

SAFETY DATA SHEET

(REACH regulation (EC) n° 1907/2006 - n° 453/2010)

SECTION 1 : IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1. Product identifier

Product name : GIGAZYME® PLUS³
Product code : 2492000

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

Cleaning and pre-disinfection of medical devices
For further information on product indication, please see the label.

1.3. Details of the supplier of the safety data sheet

Registered company name : SCHULKE & MAYR UK LTD.
Address : Cygent House 1 Jenkin Rd Meadowhall..Sheffield S9 1AT.UK.
Telephone : + 44 (0)114 254 35 00. Fax : + 44 (0)114 254 35 01.
mail.uk@schulke-mayr.com

1.4. Emergency telephone number : + 33 (0)1 45 42 59 59.

Association/Organisation : INRS .

SECTION 2 : HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture

In compliance with EC regulation No. 1272/2008 and its amendments.

Skin irritation, Category 2 (Skin Irrit. 2, H315).
Serious eye damage, Category 1 (Eye Dam. 1, H318).
Specific target organ toxicity (repeated exposure), Category 2 (STOT RE 2, H373).
Hazardous to the aquatic environment - Acute hazard, Category 1 (Aquatic Acute 1, H400).
Hazardous to the aquatic environment - Chronic hazard, Category 2 (Aquatic Chronic 2, H411).
This mixture does not present a physical hazard. Refer to the recommendations regarding the other products present on the site.

In compliance with directives 67/548/EEC, 1999/45/EC and their amendments.

Acute oral toxicity: harmful (Xn, R 22).
Serious effects after prolonged or repeated oral exposure: harmful (Xn, R 48/22).
Skin irritation (Xi, R 38).
Serious eye damage (Xi, R 41).
Aquatic environmental hazard, acute toxicity: very toxic (N, R 50).
This mixture does not present a physical hazard. Refer to the recommendations regarding the other products present on the site.

2.2. Label elements

Detergent mixture (see section 15).
This mixture being intended for professional use only, the labelling for contents under detergent regulation does not appear on the label but is resumed in section 15

In compliance with EC regulation No. 1272/2008 and its amendments.

Hazard pictograms :



GHS05



GHS09



GHS08

Signal Word :

DANGER

Product identifiers :

EC 292-562-0

CAS 71060-57-6

CAS 894406-76-9

AMINES, N-C12-14-ALKYLTRIMETHYLENEDI-
ALKYL POLYGLYCOL ETHER C8-10 WITH EO
N N-DIDECYL-N N-DIMETHYLAMMONIUM CARBONATE

Hazard statements :

H315

Causes skin irritation.

H318

Causes serious eye damage.

H373

May cause damage to organs through prolonged or repeated exposure (if swallowed).

H410

Very toxic to aquatic life with long lasting effects.

Precautionary statements - General :

P102 Keep out of reach of children.

Precautionary statements - Prevention :

P273 Avoid release to the environment.

P280 Wear protective gloves and eye protection/face protection.

Precautionary statements - Response :

P302 + P352 IF ON SKIN: Wash with plenty of water.

P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P310 Immediately call a POISON CENTER or doctor/physician.

Precautionary statements - Disposal :

P501 Dispose of product and its container as hazardous waste.

2.3. Other hazards

The mixture does not contain substances classified as 'Substances of Very High Concern' (SVHC) $\geq 0.1\%$ published by the European Chemicals Agency (ECHA) under article 57 of REACH: <http://echa.europa.eu/fr/candidate-list-table>
No other hazard identified in the current state of knowledge.

SECTION 3 : COMPOSITION/INFORMATION ON INGREDIENTS

Title for H, EUH and R indications: see § 16.

3.2. Mixtures

Composition :

