# GAMAZYME FC

## Wilhelmsen Ships Service AS* Central Warehouse

Part Number: **659391**
Version No: **8.14**
Safety Data Sheet (Conforms to Annex II of REACH (1907/2006) - Regulation 2020/878)

Initial Date: **24/11/2017**
Revision Date: **21/06/2024**
Print Date: **18/02/2026**
L.REACH.HRV.EN

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

### 1.1. Product Identifier

| | |
|---|---|
| **Product name** | GAMAZYME FC |
| **Chemical Name** | Not Applicable |
| **Synonyms** | Product Part Number: 659391 (4 x 5 liter) |
| **Chemical formula** | Not Applicable |
| **Other means of identification** | 659391 \| UFI: 9P5W-0VS4-X101-8N8D |

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

| | | |
|---|---|---|
| **Chemical Product Category** | PC35 | Washing and cleaning products |
| **Sectors of Use** | SU22 | Professional uses |
| | SU3 | Industrial uses |
| **Relevant identified uses** | Liquid formulation containing a mixture of microorganisms used as floor cleaner. Pr No: 54316 Norway | |
| **Uses advised against** | No specific uses advised against are identified. | |

### 1.3. Details of the manufacturer or importer of the safety data sheet

| | | |
|---|---|---|
| **Manufacturer/Supplier** | **Wilhelmsen Ships Service AS* Central Warehouse** | **Outback (M)SDS portal: https://jr.chemwatch.net/outb/account/autologin?login=wilhelmsen** |
| **Address** | Willem Barentszstraat 50 Rotterdam 3165AB Netherlands | --------- Use our Outback portal to obtain our (M)SDSs in other languages and/or format. --------- For questions relating to our SDSs, please use Email: WSS.GLOBAL.SDSINFO@wilhelmsen.com --------- Norway |
| **Telephone** | +31 10 4877 777 | Not Available |
| **Fax** | Not Available | Not Available |
| **Website** | https://www.wilhelmsen.com/ | https://www.wilhelmsen.com |
| **Email** | wss.rotterdam@wilhelmsen.com | wss.global.sdsinfo@wilhelmsen.com |

### 1.4. Emergency telephone number

| | | | |
|---|---|---|---|
| **Association / Organisation** | **Croatian Institute of Public Health, Division for Toxicology** | **Dutch nat. poison centre** | **24hrs - Chemwatch** |
| **Emergency telephone number(s)** | **+3851 2348 342** | **+ 31 88 7558561** | **+31-10-4877700** |
| **Other emergency telephone number(s)** | **Not Available** | **+ 31 10 4877700** | **+31-10-4877700** |

| | |
|---|---|
| **Association / Organisation** | **CHEMWATCH EMERGENCY RESPONSE (24/7)** |
| **Emergency telephone number(s)** | **+61 3 9573 3188 (ID#: 9-221918)** |
| **Other emergency telephone number(s)** | **Not Available** |

**Page 1 continued...**

## SECTION 2 Hazards identification

### 2.1. Classification of the substance or mixture

| | |
|---|---|
| **Classification according to regulation (EC) No 1272/2008 [CLP] and amendments [1]** | H318 - Serious Eye Damage/Eye Irritation Category 1 |
| ***Legend:*** | ***1. Classified by Chemwatch; 2. Classification drawn from Regulation (EU) No 1272/2008 - Annex VI*** |

### 2.2. Label elements

| | |
|---|---|
| **Hazard pictogram(s)** |  |
| **Signal word** | **Danger** |

### Hazard statement(s)

| | |
|---|---|
| **H318** | Causes serious eye damage. |

### Supplementary statement(s)

| | |
|---|---|
| **EUH208** | Contains lipase. May produce an allergic reaction. |

### Precautionary statement(s) General

| | |
|---|---|
| **P101** | If medical advice is needed, have product container or label at hand. |
| **P102** | Keep out of reach of children. |
| **P103** | Read carefully and follow all instructions. |

### Precautionary statement(s) Prevention

| | |
|---|---|
| **P280** | Wear protective gloves/protective clothing/eye protection/face protection. |

### Precautionary statement(s) Response

| | |
|---|---|
| **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/doctor/physician/first aider. |

### Precautionary statement(s) Storage

Not Applicable

### Precautionary statement(s) Disposal

Not Applicable

Material contains Polyethoxylated alcohols, sodium lauryl ether sulfate, lipase, EDTA tetrasodium salt.

### 2.3. Other hazards

| | |
|---|---|
| **1,2-benzisothiazoline-3-one** | Determined to have endocrine-disrupting properties according to Europe Regulation (EU) 528/2012, Europe Regulation (EU) 2017/2100, and Europe Regulation (EU) 2018/605. |

This substance/mixture does not meet the criteria for classification as Persistent, Bioaccumulative, and Toxic (PBT) in accordance with Annex XIII, Commission Delegated Regulation (EU) 2017/2100, and Commission Regulation (EU) 2018/605.

This substance/mixture does not meet the criteria for classification as very Persistent and very Bioaccumulative (vPvB) in accordance with Annex XIII, Commission Delegated Regulation (EU) 2017/2100, and Commission Regulation (EU) 2018/605.

This substance/mixture does not meet the criteria for classification as Persistent, Mobile and Toxic (PMT) in accordance with Commission Delegated Regulation (EU) 2023/707.

This substance/mixture does not meet the criteria for classification as very Persistent and very Mobile (vPvM) in accordance with Commission Delegated Regulation (EU) 2023/707.

No further product hazard information.

**Continued...**

## SECTION 3 Composition / information on ingredients

### 3.1.Substances

See 'Composition on ingredients' in Section 3.2

### 3.2.Mixtures

| 1. CAS No<br>2.EC No<br>3.Index No<br>4.REACH No | %[weight] | Name | Classification according to regulation (EC) No 1272/2008 [CLP] and amendments | SCL / M-Factor | Nanoform Particle Characteristics |
|---|---|---|---|---|---|
| 1. 68439-46-3<br>2.Not Available<br>3.Not Available<br>4.Not Available | <5 | Polyethoxylated alcohols | Acute Toxicity (Oral) Category 4, Serious Eye Damage/Eye Irritation Category 1; H302, H318 [1] | SCL: Not Available<br>Acute M factor: Not Applicable<br>Chronic M factor: Not Applicable | Not Available |
| 1. 9001-62-1<br>2.232-619-9<br>3.Not Available<br>4.Not Available | <1 | lipase | Sensitisation (Respiratory) Category 1; H334 [1] | SCL: Not Available<br>Acute M factor: Not Applicable<br>Chronic M factor: Not Applicable | Not Available |
| 1. 2634-33-5<br>2.220-120-9<br>3.613-088-00-6<br>4.Not Available | <0,1 | 1,2-benzisothiazoline-3-one **[e]** | Acute Toxicity (Oral) Category 4, Skin Corrosion/Irritation Category 2, Sensitisation (Skin) Category 1, Serious Eye Damage/Eye Irritation Category 1, Hazardous to the Aquatic Environment Acute Hazard Category 1; H302, H315, H317, H318, H400 [2] | inhalation: ATE = 0,21 mg/L (dusts or mists) \| oral: ATE = 450 mg/kg bw \| Skin Sens. 1A; H317: C ≥ 0,036 % \| M = 1 \| M = 1<br>Acute M factor: 10<br>Chronic M factor: Not Applicable | Not Available |
| 1. 9004-82-4<br>2.Not Available<br>3.Not Available<br>4.Not Available | 1-2 | sodium lauryl ether sulfate | Acute Tox. 4, Serious Eye Damage/Eye Irritation Category 2; H302, H319 [3] | SCL: Not Available<br>Acute M factor: Not Applicable<br>Chronic M factor: Not Applicable | Not Available |
| 1. 64-02-8<br>2.200-573-9<br>3.607-428-00-2<br>4.None | <1 | EDTA tetrasodium salt | Acute Toxicity (Oral) Category 4, Serious Eye Damage/Eye Irritation Category 1; H302, H318 [2] | SCL: Not Available<br>Acute M factor: Not Applicable<br>Chronic M factor: Not Applicable | Not Available |

| | |
|---|---|
| ***Legend:*** | ***1. Classified by Chemwatch; 2. Classification drawn from Regulation (EU) No 1272/2008 - Annex VI; 3. Classification drawn from C&L; * EU IOELVs available; [e] Substance identified as having endocrine disrupting properties*** |

## SECTION 4 First aid measures

### 4.1. Description of first aid measures

| | |
|---|---|
| **Eye Contact** | If this product comes in contact with the eyes:<br>▸ Immediately hold eyelids apart and flush the eye continuously with running water.<br>▸ Ensure complete irrigation of the eye by keeping eyelids apart and away from eye and moving the eyelids by occasionally lifting the upper and lower lids.<br>▸ Continue flushing until advised to stop by the Poisons Information Centre or a doctor, or for at least 15 minutes.<br>▸ Transport to hospital or doctor without delay.<br>▸ Removal of contact lenses after an eye injury should only be undertaken by skilled personnel. |
| **Skin Contact** | If skin or hair contact occurs:<br>▸ Flush skin and hair with running water (and soap if available).<br>▸ Seek medical attention in event of irritation. |
| **Inhalation** | ▸ If fumes, aerosols or combustion products are inhaled remove from contaminated area.<br>▸ Other measures are usually unnecessary. |
| **Ingestion** | ▸ Immediately give a glass of water.<br>▸ First aid is not generally required. If in doubt, contact a Poisons Information Centre or a doctor. |

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

**Continued...**

See Section 11

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

Treat symptomatically.

