reaction known under conditions of normal use.

10.4 Conditions to avoid

Conditions to avoid : Protect from frost, heat and sunlight.

10.5 Incompatible materials

Materials to avoid : Never mix concentrates directly.

10.6 Hazardous decomposition products

None reasonably foreseeable.

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Acute toxicity

Harmful if swallowed.

Product:

Acute oral toxicity : Acute toxicity estimate: 1,918 mg/kg

SAFETY DATA SHEET

According to REACH etc. (Amendment etc.) (EU Exit) Regulations
2019

schülke 

gigazyme® X-tra *No Change Service!*

Version
02.08

Revision Date:
06.09.2022

Date of last issue: 16.05.2022

Method: Calculation method

Acute inhalation toxicity : Acute toxicity estimate: > 5 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Method: Calculation method

Components:

Poly(oxy-1,2-ethanediyl), .alpha.-tridecyl-omega.-hydroxy-, branched:

Acute oral toxicity : LD50 (Rat): > 300 - 2,000 mg/kg
Acute inhalation toxicity : Remarks: No data available
Acute dermal toxicity : LD50: > 5,000 mg/kg
Method: literature value

didecyldimethylammonium chloride:

Acute oral toxicity : LD50 (Rat): 238 mg/kg
Method: OECD Test Guideline 401
Assessment: Toxic if swallowed.
Acute inhalation toxicity : Remarks: No data available
Acute dermal toxicity : LD50 (Rabbit): 3,342 mg/kg

propan-2-ol:

Acute oral toxicity : LD50 (Rat): 5,840 mg/kg
Acute inhalation toxicity : LC50 (Rat): 39 mg/l
Exposure time: 4 h
Test atmosphere: vapour
Acute dermal toxicity : LD50 (Rabbit): 13,900 mg/kg
Method: OECD Test Guideline 402

polyhexamethylene biguanide hydrochloride:

Acute oral toxicity : LD50 (Rat): 500 - 1,000 mg/kg
Assessment: Harmful if swallowed.
Acute inhalation toxicity : LC50 (Rat): 0.37 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Assessment: Fatal if inhaled.
Acute dermal toxicity : Remarks: No data available

subtilisin:

Acute oral toxicity : LD50 (Rat): 1,800 mg/kg
Method: OECD Test Guideline 401

SAFETY DATA SHEET

According to REACH etc. (Amendment etc.) (EU Exit) Regulations
2019

schülke 

gigazyme® X-tra *No Change Service!*

Version
02.08

Revision Date:
06.09.2022

Date of last issue: 16.05.2022

Acute dermal toxicity : Remarks: No data available

glycerol:

Acute oral toxicity : LD50 (Rat, female): 27,200 mg/kg
Method: OECD Test Guideline 401

Acute dermal toxicity : LD50 (Guinea pig, male and female): 56,750 mg/kg

Skin corrosion/irritation

Causes severe burns.

Components:

Poly(oxy-1,2-ethanediyl), .alpha.-tridecyl-.omega.-hydroxy-, branched:

Species : Rabbit
Method : OECD Test Guideline 404
Result : No skin irritation

didecyldimethylammonium chloride:

Species : Rabbit
Exposure time : 4 h
Method : OECD Test Guideline 404
Result : Corrosive after 3 minutes to 1 hour of exposure

propan-2-ol:

Result : No skin irritation

polyhexamethylene biguanide hydrochloride:

Result : Skin irritation
Remarks : Irritating to skin.

subtilisin:

Method : OECD Test Guideline 404
Result : Skin irritation

Serious eye damage/eye irritation

Causes serious eye damage.

Components:

Poly(oxy-1,2-ethanediyl), .alpha.-tridecyl-.omega.-hydroxy-, branched:

Species : Rabbit
Method : Draize Test
Result : Irreversible effects on the eye

didecyldimethylammonium chloride:

Result : Irreversible effects on the eye

propan-2-ol:

SAFETY DATA SHEET

According to REACH etc. (Amendment etc.) (EU Exit) Regulations
2019

schülke 

gigazyme® X-tra *No Change Service!*

Version
02.08

Revision Date:
06.09.2022

Date of last issue: 16.05.2022

|||Result : Eye irritation

polyhexamethylene biguanide hydrochloride:

|||Result : Eye irritation
|||Remarks : May irritate eyes.

subtilisin:

|||Method : OECD Test Guideline 405
|||Result : Irreversible effects on the eye

Respiratory or skin sensitisation

Skin sensitisation

Not classified based on available information.

