

GAMAZYME BTC

Wilhelmsen Ships Service AS

Part Number: 589945

Version No: 12.26

Safety Data Sheet (Conforms to Annex II of REACH (1907/2006) - Regulation 2020/878)

Issue Date: 17/10/2024

Print Date: 30/12/2024

L.REACH.NOR.EN

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

1.1. Product Identifier

Product name	GAMAZYME BTC
Chemical Name	Not Applicable
Synonyms	Norway PR No 51876 Denmark PR No 4335036
Chemical formula	Not Applicable
Other means of identification	589945 UFI: M0RV-80JK-600G-YQJ7

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	Cleaning Agent	
Uses advised against	No specific uses advised against are identified.	

1.3. Details of the manufacturer or supplier of the safety data sheet

Registered company name	Wilhelmsen Ships Service AS	Outback (M)SDS portal: https://jr.chemwatch.net/outb/account/autologin?login=wilhelmsen	Wilhelmsen Ships Service AS* Central Warehouse
Address	Strandveien 20 Lysaker 1366 Norway	-----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	Willem Barentszstraat 50 Rotterdam Netherlands
Telephone	+47 67 58 40 00	Not Available	+31 10 4877 777
Fax	Not Available	Not Available	Not Available
Website	https://www.wilhelmsen.com/	https://www.wilhelmsen.com	https://www.wilhelmsen.com
Email	wss.norway.cs@wilhelmsen.com	wss.global.sdsinfo@wilhelmsen.com	wss.rotterdam@wilhelmsen.com

1.4. Emergency telephone number

Association / Organisation	Giftinformasjonssentralen - 24 timer	24hrs - Chemwatch	Dutch nat. poison centre
Emergency telephone number(s)	+47 22591300	+31-10-4877700	+ 31 88 7558561
Other emergency telephone number(s)	+31-10-4877700	+31-10-4877700	+ 31 10 4877700

Association / Organisation	CHEMWATCH EMERGENCY RESPONSE (24/7)
Emergency telephone number(s)	+47 23 25 25 84

Other emergency telephone number(s)	+61 3 9573 3188
-------------------------------------	-----------------

Once connected and if the message is not in your preferred language then please dial 01


SECTION 2 Hazards identification

2.1. Classification of the substance or mixture

Considered a hazardous mixture according to Reg. (EC) No 1272/2008 and their amendments. Not classified as Dangerous Goods for transport purposes.

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 1,2-benzisothiazoline-3-one. May produce an allergic reaction.
--------	---

CLP classification (additional)

Not Applicable

Precautionary statement(s) Prevention

P280	Wear protective gloves, protective clothing, eye protection and 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 Fatty alcohol ethoxylates, 1,2-benzisothiazoline-3-one.

2.3. Other hazards

Ingestion may produce health damage*.

May produce skin discomfort*.

Eye contact may produce serious damage*.

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
-----------------------------	--