## SECTION 5 Firefighting measures

### 5.1. Extinguishing media

- There is no restriction on the type of extinguisher which may be used.
- Use extinguishing media suitable for surrounding area.

### 5.2. Special hazards arising from the substrate or mixture

| | |
|---|---|
| **Fire Incompatibility** | None known. |

### 5.3. Advice for firefighters

| | |
|---|---|
| **Fire Fighting** | - Alert Fire Brigade and tell them location and nature of hazard.<br>- Wear breathing apparatus plus protective gloves in the event of a fire.<br>- Prevent, by any means available, spillage from entering drains or water courses.<br>- Use fire fighting procedures suitable for surrounding area.<br>- **DO NOT** approach containers suspected to be hot.<br>- Cool fire exposed containers with water spray from a protected location.<br>- If safe to do so, remove containers from path of fire. |
| **Fire/Explosion Hazard** | - Non combustible.<br>- Not considered a significant fire risk, however containers may burn.<br>May emit corrosive fumes. |

## SECTION 6 Accidental release measures

### 6.1. Personal precautions, protective equipment and emergency procedures

See section 8

### 6.2. Environmental precautions

See section 12

### 6.3. Methods and material for containment and cleaning up

| | |
|---|---|
| **Minor Spills** | - Clean up all spills immediately.<br>- Avoid breathing vapours and contact with skin and eyes.<br>- Control personal contact with the substance, by using protective equipment.<br>- Contain and absorb spill with sand, earth, inert material or vermiculite.<br>- Wipe up.<br>- Place in a suitable, labelled container for waste disposal. |
| **Major Spills** | - Absorb or contain isothiazolinone liquid spills with sand, earth, inert material or vermiculite.<br>- The absorbent (and surface soil to a depth sufficient to remove all of the biocide) should be shovelled into a drum and treated with an 11% solution of sodium metabisulfite ($Na_2S_2O_5$) or sodium bisulfite ($NaHSO_3$), or 12% sodium sulfite ($Na_2SO_3$) and 8% hydrochloric acid (HCl).<br>- Glutathione has also been used to inactivate the isothiazolinones.<br>- Use 20 volumes of decontaminating solution for each volume of biocide, and let containers stand for at least 30 minutes to deactivate microbicide before disposal.<br>- If contamination of drains or waterways occurs, advise emergency services.<br>- After clean up operations, decontaminate and launder all protective clothing<br>- and equipment before storing and re-using. |

### 6.4. Reference to other sections

Personal Protective Equipment advice is contained in Section 8 of the SDS.

## SECTION 7 Handling and storage

### 7.1. Precautions for safe handling

| | |
|---|---|
| **Safe handling** | - Avoid skin contact, including inhalation.<br>- Wear protective clothing when risk of exposure occurs.<br>- Use in a well-ventilated area.<br>- Avoid contact with moisture.<br>- Avoid contact with incompatible materials.<br>- When handling, **DO NOT** eat, drink or smoke.<br>- Keep containers securely sealed when not in use. |

**Continued...**

| | |
|---|---|
| **Fire and explosion protection** | See section 5 |
| **Other information** | |

### 7.2. Conditions for safe storage, including any incompatibilities

| | |
|---|---|
| **Suitable container** | ▸ Polyethylene or polypropylene container.<br>▸ Packing as recommended by manufacturer.<br>▸ Check all containers are clearly labelled and free from leaks. |
| **Storage incompatibility** | None known |
| **Hazard categories in accordance with Regulation (EC) No 2012/18/EU (Seveso III)** | Not Available |
| **Qualifying quantity (tonnes) of dangerous substances as referred to in Article 3(10) for the application of** | Not Available |



| | | | | | | |
|---|---|---|---|---|---|---|
| + | x | o | x | + | + | + |

X — ***Must not be stored together***
0 — ***May be stored together with specific preventions***
\+ — ***May be stored together***

***Note: Depending on other risk factors, compatibility assessment based on the table above may not be relevant to storage situations, particularly where large volumes of dangerous goods are stored and handled. Reference should be made to the Safety Data Sheets for each substance or article and risks assessed accordingly.***

### 7.3. Specific end use(s)

See section 1.2

## SECTION 8 Exposure controls / personal protection

### 8.1. Control parameters

| Ingredient | DNELs<br>Exposure Pattern Worker | PNECs<br>Compartment |
|---|---|---|
| Polyethoxylated alcohols | Dermal 2080 mg/kg bw/day (Systemic, Chronic)<br>Inhalation 294 mg/m³ (Systemic, Chronic)<br>***Dermal 1250 mg/kg bw/day (Systemic, Chronic) ****<br>***Inhalation 87 mg/m³ (Systemic, Chronic) ****<br>***Oral 25 mg/kg bw/day (Systemic, Chronic) **** | 0.104 mg/L (Water (Fresh))<br>0.014 mg/L (Water - Intermittent release)<br>0.104 mg/L (Water (Marine))<br>13.7 mg/kg sediment dw (Sediment (Fresh Water))<br>13.7 mg/kg sediment dw (Sediment (Marine))<br>1 mg/kg soil dw (Soil)<br>1.4 mg/L (STP) |
| lipase | Not Available | 0.0155 mg/L (Water (Fresh))<br>0.155 mg/L (Water - Intermittent release)<br>0.00155 mg/L (Water (Marine))<br>0.00185 mg/kg soil dw (Soil)<br>65 mg/L (STP) |
| 1,2-benzisothiazoline-3-one | Dermal 0.966 mg/kg bw/day (Systemic, Chronic)<br>Inhalation 6.81 mg/m³ (Systemic, Chronic)<br>***Dermal 0.345 mg/kg bw/day (Systemic, Chronic) ****<br>***Inhalation 1.2 mg/m³ (Systemic, Chronic) **** | 0.00403 mg/L (Water (Fresh))<br>0.0011 mg/L (Water - Intermittent release)<br>0.000403 mg/L (Water (Marine))<br>0.0499 mg/kg sediment dw (Sediment (Fresh Water))<br>0.00499 mg/kg sediment dw (Sediment (Marine))<br>3 mg/kg soil dw (Soil)<br>1.03 mg/L (STP) |
| sodium lauryl ether sulfate | Dermal 0.625 mg/kg bw/day (Systemic, Chronic)<br>Inhalation 1.102 mg/m³ (Systemic, Chronic)<br>Dermal 0.132 mg/cm² (Local, Chronic)<br>***Dermal 0.312 mg/kg bw/day (Systemic, Chronic) ****<br>***Inhalation 0.272 mg/m³ (Systemic, Chronic) ****<br>***Oral 0.156 mg/kg bw/day (Systemic, Chronic) ****<br>***Dermal 0.079 mg/cm² (Local, Chronic) **** | 0.052 mg/L (Water (Fresh))<br>0.071 mg/L (Water - Intermittent release)<br>0.0052 mg/L (Water (Marine))<br>0.2 mg/kg sediment dw (Sediment (Fresh Water))<br>0.02 mg/kg sediment dw (Sediment (Marine))<br>7.5 mg/kg soil dw (Soil)<br>588.899 mg/L (STP) |
| EDTA tetrasodium salt | Inhalation 1.5 mg/m³ (Systemic, Chronic)<br>Inhalation 1.5 mg/m³ (Local, Chronic)<br>Inhalation 3 mg/m³ (Systemic, Acute)<br>Inhalation 3 mg/m³ (Local, Acute)<br>***Oral 25 mg/kg bw/day (Systemic, Chronic) **** | Not Available |