Respiratory sensitisation

Not classified based on available information.

Components:

Poly(oxy-1,2-ethanediyl), .alpha.-tridecyl-.omega.-hydroxy-, branched:

|||Test Type : Maximisation Test
|||Species : Guinea pig
|||Result : Did not cause sensitisation on laboratory animals.

didecyldimethylammonium chloride:

|||Test Type : Buehler Test
|||Species : Guinea pig
|||Method : OECD Test Guideline 406
|||Result : Did not cause sensitisation on laboratory animals.
|||GLP : yes

propan-2-ol:

|||Test Type : Buehler Test
|||Species : Guinea pig
|||Result : Did not cause sensitisation on laboratory animals.

polyhexamethylene biguanide hydrochloride:

|||Exposure routes : Dermal
|||Result : May cause sensitisation by skin contact.
|||Remarks : May cause sensitisation of susceptible persons by skin contact.

subtilisin:

|||Result : Probability of respiratory sensitisation in humans based on animal testing
|||Remarks : largely based on human evidence

SAFETY DATA SHEET

According to REACH etc. (Amendment etc.) (EU Exit) Regulations
2019

schülke 

gigazyme® X-tra *No Change Service!*

Version
02.08

Revision Date:
06.09.2022

Date of last issue: 16.05.2022

Germ cell mutagenicity

Not classified based on available information.

Components:

Poly(oxy-1,2-ethanediyl), .alpha.-tridecyl-.omega.-hydroxy-, branched:

Genotoxicity in vitro : Test Type: Microbial mutagenesis assay (Ames test)
Test system: Salmonella typhimurium
Metabolic activation: with and without metabolic activation
Result: negative

didecyldimethylammonium chloride:

Genotoxicity in vitro : Test system: Salmonella typhimurium
Metabolic activation: Metabolic activation
Method: OECD Test Guideline 471
Result: Not mutagenic in Ames Test

Genotoxicity in vivo : Test Type: Mutagenicity (in vivo mammalian bone-marrow
cytogenetic test, chromosomal analysis)
Species: Rat
Application Route: Oral
Method: OECD Test Guideline 475
Result: negative

Germ cell mutagenicity- Assessment : Animal testing did not show any mutagenic effects.

propan-2-ol:

Genotoxicity in vitro : Test Type: Ames test
Method: Mutagenicity (Escherichia coli - reverse mutation
assay)
Result: Non mutagenic

Genotoxicity in vivo : Species: Mouse
Method: Mutagenicity (micronucleus test)
Result: Non mutagenic

Germ cell mutagenicity- Assessment : Not mutagenic in Ames Test

polyhexamethylene biguanide hydrochloride:

Germ cell mutagenicity- Assessment : No data available

subtilisin:

Genotoxicity in vitro : Method: OECD Test Guideline 471
Result: Non mutagenic

Germ cell mutagenicity- Assessment : Animal testing did not show any mutagenic effects.

SAFETY DATA SHEET

According to REACH etc. (Amendment etc.) (EU Exit) Regulations
2019

schülke 

gigazyme® X-tra **No Change Service!**

Version
02.08

Revision Date:
06.09.2022

Date of last issue: 16.05.2022

Carcinogenicity

Not classified based on available information.

Components:

Poly(oxy-1,2-ethanediyl), .alpha.-tridecyl-.omega.-hydroxy-, branched:

Remarks : This information is not available.

didecyldimethylammonium chloride:

Carcinogenicity - Assessment : Animal testing did not show any carcinogenic effects.

propan-2-ol:

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

polyhexamethylene biguanide hydrochloride:

Carcinogenicity - Assessment : Limited evidence of a carcinogenic effect.

subtilisin:

Carcinogenicity - Assessment : No data available

Reproductive toxicity

Not classified based on available information.

Components:

Poly(oxy-1,2-ethanediyl), .alpha.-tridecyl-.omega.-hydroxy-, branched:

Effects on fertility : Remarks: Animal testing did not show any effects on fertility.

Effects on foetal development : Remarks: No effects on fertility and early embryonic development were detected.

didecyldimethylammonium chloride:

Reproductive toxicity - Assessment : No data available

propan-2-ol:

Effects on foetal development : Species: Rat
Application Route: Oral
General Toxicity Maternal: NOAEL: 400 mg/kg body weight

Reproductive toxicity - Assessment : Based on available data, the classification criteria are not met.

polyhexamethylene biguanide hydrochloride:

Reproductive toxicity - Assessment : Did not show teratogenic effects in animal experiments.