Identification	(EC) 1272/2008	67/548/EEC	Note	%
INDEX: 016-026-00-0	GHS07	Xi		2.5 \leq x % < 10
CAS: 5329-14-6	Wng	Xi;R36/38		
EC: 226-218-8	Eye Irrit. 2, H319	R52/53		
REACH: 01-2119488633-28	Skin Irrit. 2, H315 Aquatic Chronic 3, H412			
SULPHAMIDIC ACID				
CAS: 90640-43-0	GHS06, GHS05, GHS09,	T,N		2.5 \leq x % < 10
EC: 292-562-0	GHS08	T;R48/25-R25		
REACH: 01-2119957843-25	Dgr Acute Tox. 3, H301 Skin Corr. 1B, H314 STOT RE 1, H372	C;R34 N;R50		
AMINES, N-C12-14-ALKYLTRIMET HYLENEDI-	Aquatic Acute 1, H400 M Acute = 100 Aquatic Chronic 1, H410 M Chronic = 1			
CAS: 71060-57-6	GHS07, GHS05	Xn		2.5 \leq x % < 10
ALKYL POLYGLYCOL ETHER C8-10 WITH EO	Dgr Acute Tox. 4, H302 Eye Dam. 1, H318	Xn;R22 Xi;R41		
CAS: 894406-76-9	GHS06, GHS05, GHS09	C,N		0 \leq x % < 2.5
REACH: 01-0000019102-83	Dgr Acute Tox. 3, H301 Skin Corr. 1B, H314 Aquatic Chronic 2, H411	C;R34 Xn;R22 N;R50		
N N-DIDECYL-N N-DIMETHYLAMMONIUM CARBONATE	Aquatic Acute 1, H400 M Acute = 10			
FATTY ALCOHOL ALKOXYLATE 8 / REF.NO.: 02-2119548508-30-000 0	GHS07 Wng Skin Irrit. 2, H315	Xi Xi;R38		0 \leq x % < 2.5

SECTION 4 : FIRST AID MEASURES

As a general rule, in case of doubt or if symptoms persist, always call a doctor.
NEVER induce swallowing by an unconscious person.
Reminder: any unconscious person must be placed in the lateral recovery position.

4.1. Description of first aid measures

In the event of exposure by inhalation :

Move the person away from the place of exposure and take him/her outside.

In the event of splashes or contact with eyes :

If applicable, remove contact lenses.

Wash thoroughly with soft clean water for 15 minutes, holding the eyelids open.

Take care not to introduce rinsing water in the undamaged eye.

Additional treatment to be provided immediately in an eye clinic or by an ophthalmologist.

Continue rinsing until medical advice is obtained.

In the event of splashes or contact with skin :

Remove all contaminated or stained clothing immediately. Do not use them again until they have been decontaminated.

Rinse immediately and thoroughly with water.

In the event of skin irritation, seek medical advice. Show this container or label.

In the event of swallowing :

Rinse out the mouth, do not allow to drink, do not induce vomiting. Calm the person down and transfer immediately to hospital or doctor. Show the label to the doctor.

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

Cf. § 11

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

Refer to the recommendation of the doctor.

SECTION 5 : FIREFIGHTING MEASURES

5.1. Extinguishing media

Suitable methods of extinction

Any extinguishing agents are authorized: foam, sand, carbon dioxide, water, powder.

5.2. Special hazards arising from the substance or mixture

A fire will often produce a thick black smoke. Exposure to decomposition products may be hazardous to health.

Do not breathe in smoke.

5.3. Advice for firefighters

Use autonomous insulating breathing apparatus and a full protective suit.

SECTION 6 : ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures

Consult the safety measures listed under headings 7 and 8.

Avoid all contact with skin or eyes.

6.2. Environmental precautions

Contain and control the leaks or spills with non-combustible absorbent materials such as sand, earth, vermiculite, diatomaceous earth in drums for waste disposal.

Do not get rid in natural spaces (waterways, ground and vegetations...)

6.3. Methods and material for containment and cleaning up

Absorb any spilled product with absorbent non-combustible materials, and sweep away or remove with a shovel. Put any waste in drums for disposal. Do not mix with any other waste. Wash the contaminated surface thoroughly with water.

Do not put any spill product back into its original container with the intention of re-use.

Do not get rid in natural spaces.

6.4. Reference to other sections

Disposal considerations: see section 13.

SECTION 7 : HANDLING AND STORAGE

7.1. Precautions for safe handling

Product for external use - do not swallow.

Avoid all contact with skin, eyes and clothes.

Handle in accordance with user instructions on label

Handle at a temperature not exceeding 60° C.

Recommended equipment and procedures :

- For personal protection, see section 8.
- Observe precautions stated on label and also industrial safety regulations.
- Avoid eye contact with this mixture at all times.
- Safety shower, eye bath and water point nearby.

Prohibited equipment and procedures :

No smoking, eating or drinking in areas where the mixture is used.

7.2. Conditions for safe storage, including any incompatibilities

- Keep the container tightly closed
- Keep ONLY in the original container
- Store between + 5 °C and + 35 °C in a dry, well ventilated place
- Do not use after the expiry date mentioned on the packaging.
- Keep out of the reach of children
- Store away from incompatible materials (see section 10)

7.3. Specific end use(s)

- For professional use only
- Refer to paragraph 1 for product indication

SECTION 8 : EXPOSURE CONTROLS/PERSONAL PROTECTION

The information in this chapter refers to the product specifically described in this document. If the product is handled and/or exposed simultaneously with other chemical agents, these must be taken into consideration when choosing personal safety equipment.