SECTION 3 Composition / information on ingredients

GAMAZYME BTC

3.1.Substances

See 'Composition on ingredients' in Section 3.2

3.2.Mixtures

1. CAS No 2. EC No 3. Index No 4. REACH No	% [weight]	Name	Classification according to regulation (EC) No 1272/2008 [CLP] and amendments	SCL / M-Factor	Nanoform Particle Characteristics
1. 2634-33-5 2. 220-120-9 3. 613-088-00-6 4. Not Available	0.01-0.1	<u>1,2-benzisothiazoline-3-one</u> [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]	Sensitisation (Skin) Category 1; H317: C ≥ 0,05 % Acute M factor: 10 Chronic M factor: Not Applicable	Not Available
1. Not Available 2. Not Applicable 3. Not Applicable 4. Not Available	1-5	<u>Non-hazardous ingredient</u>	Non hazardous [1]	SCL: Not Available Acute M factor: Not Applicable Chronic M factor: Not Applicable	Not Available
1. 68439-46-3 2. Not Available 3. Not Available 4. Not Available	1-3	<u>alcohols c9-11 ethoxylated</u>	Serious Eye Damage/Eye Irritation Category 2; H319 [1]	SCL: Not Available Acute M factor: Not Applicable Chronic M factor: Not Applicable	Not Available
1. 160875-66-1 2. Not Available 3. Not Available 4. Not Available	1-3	<u>Fatty alcohol ethoxylates</u>	Acute Toxicity (Oral) Category 4, Serious Eye Damage/Eye Irritation Category 1; H302, H318 [1]	SCL: Not Available Acute M factor: Not Applicable 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	<p>If this product comes in contact with the eyes:</p> <ul style="list-style-type: none"> ▶ Immediately hold eyelids apart and flush the eye continuously with running water. ▶ 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. ▶ Continue flushing until advised to stop by the Poisons Information Centre or a doctor, or for at least 15 minutes. ▶ Transport to hospital or doctor without delay. ▶ Removal of contact lenses after an eye injury should only be undertaken by skilled personnel.
Skin Contact	<p>If skin or hair contact occurs:</p> <ul style="list-style-type: none"> ▶ Flush skin and hair with running water (and soap if available). ▶ Seek medical attention in event of irritation.
Inhalation	<ul style="list-style-type: none"> ▶ If fumes, aerosols or combustion products are inhaled remove from contaminated area. ▶ Other measures are usually unnecessary.
Ingestion	<ul style="list-style-type: none"> ▶ Immediately give a glass of water. ▶ 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

See Section 11

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

Treat symptomatically.

SECTION 5 Firefighting measures

Continued...

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	<ul style="list-style-type: none"> ▶ Alert Fire Brigade and tell them location and nature of hazard. ▶ Wear breathing apparatus plus protective gloves in the event of a fire. ▶ Prevent, by any means available, spillage from entering drains or water courses.
Fire/Explosion Hazard	<ul style="list-style-type: none"> ▶ Non combustible. ▶ Not considered a significant fire risk, however containers may burn. 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	<ul style="list-style-type: none"> ▶ Clean up all spills immediately. ▶ Avoid breathing vapours and contact with skin and eyes. ▶ Control personal contact with the substance, by using protective equipment.
Major Spills	<ul style="list-style-type: none"> ▶ Absorb or contain isothiazolinone liquid spills with sand, earth, inert material or vermiculite. ▶ 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 (Na₂S₂O₅) or sodium bisulfite (NaHSO₃), or 12% sodium sulfite (Na₂SO₃) and 8% hydrochloric acid (HCl). ▶ Glutathione has also been used to inactivate the isothiazolinones.

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	<ul style="list-style-type: none"> ▶ Avoid all personal contact, including inhalation. ▶ Wear protective clothing when risk of exposure occurs. ▶ Use in a well-ventilated area.
Fire and explosion protection	See section 5
Other information	

7.2. Conditions for safe storage, including any incompatibilities

Suitable container	<ul style="list-style-type: none"> ▶ Polyethylene or polypropylene container. ▶ Packing as recommended by manufacturer. ▶ 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

GAMAZYME BTC



X — Must not be stored together

O — 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 Exposure Pattern Worker	PNECs Compartment
1,2-benzisothiazoline-3-one	Dermal 0.966 mg/kg bw/day (Systemic, Chronic) Inhalation 6.81 mg/m ³ (Systemic, Chronic) Dermal 0.345 mg/kg bw/day (Systemic, Chronic) * Inhalation 0.0012 mg/m ³ (Systemic, Chronic) *	0.00403 mg/L (Water (Fresh)) 0.0011 mg/L (Water - Intermittent release) 0.000403 mg/L (Water (Marine)) 0.0499 mg/kg sediment dw (Sediment (Fresh Water)) 0.00499 mg/kg sediment dw (Sediment (Marine)) 3 mg/kg soil dw (Soil) 1.03 mg/L (STP)

* 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

Ingredient	Original IDLH	Revised IDLH
1,2-benzisothiazoline-3-one	Not Available	Not Available
Non-hazardous ingredient	Not Available	Not Available
alcohols c9-11 ethoxylated	Not Available	Not Available
Fatty alcohol ethoxylates	Not Available	Not Available

Occupational Exposure Banding

Ingredient	Occupational Exposure Band Rating	Occupational Exposure Band Limit
1,2-benzisothiazoline-3-one	E	≤ 0.01 mg/m ³
Fatty alcohol ethoxylates	E	≤ 0.1 ppm

Notes: Occupational exposure banding is a process of assigning chemicals into specific categories or bands based on a chemical's potency and the adverse health outcomes associated with exposure. The output of this process is an occupational exposure band (OEB), which corresponds to a range of exposure concentrations that are expected to protect worker health.