SAFETY DATA SHEET

According to REACH etc. (Amendment etc.) (EU Exit) Regulations
2019

schülke 

gigazyme® X-tra **No Change Service!**

Version
02.08

Revision Date:
06.09.2022

Date of last issue: 16.05.2022

||

subtilisin:

|| Reproductive toxicity - As- : No data available
|| sessment

STOT - single exposure

Not classified based on available information.

Components:

Poly(oxy-1,2-ethanediyl), .alpha.-tridecyl-.omega.-hydroxy-, branched:

|| Remarks : No data available

didecyldimethylammonium chloride:

|| Remarks : No data available

propan-2-ol:

|| Assessment : May cause drowsiness or dizziness.

polyhexamethylene biguanide hydrochloride:

|| Assessment : No data available

subtilisin:

|| Target Organs : Respiratory Tract
|| Assessment : May cause respiratory irritation.

STOT - repeated exposure

Not classified based on available information.

Components:

Poly(oxy-1,2-ethanediyl), .alpha.-tridecyl-.omega.-hydroxy-, branched:

|| Remarks : No data available

didecyldimethylammonium chloride:

|| Remarks : No data available

propan-2-ol:

|| Remarks : Based on available data, the classification criteria are not met.

polyhexamethylene biguanide hydrochloride:

|| Assessment : Causes damage to organs through prolonged or repeated exposure.

SAFETY DATA SHEET

According to REACH etc. (Amendment etc.) (EU Exit) Regulations
2019

schülke 

gigazyme® X-tra *No Change Service!*

Version
02.08

Revision Date:
06.09.2022

Date of last issue: 16.05.2022

Repeated dose toxicity

Components:

Poly(oxy-1,2-ethanediyl), .alpha.-tridecyl-.omega.-hydroxy-, branched:

Species	: Rat
NOAEL	: 50 mg/kg
Application Route	: Oral
Exposure time	: 2 yr
Target Organs	: Heart, Liver, Kidney

didecyldimethylammonium chloride:

Remarks	: No data available
---------	---------------------

propan-2-ol:

Remarks	: No data available
---------	---------------------

polyhexamethylene biguanide hydrochloride:

Remarks	: Toxic: danger of serious damage to health by prolonged exposure through inhalation.
---------	---

Aspiration toxicity

Not classified based on available information.

Further information

Product:

Remarks	: The product has not been tested.
---------	------------------------------------

SECTION 12: Ecological information

12.1 Toxicity

Components:

Poly(oxy-1,2-ethanediyl), .alpha.-tridecyl-.omega.-hydroxy-, branched:

Toxicity to fish	: LC50 (Danio rerio (zebra fish)): 2.5 mg/l Exposure time: 96 h
Toxicity to daphnia and other aquatic invertebrates	: EC50 (Daphnia magna (Water flea)): 1.5 mg/l Exposure time: 48 h
Toxicity to algae/aquatic plants	: ErC50 (Desmodesmus subspicatus (green algae)): 2.5 mg/l Exposure time: 72 h EC10 (Desmodesmus subspicatus (green algae)): 0.6 mg/l Exposure time: 72 h Method: OECD Test Guideline 201
Toxicity to fish (Chronic toxicity)	: NOEC: 1.73 mg/l Method: QSAR

SAFETY DATA SHEET

According to REACH etc. (Amendment etc.) (EU Exit) Regulations
2019

schülke 

gigazyme® X-tra *No Change Service!*

Version
02.08

Revision Date:
06.09.2022

Date of last issue: 16.05.2022

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC: 1.36 mg/l
Exposure time: 21 d
Species: Daphnia magna (Water flea)
Method: QSAR

didecyldimethylammonium chloride:

Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): 0.19 mg/l
Exposure time: 96 h
GLP: yes

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 0.062 mg/l
Exposure time: 48 h
GLP: yes

Toxicity to algae/aquatic plants : ErC50 (Pseudokirchneriella subcapitata (green algae)): 0.026 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 201
GLP: yes

M-Factor (Acute aquatic toxicity) : 10

Toxicity to fish (Chronic toxicity) : NOEC: 0.032 mg/l
Exposure time: 34 d
Species: Danio rerio (zebra fish)
Method: OECD Test Guideline 210

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC: 0.014 mg/l
Exposure time: 21 d
Species: Daphnia magna (Water flea)
Method: Expert judgement and weight of evidence determination.