**Continued...**

| Ingredient | DNELs<br>Exposure Pattern Worker | PNECs<br>Compartment |
|---|---|---|
| | ***Inhalation 0.6 mg/m³ (Local, Chronic) ****<br>***Inhalation 1.2 mg/m³ (Local, Acute) **** | |

* Values for General Population

**Occupational Exposure Limits (OEL)**

**INGREDIENT DATA**

| Source | Ingredient | Material name | TWA | STEL | Peak | Notes |
|---|---|---|---|---|---|---|
| Not Available | Not Available | Not Available | Not Available | Not Available | Not Available | Not Available |

Not Applicable

**MATERIAL DATA**

Sensory irritants are chemicals that produce temporary and undesirable side-effects on the eyes, nose or throat. Historically occupational exposure standards for these irritants have been based on observation of workers' responses to various airborne concentrations. Present day expectations require that nearly every individual should be protected against even minor sensory irritation and exposure standards are established using uncertainty factors or safety factors of 5 to 10 or more. On occasion animal no-observable-effect-levels (NOEL) are used to determine these limits where human results are unavailable. An additional approach, typically used by the TLV committee (USA) in determining respiratory standards for this group of chemicals, has been to assign ceiling values (TLV C) to rapidly acting irritants and to assign short-term exposure limits (TLV STELs) when the weight of evidence from irritation, bioaccumulation and other endpoints combine to warrant such a limit. In contrast the MAK Commission (Germany) uses a five-category system based on intensive odour, local irritation, and elimination half-life. However this system is being replaced to be consistent with the European Union (EU) Scientific Committee for Occupational Exposure Limits (SCOEL); this is more closely allied to that of the USA.
1,2-Benzisothiazoline-3-one (BIT) produces sensitising effects and causes skin irritation at concentrations of 0.05%. Solutions containing the substance should contain levels considerably lower than 0.05%.
CEL TWA: 0.1 mg/m3; STEL 0.3 mg/m3 total isothiazolinones (Rohm and Haas)
(CEL = Chemwatch Exposure Limit)

## 8.2. Exposure controls

| | |
|---|---|
| **8.2.1. Appropriate engineering controls** | Engineering controls are used to remove a hazard or place a barrier between the worker and the hazard. Well-designed engineering controls can be highly effective in protecting workers and will typically be independent of worker interactions to provide this high level of protection.<br>The basic types of engineering controls are:<br>Process controls which involve changing the way a job activity or process is done to reduce the risk.<br>Enclosure and/or isolation of emission source which keeps a selected hazard "physically" away from the worker and ventilation that strategically "adds" and "removes" air in the work environment. Ventilation can remove or dilute an air contaminant if designed properly. The design of a ventilation system must match the particular process and chemical or contaminant in use.<br>Employers may need to use multiple types of controls to prevent employee overexposure. |
| **8.2.2. Individual protection measures, such as personal protective equipment** |  |
| **Eye and face protection** | ‣ Safety glasses with side shields.<br>‣ Chemical goggles. [AS/NZS 1337.1, EN166 or national equivalent]<br>‣ Contact lenses may pose a special hazard; soft contact lenses may absorb and concentrate irritants. A written policy document, describing the wearing of lenses or restrictions on use, should be created for each workplace or task. This should include a review of lens absorption and adsorption for the class of chemicals in use and an account of injury experience. Medical and first-aid personnel should be trained in their removal and suitable equipment should be readily available. In the event of chemical exposure, begin eye irrigation immediately and remove contact lens as soon as practicable. |
| **Skin protection** | See Hand protection below |
| **Hands/feet protection** | The selection of suitable gloves does not only depend on the material, but also on further marks of quality which vary from manufacturer to manufacturer. Where the chemical is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.<br>The exact break through time for substances has to be obtained from the manufacturer of the protective gloves and has to be observed when making a final choice.<br>Personal hygiene is a key element of effective hand care. Gloves must only be worn on clean hands. After using gloves, hands should be washed and dried thoroughly. Application of a non-perfumed moisturiser is recommended.<br>‣ Butyl rubber gloves<br>· Nitrile rubber gloves (Note: Nitric acid penetrates nitrile gloves in a few minutes.)<br>‣ Wear chemical protective gloves, e.g. PVC.<br>‣ Wear safety footwear or safety gumboots, e.g. Rubber |
| **Body protection** | See Other protection below |
| **Other protection** | ‣ Overalls.<br>‣ P.V.C apron.<br>‣ Barrier cream.<br>‣ Skin cleansing cream.<br>‣ Eye wash unit. |

**Continued...**

### 8.2.3. Environmental exposure controls

See section 12

## SECTION 9 Physical and chemical properties

### 9.1. Information on basic physical and chemical properties

| | |
|---|---|
| **Appearance** | Clear brown liquid with chateristic odour mixes with water. |

| | | | |
|---|---|---|---|
| **Physical state** | Liquid | **Relative density (Water = 1)** | 1.00 |
| **Odour** | Not Available | **Partition coefficient n-octanol / water** | Not Available |
| **Odour threshold** | Not Available | **Auto-ignition temperature (°C)** | Not Applicable |
| **pH (as supplied)** | 8-9.5 | **Decomposition temperature (°C)** | Not Applicable |
| **Melting point / freezing point (°C)** | Not Applicable | **Viscosity (cSt)** | Not Applicable |
| **Initial boiling point and boiling range (°C)** | ~100 | **Molecular weight (g/mol)** | Not Applicable |
| **Flash point (°C)** | Not Applicable | **Taste** | Not Available |
| **Evaporation rate** | Not Available BuAC = 1 | **Explosive properties** | Not Available |
| **Flammability** | Not Applicable | **Oxidising properties** | Not Available |
| **Upper Explosive Limit (%)** | Not Applicable | **Surface Tension (dyn/cm or mN/m)** | Not Available |
| **Lower Explosive Limit (%)** | Not Applicable | **Volatile Component (%vol)** | Not Applicable |
| **Vapour pressure (kPa)** | Not Applicable | **Gas group** | Not Available |
| **Solubility in water** | Miscible | **pH as a solution (1%)** | Not Applicable |
| **Vapour density (Air = 1)** | Not Applicable | **VOC g/L** | Not Applicable |
| **Heat of Combustion (kJ/g)** | Not Available | **Ignition Distance (cm)** | Not Available |
| **Flame Height (cm)** | Not Available | **Flame Duration (s)** | Not Available |
| **Enclosed Space Ignition Time Equivalent (s/m3)** | Not Available | **Enclosed Space Ignition Deflagration Density (g/m3)** | Not Available |
| **Nanoform Solubility** | Not Available | **Nanoform Particle Characteristics** | Not Available |
| **Particle Size** | Not Available | | |

### 9.2. Other information

Not Available

## SECTION 10 Stability and reactivity

| | |
|---|---|
| **10.1.Reactivity** | See section 7.2 |
| **10.2. Chemical stability** | ▸ Unstable in the presence of incompatible materials.<br>▸ Product is considered stable.<br>▸ Hazardous polymerisation will not occur. |
| **10.3. Possibility of hazardous reactions** | See section 7.2 |
| **10.4. Conditions to avoid** | See section 7.2 |
| **10.5. Incompatible materials** | See section 7.2 |
| **10.6. Hazardous decomposition products** | See section 5.3 |

## SECTION 11 Toxicological information

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

| | |
|---|---|
| **a) Acute Toxicity** | Based on available data, the classification criteria are not met. |
| **b) Skin Irritation/Corrosion** | Based on available data, the classification criteria are not met. |