8.1. Control parameters

Not applicable

8.2. Exposure controls

Personal protection measures, such as personal protective equipment

- Use personal protective equipment that is clean and has been properly maintained.
- Store personal protective equipment in a clean place, away from the work area.
- Never eat, drink or smoke during use. Remove and wash contaminated clothing before re-using. Ensure that there is adequate ventilation, especially in confined areas.

- Eye / face protection

- Prescription glasses are not considered as protection.
- Make safety goggles with side protection available to the personnel.
- Provide eye washes in workshops.
- If necessary, the nearest water supply

- Hand protection

- Use suitable protective gloves that are resistant to chemical agents in accordance with standard EN374.
- Gloves must be selected according to the application and duration of use at the workstation.
- Protective gloves need to be selected according to their suitability for the workstation in question : other chemical products that may be handled, necessary physical protections (cutting, pricking, heat protection), level of dexterity required.
- Nitrile, latex or vinyl gloves.
- Gloves must be replaced immediately if they show signs of wear and tear.

- Body protection

- Avoid skin contact.
- Work clothing worn by personnel shall be laundered regularly.
- After contact with the product, all parts of the body that have been soiled must be washed.

- Respiratory protection

- Not applicable in normal conditions of use.

SECTION 9 : PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

General information :

Physical state :	Fluid liquid.
Colour:	Orange
Odour:	sweet-smelling

Important health, safety and environmental information

pH :	8.50 Slightly basic.
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Boiling point/boiling range :	Not specified.
Flash point interval :	Not relevant.
Vapour pressure (50°C) :	Not relevant.
Density :	+/- 1,2
Water solubility :	Soluble.
Melting point/melting range :	Not specified.
Self-ignition temperature :	Not specified.
Decomposition point/decomposition range :	Not specified.

9.2. Other information

No data available.

SECTION 10 : STABILITY AND REACTIVITY

10.1. Reactivity

No hazardous reaction if the instructions/indications for storage and handling are respected.

10.2. Chemical stability

This mixture is stable under the recommended handling and storage conditions in section 7.

10.3. Possibility of hazardous reactions

Cf. § 10.1 and 10.2

10.4. Conditions to avoid

Avoid :

- frost

10.5. Incompatible materials

Do not mix with other products.

10.6. Hazardous decomposition products

At high temperatures, dangerous decomposition products may be produced, such as fumes, carbon dioxide and carbon monoxide, nitrogen oxide.

SECTION 11 : TOXICOLOGICAL INFORMATION

11.1. Information on toxicological effects

11.1.1. Substances

Not specified

11.1.2. Mixture

The toxicological data of the mixture (resulting from studies or in accordance with conventional methods) are outlined below.

Acute toxicity :

Acute toxicity estimate (ATE)* :

Oral ATE : > 2000 mg/kg

* according to the method of calculation describe in the CLP regulation (Classification, Labelling, Packaging) Part 3 Chapter 3.1 based on the data of the different components present in the product.

If swallowed: burns to upper digestive and respiratory tract, abdominal pain, vomiting blood, serious lesions to mucous membranes and risk of perforation.

Skin corrosion/skin irritation :

Skin irritation: itching, light to moderate local redness, burning sensation...

Serious damage to eyes/eye irritation :

Serious eyes damage.

Burns, characterized by discomfort or pain, excessive blinking, lacrimation and redness, swelling of the conjunctiva.

SECTION 12 : ECOLOGICAL INFORMATION

Following information is based on data from the compounds.

Avoid any product release into waterways.

12.1. Toxicity

12.1.1. Substances

Not specified

12.1.2. Mixtures

Acute toxicity:

Very toxic to aquatic organisms.

Chronic toxicity:

Toxic to aquatic life with long lasting effects.

12.2. Persistence and degradability

The surfactant(s) contained in this preparation complies(comply) with the biodegradability criteria as laid down in Regulation (EC) No.648/2004 on detergents.

Data to support this assertion are held at the disposal of the competent authorities of the Member States and will be made available to them, at their direct request or at the request of a detergent manufacturer.

12.3. Bioaccumulative potential

No data available.

12.4. Mobility in soil

No data available.

12.5. Results of PBT and vPvB assessment

No data available.

12.6. Other adverse effects

No data available.