M-Factor (Chronic aquatic toxicity) : 1

propan-2-ol:

Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): 9,640 mg/l
Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 10,000 mg/l
Exposure time: 48 h

Toxicity to algae/aquatic plants : EC50 (Desmodesmus subspicatus (green algae)): > 100 mg/l
Exposure time: 72 h
Test Type: static test

EC50 (green algae): 1,800 mg/l
Exposure time: 7 d

polyhexamethylene biguanide hydrochloride:

SAFETY DATA SHEET

According to REACH etc. (Amendment etc.) (EU Exit) Regulations
2019

schülke 

gigazyme® X-tra **No Change Service!**

Version
02.08

Revision Date:
06.09.2022

Date of last issue: 16.05.2022

Toxicity to fish	:	LC50 (Oncorhynchus mykiss): 0.026 mg/l Exposure time: 96 h
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia magna (Water flea)): 0.09 mg/l Exposure time: 48 h Method: OECD Test Guideline 202
Toxicity to algae/aquatic plants	:	ErC50 (Pseudokirchneriella subcapitata (green algae)): 0.019 mg/l Exposure time: 72 h Method: OECD Test Guideline 201
M-Factor (Acute aquatic toxicity)	:	10
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	:	NOEC: 0.0084 mg/l Exposure time: 21 d Species: Daphnia magna (Water flea) Method: OECD Test Guideline 211
M-Factor (Chronic aquatic toxicity)	:	10

subtilisin:

Toxicity to fish	:	LC50 (Fish): 8.2 mg/l Exposure time: 96 h Method: OECD Test Guideline 203
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia magna): 0.586 mg/l Exposure time: 48 h Method: OECD Test Guideline 202
Toxicity to algae/aquatic plants	:	ErC50 (algae): 0.83 mg/l Exposure time: 72 h Method: OECD Test Guideline 201 NOEC (Pseudokirchneriella subcapitata (green algae)): 0.041 mg/l Exposure time: 72 h
M-Factor (Acute aquatic toxicity)	:	1
Toxicity to fish (Chronic toxicity)	:	NOEC: 0.017 mg/l Exposure time: 32 d Species: Pimephales promelas (fathead minnow) Method: OECD Test Guideline 210
M-Factor (Chronic aquatic toxicity)	:	1

glycerol:

Toxicity to fish	:	LC50 (Oncorhynchus mykiss): 54,000 mg/l
------------------	---	---

SAFETY DATA SHEET

According to REACH etc. (Amendment etc.) (EU Exit) Regulations
2019

schülke -+

gigazyme® X-tra **No Change Service!**

Version
02.08

Revision Date:
06.09.2022

Date of last issue: 16.05.2022

Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): > 10,000 mg/l
Exposure time: 24 h

12.2 Persistence and degradability

Product:

Biodegradability : Result: Readily biodegradable, according to appropriate OECD test.
Method: OECD 301D / EEC 84/449 C6

Components:

Poly(oxy-1,2-ethanediyl), .alpha.-tridecyl-.omega.-hydroxy-, branched:

Biodegradability : Test Type: aerobic
Inoculum: activated sludge
Result: Readily biodegradable.
Biodegradation: > 60 %
Exposure time: 28 d
Method: OECD Test Guideline 301B

didecyldimethylammonium chloride:

Biodegradability : Concentration: 10 mg/l
Result: Readily biodegradable.
Biodegradation: 72 %
Exposure time: 28 d
Method: OECD 301B/ ISO 9439/ EEC 84/449 C5
GLP: yes

propan-2-ol:

Biodegradability : Result: Readily biodegradable.

polyhexamethylene biguanide hydrochloride:

Biodegradability : Result: Not readily biodegradable.

subtilisin:

Biodegradability : Result: Readily biodegradable.
Method: OECD Test Guideline 301B

12.3 Bioaccumulative potential

Components:

Poly(oxy-1,2-ethanediyl), .alpha.-tridecyl-.omega.-hydroxy-, branched:

Bioaccumulation : Remarks: None reasonably foreseeable.