**Continued...**

| | |
|---|---|
| **c) Serious Eye Damage/Irritation** | There is sufficient evidence to classify this material as eye damaging or irritating |
| **d) Respiratory or Skin sensitisation** | Based on available data, the classification criteria are not met. |
| **e) Mutagenicity** | Based on available data, the classification criteria are not met. |
| **f) Carcinogenicity** | Based on available data, the classification criteria are not met. |
| **g) Reproductivity** | Based on available data, the classification criteria are not met. |
| **h) STOT - Single Exposure** | Based on available data, the classification criteria are not met. |
| **i) STOT - Repeated Exposure** | Based on available data, the classification criteria are not met. |
| **j) Aspiration Hazard** | Based on available data, the classification criteria are not met. |

| | |
|---|---|
| **Inhaled** | The material is not thought to produce adverse health effects or irritation of the respiratory tract (as classified by EC Directives using animal models). Nevertheless, good hygiene practice requires that exposure be kept to a minimum and that suitable control measures be used in an occupational setting. |
| **Ingestion** | The material has **NOT** been classified by EC Directives or other classification systems as "harmful by ingestion". This is because of the lack of corroborating animal or human evidence. The material may still be damaging to the health of the individual, following ingestion, especially where pre-existing organ (e.g liver, kidney) damage is evident. Present definitions of harmful or toxic substances are generally based on doses producing mortality rather than those producing morbidity (disease, ill-health). Gastrointestinal tract discomfort may produce nausea and vomiting. In an occupational setting however, ingestion of insignificant quantities is not thought to be cause for concern.<br>Isothiazolinones are moderately to highly toxic by oral administration. The major signs of toxicity were severe gastric irritation, lethargy, and ataxia |
| **Skin Contact** | The material is not thought to produce adverse health effects or skin irritation following contact (as classified by EC Directives using animal models). Nevertheless, good hygiene practice requires that exposure be kept to a minimum and that suitable gloves be used in an occupational setting.<br>Solutions of 0.5% strength 1,2-benzisothiazoline-3-one (BIT) are irritating to the skin. Allergenic effects also begin at 0.05% and have been confirmed in a series of case and patch test studies. When the substance was applied to human volunteers under an occlusive patch the maximum tolerated doses was 0.05%. Five hours after application of 0.1% (1000 ppm) one person showed moderate erythema with papule development which was interpreted as a reaction to the sticking plaster; in four persons there was mild reddening of the skin. The reaction had ameliorated in several persons after 72 hours. A second application produced various severe dermal reactions (erythema and papules) in 8 persons. A third application to several of the group produced erythema.<br>Aqueous solutions of isothiazolinones may be irritating or even corrosive depending on concentration. Solutions containing more than 0.5% (5000 ppm active substance) may produce severe irritation of human skin whilst solutions containing more than 100 ppm may irritate the skin. |
| **Eye** | When applied to the eye(s) of animals, the material produces severe ocular lesions which are present twenty-four hours or more after instillation.<br>Solutions containing isothiazolinones may produce corrosion of the mucous membranes and cornea. Instillation of 0.1 ml of an aqueous solution containing 560 ppm isothiazolinone into rabbit eye did not produce irritation whereas concentrations, typically around 3% and 5.5 %, were severely irritating or corrosive to the eye.. Symptoms included clouding of the cornea, chemosis and swelling of the eyelids. |
| **Chronic** | Long-term exposure to the product is not thought to produce chronic effects adverse to health (as classified by EC Directives using animal models); nevertheless exposure by all routes should be minimised as a matter of course.<br>In a teratogenic study in rats concentrations of up to 40 mg/kg 1,2-benzisothiazoline-3-one (BIT) were neither embryotoxic nor teratogenic. The material is not mutagenic. In a 2-year carcinogenicity study with rats, BIT did not produce excess tumours. The results derived from this test are questionable because no dose series was administered and because there were too few animals.<br>A 90-day study with beagle dogs receiving oral doses showed reduced food consumption and body weight gain as well as mild anaemia, increases in the weights of liver and in male animals, brain and spleen weights.<br>The no-observed-effect-level (NOEL) was given as 165 mg/kg (ie 0.5 BIT in the diet). A 90-day study with rats receiving dietary BIT showed reduced liver and pituitary weights in males.<br>The isothiazolinones are known contact sensitisers. Data are presented which demonstrate that, in comparison with the chlorinated and dichlorinated compounds which share immunological cross-reactivity, the non-chlorinated isothiazolinones have a lower potential for sensitization and no documented immunological cross-reaction with the chlorinated isothiazolinones. The risk of sensitization depends on how contact with the product occurs. The risk is greater when the skin barrier has been damaged and smaller when the skin is healthy. Dermatological studies have demonstrated that mixed isothiazolinone concentrations below 20 ppm may cause sensitisation and that allergic reactions can be provoked in sensitized persons even with concentrations in the range of 7-15 ppm active isothiazolinones.<br>The isothiazolinones are a group of heterocyclic sulfur-containing compounds. In general all are electrophilic molecules containing an activated N-S bond that enables them with nucleophilic cell entities, thus exerting biocidal activity. |

| | | |
|---|---|---|
| **GAMAZYME FC** | **TOXICITY** | **IRRITATION** |
| | Not Available | Not Available |

**Continued...**

| | | |
|---|---|---|
| **Polyethoxylated alcohols** | **TOXICITY** | **IRRITATION** |
| | Dermal (rabbit) LD50: >2000 mg/kg[2] | Eye: adverse effect observed (irritating)[1] |
| | Dermal (rabbit) LD50: >5000 mg/kg *[2] | Skin: no adverse effect observed (not irritating)[1] |
| | Oral (Rat) LD50: 1378 mg/kg[2] | |
| | Oral (Rat) LD50: 1400 mg/kg *[2] | |
| | Oral (Rat) LD50: 2700 mg/kg *[2] | |
| **lipase** | **TOXICITY** | **IRRITATION** |
| | Intraperitoneal (mouse) LD50: 833 mg/kg[2] | Eye: no adverse effect observed (not irritating)[1] |
| | Intraperitoneal (rat) LD50: 630 mg/kg[2] | Skin: no adverse effect observed (not irritating)[1] |
| | Intravenous (Mouse) LD50: 127 mg/kg[2] | |
| | Intravenous (rat) LD50: 104 mg/kg[2] | |
| **1,2-benzisothiazoline-3-one** | **TOXICITY** | **IRRITATION** |
| | dermal (rat) LD50: >2000 mg/kg[1] | Eye: adverse effect observed (irreversible damage)[1] |
| | Oral (Rat) LD50: 454 mg/kg[1] | Skin (Human - man): 0.05% |
| | | Skin (Human): 1%/1H |
| | | Skin (Human): 5%/48H - Mild |
| | | Skin: no adverse effect observed (not irritating)[1] |
| **sodium lauryl ether sulfate** | **TOXICITY** | **IRRITATION** |
| | Oral (Rat) LD50: 1600 mg/kg[2] | Eye (Rodent - rabbit): 100uL/24H - Severe |
| | | Eye (Rodent - rabbit): 20mg/24H - Moderate |
| | | Eye: adverse effect observed (irreversible damage)[1] |
| | | Eye: adverse effect observed (irritating)[1] |
| | | Skin (Rodent - guinea pig): 5%/9H(intermittent) |
| | | Skin (Rodent - rabbit): 25mg/24H - Moderate |
| | | Skin (Rodent - rabbit): 500mg/24H - Severe |
| | | Skin: adverse effect observed (irritating)[1] |
| **EDTA tetrasodium salt** | **TOXICITY** | **IRRITATION** |
| | Oral (Rat) LD50: 630 mg/kg[2] | Eye (Rodent - rabbit): 100mg/24H - Moderate |
| | | Eye (Rodent - rabbit): 1900ug |
| | | Eye: adverse effect observed (irritating)[1] |
| | | Skin (Human - man): 0.2% |
| | | Skin (Rodent - rabbit): 500mg/24H - Moderate |
| | | Skin: no adverse effect observed (not irritating)[1] |

| | |
|---|---|
| *Legend:* | ***1. Value obtained from Europe ECHA Registered Substances - Acute toxicity 2. Value obtained from manufacturer's SDS. Unless otherwise specified data extracted from RTECS - Register of Toxic Effect of chemical Substances*** |

| | |
|---|---|
| **Polyethoxylated alcohols** | Human beings have regular contact with alcohol ethoxylates through a variety of industrial and consumer products such as soaps, detergents, and other cleaning products . Exposure to these chemicals can occur through ingestion, inhalation, or contact with the skin or eyes. Studies of acute toxicity show that volumes well above a reasonable intake level would have to occur to produce any toxic response. Moreover, no fatal case of poisoning with alcohol ethoxylates has ever been reported. Multiple studies investigating the acute toxicity of alcohol ethoxylates have shown that the use of these compounds is of low concern in terms of oral and dermal toxicity .<br>Clinical animal studies indicate these chemicals may produce gastrointestinal irritation such as ulcerations of the stomach, pilo-erection, diarrhea, and lethargy. Similarly, slight to severe irritation of the skin or eye was generated when undiluted alcohol ethoxylates were applied to the skin and eyes of rabbits and rats.<br>Alcohol ethoxylates are according to CESIO (2000) classified as Irritant or Harmful depending on the number of EO-units:<br>EO < 5 gives Irritant (Xi) with R38 (Irritating to skin) and R41 (Risk of serious damage to eyes)<br>EO > 5-15 gives Harmful (Xn) with R22 (Harmful if swallowed) - R38/41<br>EO > 15-20 gives Harmful (Xn) with R22-41<br>>20 EO is not classified (CESIO 2000)<br>Oxo-AE, C13 EO10 and C13 EO15, are Irritating (Xi) with R36/38 (Irritating to eyes and skin) .<br>AE are not included in Annex 1 of the list of dangerous substances of the Council Directive 67/548/EEC |