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.

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. The basic types of engineering controls are: Process controls which involve changing the way a job activity or process is done to reduce the risk.
--	---

Continued...

8.2.2. Individual protection measures, such as personal protective equipment	
Eye and face protection	<ul style="list-style-type: none"> ▶ Safety glasses with side shields. ▶ Chemical goggles. [AS/NZS 1337.1, EN166 or national equivalent] ▶ Contact lenses may pose a special hazard; soft contact lenses may absorb and concentrate irritants.
Skin protection	See Hand protection below
Hands/feet protection	<p>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.</p> <p>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.</p> <ul style="list-style-type: none"> ▶ Butyl rubber gloves · Nitrile rubber gloves (Note: Nitric acid penetrates nitrile gloves in a few minutes.) ▶ Wear chemical protective gloves, e.g. PVC. ▶ Wear safety footwear or safety gumboots, e.g. Rubber
Body protection	See Other protection below
Other protection	<ul style="list-style-type: none"> ▶ Overalls. ▶ P.V.C apron. ▶ Barrier cream.

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	Green		
Physical state	Liquid	Relative density (Water = 1)	1-1.01
Odour	Not Available	Partition coefficient n-octanol / water	Not Available
Odour threshold	Not Available	Auto-ignition temperature (°C)	Not Available
pH (as supplied)	8.5	Decomposition temperature (°C)	Not Available
Melting point / freezing point (°C)	Not Available	Viscosity (cSt)	Not Available
Initial boiling point and boiling range (°C)	~100	Molecular weight (g/mol)	Not Available
Flash point (°C)	Not Available	Taste	Not Available
Evaporation rate	Not Available BuAC = 1	Explosive properties	Not Available
Flammability	Not Available	Oxidising properties	Not Available
Upper Explosive Limit (%)	Not Available	Surface Tension (dyn/cm or mN/m)	Not Available
Lower Explosive Limit (%)	Not Available	Volatile Component (%vol)	Not Available
Vapour pressure (kPa)	Not Available	Gas group	Not Available
Solubility in water	Miscible	pH as a solution (1%)	Not Available
Vapour density (Air = 1)	Not Available	VOC g/L	Not Available
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/m ³)	Not Available	Enclosed Space Ignition Deflagration Density (g/m ³)	Not Available
Nanoform Solubility	Not Available	Nanoform Particle Characteristics	Not Available
Particle Size	Not Available		

9.2. Other information

Not Available

Continued...

SECTION 10 Stability and reactivity

10.1.Reactivity	See section 7.2
10.2. Chemical stability	<ul style="list-style-type: none"> ▶ Unstable in the presence of incompatible materials. ▶ Product is considered stable. ▶ 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

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. 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. Solutions of 0.5% strength 1,2-benzisothiazoline-3-one (BIT) are irritating to the skin. Allergic 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%. 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. 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. 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 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.

GAMAZYME BTC	TOXICITY	IRRITATION
	Not Available	Not Available
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]
Non-hazardous ingredient	TOXICITY	IRRITATION
	Not Available	Not Available
alcohols c9-11 ethoxylated	TOXICITY	IRRITATION
	Dermal (rabbit) LD50: >2000 mg/kg ^[2]	Not Available
	Dermal (rabbit) LD50: >5000 mg/kg ^{*[2]}	

GAMAZYME BTC

	Oral (Rat) LD50: 1378 mg/kg ^[2]	
	Oral (Rat) LD50: 1400 mg/kg * ^[2]	
	Oral (Rat) LD50: 2700 mg/kg * ^[2]	
Fatty alcohol ethoxylates	TOXICITY Not Available	IRRITATION Not Available

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

The following information refers to contact allergens as a group and may not be specific to this product. 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. 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. Humans may be exposed to biocidal products in different ways in both occupational and domestic settings. 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. **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. 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.