Partition coefficient: n-octanol/water : Remarks: Not applicable

SAFETY DATA SHEET

According to REACH etc. (Amendment etc.) (EU Exit) Regulations
2019

schülke 

gigazyme® X-tra *No Change Service!*

Version
02.08

Revision Date:
06.09.2022

Date of last issue: 16.05.2022

didecyldimethylammonium chloride:

Bioaccumulation : Species: *Lepomis macrochirus* (Bluegill sunfish)
Exposure time: 46 d
Bioconcentration factor (BCF): 81

propan-2-ol:

Bioaccumulation : Remarks: No bioaccumulation is to be expected (log Pow <= 4).
Partition coefficient: n-octanol/water : log Pow: 0.05 (20 °C)
Method: OECD Test Guideline 107

polyhexamethylene biguanide hydrochloride:

Bioaccumulation : Remarks: Bioaccumulation is unlikely.

subtilisin:

Bioaccumulation : Remarks: Does not bioaccumulate.
Partition coefficient: n-octanol/water : log Pow: < 0

glycerol:

Partition coefficient: n-octanol/water : log Pow: -1.75 (25 °C)
Method: OECD Test Guideline 107

12.4 Mobility in soil

Components:

Poly(oxy-1,2-ethanediyl), .alpha.-tridecyl-.omega.-hydroxy-, branched:

Mobility : Remarks: No data available

didecyldimethylammonium chloride:

Mobility : Remarks: Mobile in soils

propan-2-ol:

Mobility : Remarks: Mobile in soils

polyhexamethylene biguanide hydrochloride:

Mobility : Remarks: After release, adsorbs onto soil.

subtilisin:

Mobility : Remarks: No data available

12.5 Results of PBT and vPvB assessment

Product:

SAFETY DATA SHEET

According to REACH etc. (Amendment etc.) (EU Exit) Regulations
2019

schülke 

gigazyme® X-tra **No Change Service!**

Version
02.08

Revision Date:
06.09.2022

Date of last issue: 16.05.2022

Assessment : This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

Components:

polyhexamethylene biguanide hydrochloride:

Assessment : This substance is not considered to be persistent, bioaccumulating and toxic (PBT).. This substance is not considered to be very persistent and very bioaccumulating (vPvB).

12.6 Other adverse effects

Product:

Endocrine disrupting potential : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Additional ecological information : No data is available on the product itself.

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product : Disposal together with normal waste is not allowed. Special disposal required according to local regulations.

Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal.

SECTION 14: Transport information

14.1 UN number

ADR : UN 3082

IMDG : UN 3082

IATA : UN 3082

14.2 UN proper shipping name

ADR : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.
(didecyldimethylammonium chloride)

IMDG : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.
(didecyldimethylammonium chloride)

SAFETY DATA SHEET

According to REACH etc. (Amendment etc.) (EU Exit) Regulations
2019

schülke 

gigazyme® X-tra *No Change Service!*

Version
02.08

Revision Date:
06.09.2022

Date of last issue: 16.05.2022

IATA : Environmentally hazardous substance, liquid, n.o.s.
(didecyldimethylammonium chloride)

14.3 Transport hazard class(es)

ADR : 9

IMDG : 9

IATA : 9

14.4 Packing group

ADR

Packing group : III
Classification Code : M6
Hazard Identification Number : 90
Labels : 9
Tunnel restriction code : (-)

IMDG

Packing group : III
Labels : 9
EmS Code : F-A, S-F

IATA (Cargo)

Packing instruction (cargo aircraft) : 964
Packing instruction (LQ) : Y964
Packing group : III
Labels : Miscellaneous

IATA (Passenger)

Packing instruction (passenger aircraft) : 964
Packing instruction (LQ) : Y964
Packing group : III
Labels : Miscellaneous

14.5 Environmental hazards

ADR

Environmentally hazardous : yes

IMDG

Marine pollutant : yes

14.6 Special precautions for user

Remarks : Not classified as supporting combustion according to the transport regulations.

The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

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

Not applicable for product as supplied.