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|---|---|
| | In general, alcohol ethoxylates (AE) are readily absorbed through the skin of guinea pigs and rats and through the gastrointestinal mucosa of rats. AE are quickly eliminated from the body through the urine, faeces, and expired air ($CO_2$).Orally dosed AE was absorbed rapidly and extensively in rats, and more than 75% of the dose was absorbed. When applied to the skin of humans, the doses were absorbed slowly and incompletely (50% absorbed in 72 hours). Half of the absorbed surfactant was excreted promptly in the urine and smaller amounts of AE appeared in the faeces and expired air ($CO_2$) ). The metabolism of C12 AE yields PEG, carboxylic acids, and $CO_2$ as metabolites. The LD50 values after oral administration to rats range from about 1-15 g/kg body weight indicating a low to moderate acute toxicity.<br><br>The ability of nonionic surfactants to cause a swelling of the stratum corneum of guinea pig skin has been studied. The swelling mechanism of the skin involves a combination of ionic binding of the hydrophilic group as well as hydrophobic interactions of the alkyl chain with the substrate.<br><br>The material may produce severe irritation to the eye causing pronounced inflammation. Repeated or prolonged exposure to irritants may produce conjunctivitis.<br>The material may produce severe skin irritation after prolonged or repeated exposure, and may produce a contact dermatitis (nonallergic). This form of dermatitis is often characterised by skin redness (erythema) thickening of the epidermis.<br>Histologically there may be intercellular oedema of the spongy layer (spongiosis) and intracellular oedema of the epidermis.<br>Prolonged contact is unlikely, given the severity of response, but repeated exposures may produce severe ulceration.<br>Dermal (rabbit): 4000 mg/kg * Somnolence, ataxia, diarrhoea recorded. |
| **1,2-BENZISOTHIAZOLINE-3-ONE** | In light of potential adverse effects, and to ensure a harmonised risk assessment and management, the EU regulatory framework for biocides has been established with the objective of ensuring a high level of protection of human and animal health and the environment. To this aim, it is required that risk assessment of biocidal products is carried out before they can be placed on the market. A central element in the risk assessment of the biocidal products are the utilization instructions that defines the dosage, application method and amount of applications and thus the exposure of humans and the environment to the biocidal substance.<br>Humans may be exposed to biocidal products in different ways in both occupational and domestic settings. Many biocidal products are intended for industrial sectors or professional uses only, whereas other biocidal products are commonly available for private use by non-professional users. In addition, potential exposure of non-users of biocidal products (i.e. the general public) may occur indirectly via the environment, for example through drinking water, the food chain, as well as through atmospheric and residential exposure. Particular attention should be paid to the exposure of vulnerable sub-populations, such as the elderly, pregnant women, and children. Also pets and other domestic animals can be exposed indirectly following the application of biocidal products.<br>The predominant fate of the thiazole ring is oxidative ring scission catalysed by cytochrome P450 (CYP) and formation of the corresponding alpha-dicarbonyl metabolites and thioamide derivatives. The well-established toxicity associated with thioamides and thioureas has led to the speculation that thiazole toxicity is attributed to ring scission yielding the corresponding thioamide metabolite. Ring opening has also been observed in benzothiazoles. For instance, benzothiazole itself is converted to S-methylmercaptoaniline.<br>**Acute toxicity** data show that 1,2-benzisothiazoline-3-one (BIT) is moderately toxic by the oral and dermal routes but that this chemical is a severe eye irritant. Irritation to the skin from acute data show only mild skin irritation , but repeated dermal application indicated a more significant skin irritation response.<br>The neurotoxicity observed in the rat acute oral toxicity study (piloerection and upward curvature of the spine at 300 mg/kg and above; decreased activity, prostration, decreased abdominal muscle tone, reduced righting reflex, and decreased rate and depth of breathing at 900 mg/kg) and the acute dermal toxicity study (upward curvature of the spine was observed in increased incidence, but this was absent after day 5 post-dose at a dose of 2000 mg/kg) were felt to be at exposures in excess of those expected from the use pattern of this pesticide and that such effects would not be observed at estimated exposure doses.<br>**Subchronic oral toxicity** studies showed systemic effects after repeated oral administration including decreased body weight, increased incidence of forestomach hyperplasia, and non-glandular stomach lesions in rats. In dogs, the effects occurred at lower doses than in rats, and included alterations in blood chemistry (decreased plasma albumin, total protein, and alanine aminotransferase) and increased absolute liver weight.<br>**Developmental toxicity** studies were conducted in rats with maternal effects including decreased body weight gain, decreased food consumption, and clinical toxicity signs (audible breathing, haircoat staining of the anogenital region, dry brown material around the nasal area) as well as increased mortality. Developmental effects consisted of increases in skeletal abnormalities (extra sites of ossification of skull bones, unossified sternebrae) but not external or visceral abnormalities. |
| **SODIUM LAURYL ETHER SULFATE** | * [CESIO]<br>Polyethers (such as ethoxylated surfactants and polyethylene glycols) are highly susceptible to being oxidized in the air. They then form complex mixtures of oxidation products.<br>Animal testing reveals that whole the pure, non-oxidised surfactant is non-sensitizing, many of the oxidation products are sensitisers. The oxidization products also cause irritation.<br>Alkyl ether sulfates (alcohol or alkyl ethoxysulfates) (AES) (syn: AAASD ,alkyl alcohol alkoxylate sulfates, SLES) are generally classified according to Comité Européen des Agents de Surface et leurs Intermédiaires Organiques (CESIO) as Irritant (Xi) with the risk phrases R38 (Irritating to skin) and R36 (Irritating to eyes). An exception has been made for AES (2-3E0) in a concentration of 70-75% where R36 is substituted with R41 (Risk of serious damage to eyes).<br>AES are not included in Annex 1 of the list of dangerous substances of Council Directive 67/548/EEC.<br>In assessing this family the Cosmetic Ingredient Review (CIR) Expert Panel recognized that most of the acute oral toxicity, dermal irritation and sensitization, subchronic and chronic oral toxicity, reproductive and developmental toxicity, carcinogenicity, and photosensitization studies have been conducted on ammonium laureth sulfate and sodium laureth sulfate. Sodium and ammonium laureth sulfate have not evoked adverse responses in any toxicological testing, including acute oral toxicity, sub-chronic and chronic oral toxicity, reproductive and develop-mental toxicity, carcinogenicity, and photosensitization studies. These data, however, are considered a sufficient basis for concluding that the other ingredients are safe in the practices of use and concentration described in the safety assessment because of the fundamental chemical similarities between them and because they all are chemically similar salts(salts are expected to be dissociated in any product formulation independent of whether the salt is sodium, ammonium, magnesium, or zinc) of sulfated ethoxylated alcohols, and they all function as surfactants in cosmetic formulations. Based on these considerations, safety test data on one ingredient may be extrapolated to all of them. The panel noted that sodium laureth sulfate and ammonium laureth sulfate can produce eye and/or skin irritation in experimental animals and in some human test subjects; irritation may occur in some users of cosmetic formulations containing these ingredients. The |