For high boiling ethylene glycol ethers (typically triethylene- and tetraethylene glycol ethers): **Skin absorption:** Available skin absorption data for triethylene glycol ether (TGBE), triethylene glycol methyl ether (TGME), and triethylene glycol ethylene ether (TGEE) suggest that the rate of absorption in skin of these three glycol ethers is 22 to 34 micrograms/cm²/hr, with the methyl ether having the highest permeation constant and the butyl ether having the lowest. The rates of absorption of TGBE, TGEE and TGME are at least 100-fold less than EGME, EGEE, and EGBE, their ethylene glycol monoalkyl ether counterparts, which have absorption rates that range from 214 to 2890 micrograms/cm²/hr. Therefore, an increase in either the chain length of the alkyl substituent or the number of ethylene glycol moieties appears to lead to a decreased rate of percutaneous absorption. The material may produce severe irritation to the eye causing pronounced inflammation. Repeated or prolonged exposure to irritants may produce conjunctivitis. 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. Histologically there may be intercellular oedema of the spongy layer (spongiosis) and intracellular oedema of the epidermis. Prolonged contact is unlikely, given the severity of response, but repeated exposures may produce severe ulceration. Dermal (rabbit): 4000 mg/kg * Somnolence, ataxia, diarrhoea recorded.

1,2-BENZISOTHIAZOLINE-3-ONE & Fatty alcohol ethoxylates
No significant acute toxicological data identified in literature search.

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. Alcohol ethoxylates are according to CESIO (2000) classified as Irritant or Harmful depending on the number of EO-units: EO < 5 gives Irritant (Xi) with R38 (Irritating to skin) and R41 (Risk of serious damage to eyes) EO > 5-15 gives Harmful (Xn) with R22 (Harmful if swallowed) - R38/41 EO > 15-20 gives Harmful (Xn) with R22-41 >20 EO is not classified (CESIO 2000) Oxo-AE, C13 EO10 and C13 EO15, are Irritating (Xi) with R36/38 (Irritating to eyes and skin). AE are not included in Annex 1 of the list of dangerous substances of the Council Directive 67/548/EEC 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 (CO₂). 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).

Acute Toxicity	✗	Carcinogenicity	✗
Skin Irritation/Corrosion	✗	Reproductivity	✗

GAMAZYME BTC

Serious Eye Damage/Irritation	✓	STOT - Single Exposure	✗
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 BTC	Endpoint	Test Duration (hr)	Species	Value	Source
	Not Available	Not Available	Not Available	Not Available	Not Available
1,2-benzisothiazoline-3-one	Endpoint	Test Duration (hr)	Species	Value	Source
	EC50	72h	Algae or other aquatic plants	0.07mg/L	2
	NOEC(ECx)	72h	Algae or other aquatic plants	0.04mg/L	2
	EC50	48h	Crustacea	0.097mg/L	4
Non-hazardous ingredient	Endpoint	Test Duration (hr)	Species	Value	Source
	Not Available	Not Available	Not Available	Not Available	Not Available
alcohols c9-11 ethoxylated	Endpoint	Test Duration (hr)	Species	Value	Source
	EC50	96h	Algae or other aquatic plants	1.4mg/l	2
	NOEC(ECx)	720h	Fish	0.11-0.28mg/l	2
	LC50	96h	Fish	5-7mg/l	2
Fatty alcohol ethoxylates	Endpoint	Test Duration (hr)	Species	Value	Source
	Not Available	Not Available	Not Available	Not Available	Not Available
Legend:	Extracted from 1. IUCLID Toxicity Data 2. Europe ECHA Registered Substances - Ecotoxicological Information - Aquatic Toxicity 4. US EPA, Ecotox database - Aquatic Toxicity Data 5. ECETOC Aquatic Hazard Assessment Data 6. NITE (Japan) - Bioconcentration Data 7. METI (Japan) - Bioconcentration Data 8. Vendor Data				

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 (Lepomis macrochirus) 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.