SECTION 13 : DISPOSAL CONSIDERATIONS

Proper waste management of the mixture and/or its container must be determined in accordance with Directive 2008/98/EC.

The packages must not be reused.

Do not pour into waterways.

13.1. Waste treatment methods

Waste :

Waste management is carried out without endangering human health, without harming the environment and, in particular without risk to water, air, soil, plants or animals.

Recycle or dispose of waste in compliance with current legislation, preferably via a certified collector or company.

Soiled packaging :

Empty container completely. Keep label(s) on container.

Give to a certified disposal contractor.

Codes of wastes (Decision 2001/573/EC, Directive 2006/12/EEC, Directive 94/31/EEC on hazardous waste) :

18 01 06 * chemicals consisting of or containing dangerous substances

For information :

The waste code is given for indicative purposes.

The waste code must be determined by the user, according to the application of the product.

18 = Wastes from human or animal health care and/or related research (except kitchen and restaurant wastes not arising from immediate health care)

SECTION 14 : TRANSPORT INFORMATION

Transport product in compliance with provisions of the ADR for road, RID for rail, IMDG for sea and ICAO/IATA for air transport (ADR 2013 - IMDG 2012 - ICAO/IATA 2014).

14.1. UN number

3082

14.2. UN proper shipping name

UN3082=ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.

(amines, n-c12-14-alkyltrimethylenedi-)

14.3. Transport hazard class(es)

- Classification :



9

14.4. Packing group

III

14.5. Environmental hazards

- Environmentally hazardous material :



14.6. Special precautions for user

ADR/RID	Class	Code	Pack gr.	Label	Ident.	LQ	Provis.	EQ	Cat.	Tunnel
	9	M6	III	9	90	5 L	274 335 601	E1	3	E
IMDG	Class	2°Label	Pack gr.	LQ	EMS	Provis.	EQ			
	9	-	III	5 L	F-A,S-F	274 335	E1			
IATA	Class	2°Label	Pack gr.	Passager	Passager	Cargo	Cargo	note	EQ	
	9	-	III	964	450 L	964	450 L	A97 A158	E1	
	9	-	III	Y964	30 kg G	-	-	A97 A158	E1	

For limited quantities, see part 2.7 of the OACI/IATA and chapter 3.4 of the ADR and IMDG.

For excepted quantities, see part 2.6 of the OACI/IATA and chapter 3.5 of the ADR and IMDG.

14.7. Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code

Not applicable

SECTION 15 : REGULATORY INFORMATION

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

- Labelling for detergents (EC Regulation No. 648/2004,907/2006) :

- 5 % or over but less than 15 % : nonionic surfactants
- enzymes
- disinfectants
- perfumes

15.2. Chemical safety assessment

Information from the chemical safety assessment of substances present in the product is included in the appropriate sections of this safety data sheet, whenever necessary.

SECTION 16 : OTHER INFORMATION

Since the user's working conditions are not known by us, the information supplied on this safety data sheet is based on our current level of knowledge and on national and community regulations.

It is at all times the responsibility of the user to take all necessary measures to comply with legal requirements and local regulations.

The information in this safety data sheet must be regarded as a description of the safety requirements relating to the mixture.

It is recommended that the information contained in this safety data sheet is provided to the users, if necessary in an appropriate form.

This information relates to the specifically designated product and may not be valid in combination with any another product. The product must not be used for applications other than those specified in heading 1 without having first obtained written handling instructions.

Title for H, EUH and R indications mentioned in section 3 :

H301	Toxic if swallowed.
H302	Harmful if swallowed.
H314	Causes severe skin burns and eye damage.
H315	Causes skin irritation.
H318	Causes serious eye damage.
H319	Causes serious eye irritation.
H372	Causes damage to organs through prolonged or repeated exposure .
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.
R 22	Harmful if swallowed.
R 25	Toxic if swallowed.
R 34	Causes burns.
R 36/38	Irritating to eyes and skin.
R 38	Irritating to skin.
R 41	Risk of serious damage to eyes.
R 48/25	Toxic; danger of serious damage to health by prolonged exposure if swallowed.
R 50	Very toxic to aquatic organisms.
R 52/53	Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

Abbreviations :

ADR : European agreement concerning the international carriage of dangerous goods by Road.
IMDG : International Maritime Dangerous Goods.
IATA : International Air Transport Association.
ICAO : International Civil Aviation Organisation
RID : Regulations concerning the International carriage of Dangerous goods by rail.
GHS05 : Corrosion
GHS08 : Health hazard
GHS09 : Environment