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| | irritant effects, however, are similar to those produced by other detergents, and the severity of the irritation appears to increase directly with concentration<br>**Acute toxicity:** AES are of low acute toxicity.<br>The material may produce moderate eye irritation leading to inflammation. Repeated or prolonged exposure to irritants may produce conjunctivitis. |
| **EDTA TETRASODIUM SALT** | * Sigma Aldrich - for the dihydrate<br>Asthma-like symptoms may continue for months or even years after exposure to the material ends. This may be due to a non-allergic condition known as reactive airways dysfunction syndrome (RADS) which can occur after exposure to high levels of highly irritating compound. Main criteria for diagnosing RADS include the absence of previous airways disease in a non-atopic individual, with sudden onset of persistent asthma-like symptoms within minutes to hours of a documented exposure to the irritant. Other criteria for diagnosis of RADS include a reversible airflow pattern on lung function tests, moderate to severe bronchial hyperreactivity on methacholine challenge testing, and the lack of minimal lymphocytic inflammation, without eosinophilia. RADS (or asthma) following an irritating inhalation is an infrequent disorder with rates related to the concentration of and duration of exposure to the irritating substance. On the other hand, industrial bronchitis is a disorder that occurs as a result of exposure due to high concentrations of irritating substance (often particles) and is completely reversible after exposure ceases. The disorder is characterized by difficulty breathing, cough and mucus production.<br>Steroid Receptor Coactivator (SRC) modulators (like inhibitors or knockouts) affect hormone-driven processes, potentially causing reproductive issues (dwarfism, infertility), immune dysregulation (autoimmunity, T-cell changes), metabolic shifts, and influencing cancer growth (both promoting and inhibiting depending on the context). Side effects often relate to their fundamental role in regulating steroid hormones (estrogen, androgen, progesterone) in tissues like the brain, reproductive organs, and immune cells, leading to broad systemic impacts, though specific inhibitors (like SRC-3 inhibitors in Tregs) show promise with fewer general toxicities than broader therapies<br>Key Adverse Effects & Considerations:<br>Reproductive & Endocrine:<br>Dysfunction: SRC knockout in mice causes reproductive failure, delayed puberty, and dwarfism.<br>Behavioral: SRC-1 inhibition can alter sex behaviors and brain development in rodents.<br>Immune System:<br>Treg Modulation: Inhibiting SRCs (especially SRC-3) in Regulatory T cells (Tregs) can boost anti-cancer immunity but might also impact normal immune balance.<br>Potential Autoimmunity: While SRC-3 KO Tregs seem benign, broader immune targeting can lead to severe autoimmunity, though SRC inhibitors aim to avoid this.<br>Cancer:<br>Dual Role: SRCs drive many cancers (breast, ovarian, prostate). Modulators can inhibit tumor growth, but some (like pan-SRC inhibitors) might impair anti-tumor immunity<br>General Systemic Effects:<br>Metabolic: SRC dysregulation is linked to Polycystic Ovary Syndrome (PCOS) and fibroids.<br>Brain Function: SRCs are crucial for neuroendocrine regulation, affecting seasonal cycles and hormone responses in the brain<br>Therapeutic Context Matters:<br>Specific vs. Pan-Inhibitors: Targeting specific SRCs (like SRC-3 in Tregs) or using targeted inhibitors (like SI-2) aims for anti-cancer effects with fewer systemic side effects than broader immune checkpoint inhibitors, avoiding issues like cytokine release syndrome.<br>Drug Development: Natural compounds (gossypol, bufalin) and synthetic molecules (SI-2) are being developed, showing potential for non-hormonal treatments in women's health, but clinical application needs careful study.<br>In essence, SRC modulators are powerful tools affecting fundamental hormone signaling, meaning their "adverse effects" are often the flip side of their therapeutic action, necessitating precise targeting for safe use.<br>For ethylenediaminetetraacetic acid (EDTA) and its salts:<br>EDTA is a strong organic acid (approximately 1000 times stronger than acetic acid). It has a high affinity for alkaline-earth ions (for example, calcium and magnesium) and heavy-metal ions (for example, lead and mercury). This affinity generally results in the formation of highly stable and soluble hexadentate chelate complexes. EDTA s ability to complex is used commercially to either promote or inhibit chemical reactions, depending on application.<br>EDTA and its salts are expected to be absorbed by the lungs and gastrointestinal tract; absorption through the skin is unlikely.<br>In general, EDTA and its salts are mild skin irritants but considered severe eye irritants. The greatest risk in the human body will occur when the EDTA attempts to scavenge the trace metals used and required by the body.<br>The binding of divalent and trivalent cations by EDTA can cause mineral deficiencies, which seem to be responsible for all of the known pharmacological effects. Sensitivity to the toxic effects of EDTA is, at least in part, related to the deficiency of zinc.<br>Several short term studies, reported no adverse effects from administering doses up to 5% of EDTA and its salts to lab rodents daily and for several weeks. Only diarrhoea and lowered food consumption were reported in animals given 5% disodium EDTA. |
| **1,2-BENZISOTHIAZOLINE-3-ONE & EDTA TETRASODIUM SALT** | The following information refers to contact allergens as a group and may not be specific to this product.<br>Contact allergies quickly manifest themselves as contact eczema, more rarely as urticaria or Quincke's oedema. The pathogenesis of contact eczema involves a cell-mediated (T lymphocytes) immune reaction of the delayed type. Other allergic skin reactions, e.g. contact urticaria, involve antibody-mediated immune reactions. The significance of the contact allergen is not simply determined by its sensitisation potential: the distribution of the substance and the opportunities for contact with it are equally important. A weakly sensitising substance which is widely distributed can be a more important allergen than one with stronger sensitising potential with which few individuals come into contact. From a clinical point of view, substances are noteworthy if they produce an allergic test reaction in more than 1% of the persons tested. |
| **1,2-BENZISOTHIAZOLINE-3-ONE & SODIUM LAURYL ETHER SULFATE** | No significant acute toxicological data identified in literature search. |

| | | | |
|---|---|---|---|
| **Acute Toxicity** | ✗ | **Carcinogenicity** | ✗ |
| **Skin Irritation/Corrosion** | ✗ | **Reproductivity** | ✗ |
| **Serious Eye Damage/Irritation** | ✓ | **STOT - Single Exposure** | ✗ |

**Continued...**

| | | | |
|---|---|---|---|
| **Respiratory or Skin sensitisation** | ✗ | **STOT - Repeated Exposure** | ✗ |
| **Mutagenicity** | ✗ | **Aspiration Hazard** | ✗ |

***Legend:*** ✗ ***– Data either not available or does not fill the criteria for classification***
✓ ***– Data available to make classification***

### 11.2 Information on other hazards

### 11.2.1. Endocrine disrupting properties

Many chemicals may mimic or interfere with the body s hormones, known as the endocrine system. Endocrine disruptors are chemicals that can interfere with endocrine (or hormonal) systems. Endocrine disruptors interfere with the synthesis, secretion, transport, binding, action, or elimination of natural hormones in the body. Any system in the body controlled by hormones can be derailed by hormone disruptors. Specifically, endocrine disruptors may be associated with the development of learning disabilities, deformations of the body various cancers and sexual development problems. Endocrine disrupting chemicals cause adverse effects in animals. But limited scientific information exists on potential health problems in humans. Because people are typically exposed to multiple endocrine disruptors at the same time, assessing public health effects is difficult.

### 11.2.2. Other information

See Section 11.1

## SECTION 12 Ecological information

### 12.1. Toxicity

**GAMAZYME FC**

| Endpoint | Test Duration (hr) | Species | Value | Source |
|---|---|---|---|---|
| Not Available | Not Available | Not Available | Not Available | Not Available |

**Polyethoxylated alcohols**

| Endpoint | Test Duration (hr) | Species | Value | Source |
|---|---|---|---|---|
| EC50 | 48h | Crustacea | 2.217-3.523mg/L | 4 |
| EC50 | 96h | Algae or other aquatic plants | 1.4mg/l | 2 |
| NOEC(ECx) | 720h | Fish | 0.11-0.28mg/l | 2 |
| LC50 | 96h | Fish | 7mg/l | Not Available |

**lipase**

| Endpoint | Test Duration (hr) | Species | Value | Source |
|---|---|---|---|---|
| EC50 | 72h | Algae or other aquatic plants | 94.2mg/l | 2 |
| EC50 | 48h | Crustacea | >262.3mg/l | 2 |
| NOEC(ECx) | 72h | Algae or other aquatic plants | 38.1mg/l | 2 |
| LC50 | 96h | Fish | >262.3mg/l | 2 |

**1,2-benzisothiazoline-3-one**

| Endpoint | Test Duration (hr) | Species | Value | Source |
|---|---|---|---|---|
| NOEC(ECx) | 72h | Algae or other aquatic plants | 0.04mg/L | 2 |
| EC50 | 72h | Algae or other aquatic plants | 0.07mg/L | 2 |
| EC50 | 48h | Crustacea | 0.097mg/L | 4 |
| LC50 | 96h | Fish | 0.067-0.29mg/L | 4 |

**sodium lauryl ether sulfate**

| Endpoint | Test Duration (hr) | Species | Value | Source |
|---|---|---|---|---|
| EC50 | 48h | Crustacea | 2.43-4.01mg/l | 4 |
| NOEC(ECx) | 48h | Fish | 0.26mg/L | 5 |

**EDTA tetrasodium salt**

| Endpoint | Test Duration (hr) | Species | Value | Source |
|---|---|---|---|---|
| EC50 | 72h | Algae or other aquatic plants | 1.01mg/l | 1 |
| EC50 | 48h | Crustacea | >100mg/l | 2 |
| NOEC(ECx) | 72h | Algae or other aquatic plants | 0.39mg/l | 1 |
| LC50 | 96h | Fish | >100mg/l | 2 |