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
alcohols c9-11 ethoxylated	LOW (LogKOW = 2.42)

12.4. Mobility in soil

Ingredient	Mobility
	No Data available for all ingredients

12.5. Results of PBT and vPvB assessment

	P	B	T
Relevant available data	Not Available	Not Available	Not Available
PBT	✗	✗	✗
vPvB	✗	✗	✗
PBT Criteria fulfilled?	No		
vPvB	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 disruptors 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 deformities.

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	<p>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.</p> <ul style="list-style-type: none"> ▶ DO NOT allow wash water from cleaning or process equipment to enter drains. ▶ It may be necessary to collect all wash water for treatment before disposal. ▶ In all cases disposal to sewer may be subject to local laws and regulations and these should be considered first. ▶ Recycle wherever possible. ▶ Consult manufacturer for recycling options or consult local or regional waste management authority for disposal if no suitable treatment or disposal facility can be identified. ▶ 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).
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
	Subsidiary Hazard	Not Applicable

GAMAZYME BTC

14.4. Packing group	Not Applicable	
14.5. Environmental hazard	Not Applicable	
14.6. Special precautions for user	Hazard identification (Kemler)	Not Applicable
	Classification code	Not Applicable
	Hazard Label	Not Applicable
	Special provisions	Not Applicable
	Limited quantity	Not Applicable
	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
	ICAO / IATA Subsidiary Hazard	Not Applicable
	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
	Cargo Only Packing Instructions	Not Applicable
	Cargo Only Maximum Qty / Pack	Not Applicable
	Passenger and Cargo Packing Instructions	Not Applicable
	Passenger and Cargo Maximum Qty / Pack	Not Applicable
	Passenger and Cargo Limited Quantity Packing Instructions	Not Applicable
	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	
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

GAMAZYME BTC

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
1,2-benzisothiazoline-3-one	Not Available
Non-hazardous ingredient	Not Available
alcohols c9-11 ethoxylated	Not Available
Fatty alcohol ethoxylates	Not Available

14.7.3. Transport in bulk in accordance with the IGC Code

Product name	Ship Type
1,2-benzisothiazoline-3-one	Not Available
Non-hazardous ingredient	Not Available
alcohols c9-11 ethoxylated	Not Available
Fatty alcohol ethoxylates	Not Available

SECTION 15 Regulatory information

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

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

Europe EC Inventory

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

Non-hazardous ingredient is found on the following regulatory lists

Not Applicable

alcohols c9-11 ethoxylated is found on the following regulatory lists

Not Applicable

Fatty alcohol ethoxylates is found on the following regulatory lists

Not Applicable

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	No (Fatty alcohol ethoxylates)
Canada - NDSL	No (1,2-benzisothiazoline-3-one; alcohols c9-11 ethoxylated; Fatty alcohol ethoxylates)
China - IECSC	Yes

GAMAZYME BTC

National Inventory	Status
Europe - EINEC / ELINCS / NLP	No (alcohols c9-11 ethoxylated; Fatty alcohol ethoxylates)
Japan - ENCS	Yes
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 (Fatty alcohol ethoxylates)
Vietnam - NCI	Yes
Russia - FBEPH	No (alcohols c9-11 ethoxylated; Fatty alcohol ethoxylates)
Legend:	Yes = All CAS declared ingredients are on the inventory 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	17/10/2024
Initial Date	02/01/2018

CONTACT POINT

- For quotations contact your local Customer Services - <https://wssdirectory.wilhelmsen.com/#/customerservices> - Responsible for safety data sheet Wilhelmsen Ships Service AS - Prepared by: Compliance Manager, - Email: wss.global.sdsinfo@wilhelmsen.com - Telephone: Tel.: +47 67584000

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.
H400	Very toxic to aquatic life.

SDS Version Summary

Version	Date of Update	Sections Updated
11.26	17/10/2024	Composition / information on ingredients - Ingredients, Identification of the substance / mixture and of the company / undertaking - Synonyms, Identification of the substance / mixture and of the company / undertaking - Use

Other information

Classification of the preparation and its individual components has drawn on official and authoritative sources as well as independent review by the Chemwatch Classification committee using available literature references.

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.

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

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

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

Powered by AuthorITe, from Chemwatch.