SAFETY DATA SHEET

According to REACH etc. (Amendment etc.) (EU Exit) Regulations
2019

schülke 

gigazyme® X-tra **No Change Service!**

Version
02.08

Revision Date:
06.09.2022

Date of last issue: 16.05.2022

SECTION 15: Regulatory information

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

Relevant EU provisions transposed through retained EU law

UK REACH List of restrictions (Annex 17)	:	Conditions of restriction for the following entries should be considered: Number on list 3
UK REACH Candidate list of substances of very high concern (SVHC) for Authorisation	:	Not applicable
The Persistent Organic Pollutants Regulations (retained Regulation (EU) 2019/1021 as amended for Great Britain)	:	Not applicable
Regulation (EC) No 1005/2009 on substances that deplete the ozone layer	:	Not applicable
UK REACH List of substances subject to authorisation (Annex XIV)	:	Not applicable
Volatile organic compounds	:	Directive 2010/75/EU of 24 November 2010 on industrial emissions (integrated pollution prevention and control) Volatile organic compounds (VOC) content: 3.02 %
according to Detergents Regulation EC 648/2004	:	5 % or over but less than 15 %: Non-ionic surfactants Other constituents: Enzymes, Perfumes

Other regulations:

The components of this product are reported in the following inventories:

TCSI	:	On the inventory, or in compliance with the inventory
TSCA	:	Product contains substance(s) not listed on TSCA inventory.
AIIC	:	All components are listed on the inventory, regulatory obligations/restrictions apply
DSL	:	This product contains the following components listed on the Canadian NDSL. All other components are on the Canadian DSL. 4-formylphenylboronic acid reaction mass of cis-and trans-cyclohexadec-8-en-1-one
ENCS	:	Not in compliance with the inventory
ISHL	:	Not in compliance with the inventory
KECI	:	On the inventory, or in compliance with the inventory
PICCS	:	Not in compliance with the inventory

SAFETY DATA SHEET

According to REACH etc. (Amendment etc.) (EU Exit) Regulations
2019

schülke 

gigazyme® X-tra *No Change Service!*

Version
02.08

Revision Date:
06.09.2022

Date of last issue: 16.05.2022

IECSC	:	On the inventory, or in compliance with the inventory
NZIoC	:	Not in compliance with the inventory
TECI	:	Not in compliance with the inventory

15.2 Chemical safety assessment

Exempt

SECTION 16: Other information

Full text of H-Statements

H225	:	Highly flammable liquid and vapour.
H301	:	Toxic if swallowed.
H302	:	Harmful if swallowed.
H314	:	Causes severe skin burns and eye damage.
H315	:	Causes skin irritation.
H317	:	May cause an allergic skin reaction.
H318	:	Causes serious eye damage.
H319	:	Causes serious eye irritation.
H330	:	Fatal if inhaled.
H334	:	May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H335	:	May cause respiratory irritation.
H336	:	May cause drowsiness or dizziness.
H351	:	Suspected of causing cancer.
H372	:	Causes damage to organs through prolonged or repeated exposure if inhaled.
H400	:	Very toxic to aquatic life.
H410	:	Very toxic to aquatic life with long lasting effects.
H411	:	Toxic to aquatic life with long lasting effects.
H412	:	Harmful to aquatic life with long lasting effects.

Full text of other abbreviations

Acute Tox.	:	Acute toxicity
Aquatic Acute	:	Short-term (acute) aquatic hazard
Aquatic Chronic	:	Long-term (chronic) aquatic hazard
Carc.	:	Carcinogenicity
Eye Dam.	:	Serious eye damage
Eye Irrit.	:	Eye irritation
Flam. Liq.	:	Flammable liquids
Resp. Sens.	:	Respiratory sensitisation
Skin Corr.	:	Skin corrosion
Skin Irrit.	:	Skin irritation
Skin Sens.	:	Skin sensitisation
STOT RE	:	Specific target organ toxicity - repeated exposure
STOT SE	:	Specific target organ toxicity - single exposure
GB EH40	:	UK. EH40 WEL - Workplace Exposure Limits
GB EH40 / TWA	:	Long-term exposure limit (8-hour TWA reference period)
GB EH40 / STEL	:	Short-term exposure limit (15-minute reference period)

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by Road; AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Test-

SAFETY DATA SHEET

According to REACH etc. (Amendment etc.) (EU Exit) Regulations
2019

schülke 

gigazyme® X-tra **No Change Service!**

Version
02.08

Revision Date:
06.09.2022

Date of last issue: 16.05.2022

ing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of very high concern; TCSI - Taiwan Chemical Substance Inventory; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

Further information

Classification of the mixture:

Acute Tox. 4	H302
Skin Corr. 1B	H314
Eye Dam. 1	H318
Aquatic Acute 1	H400
Aquatic Chronic 2	H411

Classification procedure:

Calculation method
Calculation method
Calculation method
Calculation method
Calculation method

Changes since the last version are highlighted in the margin. This version replaces all previous versions.

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.