***Legend:*** ***Extracted from 1. IUCLID Toxicity Data 2. Europe ECHA Registered Substances - Ecotoxicological Information - Aquatic Toxicity 3. US EPA, Ecotox database - Aquatic Toxicity Data 4. ECETOC Aquatic Hazard Assessment Data 5. NITE (Japan) - Bioconcentration Data 6. METI (Japan) - Bioconcentration Data 7. Vendor Data***

**Continued...**

Harmful to aquatic organisms.
The isothiazolinones are very toxic to marine organisms (fish, Daphnia magna and algae)
The high water solubility and low log Kow values of several chlorinated and non-chlorinated indicate a low potential for bioaccumulation.
Studies of 5-chloro-2-methyl-4-isothiazolin-3-one (CMI) in bluegill sunfish (Lepornis machrochirus) show BCF values of 102, 114 and 67 at nominal concentrations of 0.02, 0.12 and 0.8 mg/l. The BCF for 2-methyl-4-isothiazolin-3-one (MI) was determined at 2.3 at a nominal concentration of 0.12 mg/l
Primary biodegradation of MI and CMI occurred with half-lives of less than 24 hours in aerobic and anoxic sediments, and within a period of less than one week the parent compounds were depleted to very low levels that could not be clearly distinguished from analytical artifacts. The ultimate aerobic biodegradability of both MI and CMI attained levels of > 55% within 29 days. Furthermore, the proposed metabolites of MI and CMI are considered to have a low aquatic toxicity on the basis of QSAR estimates and the measured toxicity of the structurally related N-(n-octyl) malonamic acid.

### 12.2. Persistence and degradability

| Ingredient | Persistence: Water/Soil | Persistence: Air |
|---|---|---|
| | No Data available for all ingredients | No Data available for all ingredients |

### 12.3. Bioaccumulative potential

| Ingredient | Bioaccumulation |
|---|---|
| Polyethoxylated alcohols | LOW (LogKOW = 2.42) |
| sodium lauryl ether sulfate | LOW (LogKOW = 1.62) |

### 12.4. Mobility in soil

| Ingredient | Mobility |
|---|---|
| | No Data available for all ingredients |

### 12.5. Results of PBT and vPvB assessment

| | P | B | T | PBT criteria fulfilled? | vP | vB | vPvB criteria fulfilled? |
|---|---|---|---|---|---|---|---|
| GAMAZYME FC | ✗ | ✗ | ✗ | No | ✗ | ✗ | No |
| Polyethoxylated alcohols | No data available | No data available | No data available | No | No data available | No data available | No |
| lipase | No data available | No data available | No data available | No | No data available | No data available | No |
| 1,2-benzisothiazoline-3-one | No data available | No data available | No data available | No | No data available | No data available | No |
| sodium lauryl ether sulfate | No data available | No data available | No data available | No | No data available | No data available | No |
| EDTA tetrasodium salt | ✗ | ✗ | ✓ | No | ✗ | ✗ | No |

### 12.6. Endocrine disrupting properties

The evidence linking adverse effects to endocrine disruptors is more compelling in the environment than it is in humans. Endocrine distruptors profoundly alter reproductive physiology of ecosystems and ultimately impact entire populations. Some endocrine-disrupting chemicals are slow to break-down in the environment. That characteristic makes them potentially hazardous over long periods of time. Some well established adverse effects of endocrine disruptors in various wildlife species include; eggshell-thinning, displayed of characteristics of the opposite sex and impaired reproductive development. Other adverse changes in wildlife species that have been suggested, but not proven include; reproductive abnormalities, immune dysfunction and skeletal deformaties.

### 12.7. Other adverse effects

No evidence of ozone depleting properties were found in the current literature.

## SECTION 13 Disposal considerations

### 13.1. Waste treatment methods

| | |
|---|---|
| **Product / Packaging disposal** | Legislation addressing waste disposal requirements may differ by country, state and/ or territory. Each user must refer to laws operating in their area. In some areas, certain wastes must be tracked.<br>A Hierarchy of Controls seems to be common - the user should investigate:<br>▸ Reduction<br>▸ Reuse<br>▸ Recycling<br>▸ Disposal (if all else fails)<br>This material may be recycled if unused, or if it has not been contaminated so as to make it unsuitable for its intended use. If it has been contaminated, it may be possible to reclaim the product by filtration, distillation or some other means. Shelf life considerations should also be applied in making decisions of this type. Note that properties of a material may change in use, and recycling or reuse may not always be appropriate.<br>▸ In all cases disposal to sewer may be subject to local laws and regulations and these should be considered first.<br>▸ Where in doubt contact the responsible authority. |

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| | ▸ Consult local or regional waste management authority for disposal if no suitable treatment or disposal facility can be identified.<br>▸ Dispose of by: burial in a land-fill specifically licensed to accept chemical and / or pharmaceutical wastes or incineration in a licensed apparatus (after admixture with suitable combustible material).<br>▸ Decontaminate empty containers. Observe all label safeguards until containers are cleaned and destroyed. |
| **Waste treatment options** | Not Available |
| **Sewage disposal options** | Not Available |

## SECTION 14 Transport information

### Labels Required

| | |
|---|---|
| | |
| **Marine Pollutant** | NO |

### Land transport (ADR): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS

| | |
|---|---|
| 14.1. **UN number or ID number** | Not Applicable |
| 14.2. **UN proper shipping name** | Not Applicable |
| 14.3. **Transport hazard class(es)** | Class: Not Applicable<br>Subsidiary Hazard: Not Applicable |
| 14.4. **Packing group** | Not Applicable |
| 14.5. **Environmental hazard** | Not Applicable |
| 14.6. **Special precautions for user** | Hazard identification (Kemler): Not Applicable<br>Classification code: Not Applicable<br>Hazard Label: Not Applicable<br>Special provisions: Not Applicable<br>Limited quantity: Not Applicable<br>Transport Category: Not Applicable<br>Tunnel Restriction Code: Not Applicable |

### Air transport (ICAO-IATA / DGR): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS

| | |
|---|---|
| 14.1. **UN number** | Not Applicable |
| 14.2. **UN proper shipping name** | Not Applicable |
| 14.3. **Transport hazard class(es)** | ICAO/IATA Class: Not Applicable<br>ICAO / IATA Subsidiary Hazard: Not Applicable<br>ERG Code: Not Applicable |
| 14.4. **Packing group** | Not Applicable |
| 14.5. **Environmental hazard** | Not Applicable |
| 14.6. **Special precautions for user** | Special provisions: Not Applicable<br>Cargo Only Packing Instructions: Not Applicable<br>Cargo Only Maximum Qty / Pack: Not Applicable<br>Passenger and Cargo Packing Instructions: Not Applicable<br>Passenger and Cargo Maximum Qty / Pack: Not Applicable<br>Passenger and Cargo Limited Quantity Packing Instructions: Not Applicable<br>Passenger and Cargo Limited Maximum Qty / Pack: Not Applicable |

### Sea transport (IMDG-Code / GGVSee): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS

| | |
|---|---|
| 14.1. **UN number** | Not Applicable |
| 14.2. **UN proper shipping name** | Not Applicable |

**Continued...**

| | | |
|---|---|---|
| 14.3. **Transport hazard class(es)** | IMDG Class | Not Applicable |
| | IMDG Subsidiary Hazard | Not Applicable |
| 14.4. **Packing group** | Not Applicable | |
| 14.5 **Environmental hazard** | Not Applicable | |
| 14.6. **Special precautions for user** | EMS Number | Not Applicable |
| | Special provisions | Not Applicable |
| | Limited Quantities | Not Applicable |

**Inland waterways transport (ADN): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS**

| | | |
|---|---|---|
| 14.1. **UN number** | Not Applicable | |
| 14.2. **UN proper shipping name** | Not Applicable | |
| 14.3. **Transport hazard class(es)** | Not Applicable | Not Applicable |
| 14.4. **Packing group** | Not Applicable | |
| 14.5. **Environmental hazard** | Not Applicable | |
| 14.6. **Special precautions for user** | Classification code | Not Applicable |
| | Special provisions | Not Applicable |
| | Limited quantity | Not Applicable |
| | Equipment required | Not Applicable |
| | Fire cones number | Not Applicable |

### 14.7. Maritime transport in bulk according to IMO instruments

### 14.7.1. Transport in bulk according to Annex II of MARPOL and the IBC code

Not Applicable

### 14.7.2. Transport in bulk in accordance with MARPOL Annex V and the IMSBC Code

| Product name | Group |
|---|---|
| Polyethoxylated alcohols | Not Applicable |
| lipase | Not Applicable |
| 1,2-benzisothiazoline-3-one | Not Applicable |
| sodium lauryl ether sulfate | Not Applicable |
| EDTA tetrasodium salt | Not Applicable |

### 14.7.3. Transport in bulk in accordance with the IGC Code

| Product name | Ship Type |
|---|---|
| Polyethoxylated alcohols | Not Applicable |
| lipase | Not Applicable |
| 1,2-benzisothiazoline-3-one | Not Applicable |
| sodium lauryl ether sulfate | Not Applicable |
| EDTA tetrasodium salt | Not Applicable |

## SECTION 15 Regulatory information

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

**Polyethoxylated alcohols is found on the following regulatory lists**

Europe European Customs Inventory of Chemical Substances- ECICS

**lipase is found on the following regulatory lists**

Europe EC Inventory
Europe European Customs Inventory of Chemical Substances- ECICS
European Union - European Inventory of Existing Commercial Chemical Substances (EINECS)

**Continued...**

**1,2-benzisothiazoline-3-one is found on the following regulatory lists**

Europe EC Inventory
Europe European Customs Inventory of Chemical Substances- ECICS
European Union - European Inventory of Existing Commercial Chemical Substances (EINECS)
European Union (EU) Regulation (EC) No 1272/2008 on Classification, Labelling and Packaging of Substances and Mixtures - Annex VI (ATP21)

**sodium lauryl ether sulfate is found on the following regulatory lists**

Europe EC Inventory
Europe European Customs Inventory of Chemical Substances- ECICS
European Union - European Inventory of Existing Commercial Chemical Substances (EINECS)

**EDTA tetrasodium salt is found on the following regulatory lists**

Europe EC Inventory
Europe European Customs Inventory of Chemical Substances- ECICS
European Union - European Inventory of Existing Commercial Chemical Substances (EINECS)
European Union (EU) Regulation (EC) No 1272/2008 on Classification, Labelling and Packaging of Substances and Mixtures - Annex VI (ATP21)

### Additional Regulatory Information

Not Applicable

This safety data sheet is in compliance with the following EU legislation and its adaptations - as far as applicable - : Directives 98/24/EC, - 92/85/EEC, - 94/33/EC, - 2008/98/EC, - 2010/75/EU; Commission Regulation (EU) 2020/878; Regulation (EC) No 1272/2008 as updated through ATPs.

### Information according to 2012/18/EU (Seveso III):

| | |
|---|---|
| **Seveso Category** | Not Available |

### 15.2. Chemical safety assessment

No Chemical Safety Assessment has been carried out for this substance/mixture by the supplier.

### National Inventory Status

| National Inventory | Status |
|---|---|
| Australia - AIIC / Australia Non-Industrial Use | Yes |
| Canada - DSL | Yes |
| Canada - NDSL | No (Polyethoxylated alcohols; lipase; 1,2-benzisothiazoline-3-one; sodium lauryl ether sulfate; EDTA tetrasodium salt) |
| China - IECSC | Yes |
| Europe - EINEC / ELINCS / NLP | No (Polyethoxylated alcohols) |
| Japan - ENCS | No (lipase) |
| Korea - KECI | Yes |
| New Zealand - NZIoC | Yes |
| Philippines - PICCS | Yes |
| USA - TSCA | All chemical substances in this product have been designated as TSCA Inventory ‘Active' |
| Taiwan - TCSI | Yes |
| Mexico - INSQ | No (sodium lauryl ether sulfate) |
| Vietnam - NCI | Yes |
| Russia - FBEPH | No (Polyethoxylated alcohols) |
| UAE - Control List (Banned/Restricted Substances) | No (Polyethoxylated alcohols; lipase; 1,2-benzisothiazoline-3-one; sodium lauryl ether sulfate; EDTA tetrasodium salt) |
| ***Legend:*** | ***Yes = All CAS declared ingredients are on the inventory***<br>***No = One or more of the CAS listed ingredients are not on the inventory. These ingredients may be exempt or will require registration.*** |

## SECTION 16 Other information

| | |
|---|---|
| **Revision Date** | 21/06/2024 |
| **Initial Date** | 24/11/2017 |

**CONTACT POINT**

- For quotations, please find your local Customer Service team via https://www.wilhelmsen.com/contacts-locations/ or email us at wss.info@wilhelmsen.com. - Responsible for Safety Data Sheet: Wilhelmsen Ships Service AS - Prepared by: Compliance Manager - Email: wss.global.sdsinfo@wilhelmsen.com - Telephone:

**Continued...**

+47 67 58 40 00

### Full text Risk and Hazard codes

| | |
|---|---|
| **H302** | Harmful if swallowed. |
| **H315** | Causes skin irritation. |
| **H317** | May cause an allergic skin reaction. |
| **H319** | Causes serious eye irritation. |
| **H334** | May cause allergy or asthma symptoms or breathing difficulties if inhaled. |
| **H400** | Very toxic to aquatic life. |

### SDS Version Summary

| Version | Date of Update | Sections Updated |
|---|---|---|
| 7.14 | 21/06/2024 | Ecological Information - Environmental, Composition / information on ingredients - Ingredients |

### Other information

The SDS is a Hazard Communication tool and should be used to assist in the Risk Assessment. Many factors determine whether the reported Hazards are Risks in the workplace or other settings. Risks may be determined by reference to Exposures Scenarios. Scale of use, frequency of use and current or available engineering controls must be considered.

For detailed advice on Personal Protective Equipment, refer to the following EU CEN Standards:
EN 166 Personal eye-protection
EN 340 Protective clothing
EN 374 Protective gloves against chemicals and micro-organisms
EN 13832 Footwear protecting against chemicals
EN 133 Respiratory protective devices

### Definitions and abbreviations

- PC—TWA: Permissible Concentration-Time Weighted Average
- PC—STEL: Permissible Concentration-Short Term Exposure Limit
- IARC: International Agency for Research on Cancer
- ACGIH: American Conference of Governmental Industrial Hygienists
- STEL: Short Term Exposure Limit
- TEEL: Temporary Emergency Exposure Limit。
- IDLH: Immediately Dangerous to Life or Health Concentrations
- ES: Exposure Standard
- OSF: Odour Safety Factor
- NOAEL: No Observed Adverse Effect Level
- LOAEL: Lowest Observed Adverse Effect Level
- TLV: Threshold Limit Value
- LOD: Limit Of Detection
- OTV: Odour Threshold Value
- BCF: BioConcentration Factors
- BEI: Biological Exposure Index
- DNEL: Derived No-Effect Level
- PNEC: Predicted no-effect concentration
- MARPOL: International Convention for the Prevention of Pollution from Ships
- IMSBC: International Maritime Solid Bulk Cargoes Code
- IGC: International Gas Carrier Code
- IBC: International Bulk Chemical Code

- AIIC: Australian Inventory of Industrial Chemicals
- DSL: Domestic Substances List
- NDSL: Non-Domestic Substances List
- IECSC: Inventory of Existing Chemical Substance in China
- EINECS: European INventory of Existing Commercial chemical Substances
- ELINCS: European List of Notified Chemical Substances
- NLP: No-Longer Polymers
- ENCS: Existing and New Chemical Substances Inventory
- KECI: Korea Existing Chemicals Inventory
- NZIoC: New Zealand Inventory of Chemicals
- PICCS: Philippine Inventory of Chemicals and Chemical Substances
- TSCA: Toxic Substances Control Act
- TCSI: Taiwan Chemical Substance Inventory
- INSQ: Inventario Nacional de Sustancias Químicas
- NCI: National Chemical Inventory
- FBEPH: Russian Register of Potentially Hazardous Chemical and Biological Substances

### Classification and procedure used to derive the classification for mixtures according to Regulation (EC) 1272/2008 [CLP]

**Continued...**

| Classification according to regulation (EC) No 1272/2008 [CLP] and amendments | Classification Procedure |
|---|---|
| Serious Eye Damage/Eye Irritation Category 1, H318 | Calculation method |
| , EUH208 | Calculation method |

## Notes

**"This composition meets the criteria for not being harmful to the marine environment according to MARPOL Annex V and may be discharged into the sea after being used after its intended purpose"**
**“Microbial classification: All the bacteria contained in this formulation are of group 1 according to Directive 2000/54/EC (on the protection of workers from risks related to exposure to biological agents at work). Microorganisms from group 1 are unlikely to cause a human disease. When handling the product, precautions described in Annex VI of Directive 2000/54/EC have to be taken into consideration in order to make a risk assessment. Annex VI: Containment principles for industrial processes involving group 2, 3 or 4 biological agents.”**

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**end of SDS**