

Product brands by Wilhelmsen











GAMAZYME FRESH

Outback (M)SDS portal: https://jr.chemwatch.net/outb/account/autologin?

login=wilhelmsen

Part Number: **743189** Version No: 2.16

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

Issue Date: 26/07/2023 Print Date: 07/08/2024 L.REACH.ISL.EN

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

1.1. Product Identifier

| Product name | GAMAZYME FRESH |
|-------------------------------|----------------------------------|
| Chemical Name | Not Applicable |
| Synonyms | Not Available |
| Chemical formula | Not Applicable |
| Other means of identification | 743189 UFI:A38D-7481-4208-NFJQ |

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

| Product Category Consumer | PC3 Air care products | | |
|------------------------------|---|--|--|
| Sectors of Use | SU3 Industrial uses | | |
| Relevant identified uses | Liquid formulation containing a mixture of microorganisms used in odour control applications. | | |
| 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 | Outback (M)SDS portal: https://jr.chemwatch.net/outb/account/autologin? login=wilhelmsen | Wilhelmsen Ships Service AS* Central Warehouse | | |
|-------------------------|---|--|--|--|
| Address | 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 | Not Available | +31 10 4877 777 | | |
| Fax | Not Available | Not Available | | |
| Website | https://www.wilhelmsen.com | https://www.wilhelmsen.com | | |
| Email | wss.global.sdsinfo@wilhelmsen.com | wss.rotterdam@wilhelmsen.com | | |

1.4. Emergency telephone number

| Association / Organisation | 24hrs - Chemwatch | Dutch nat. poison centre | CHEMWATCH EMERGENCY RESPONSE (24/7) |
|-----------------------------------|-------------------|--------------------------|--|
| Emergency telephone numbers | +31-10-4877700 | + 31 88 7558561 | +61 3 9573 3188 |
| Other emergency telephone numbers | +31-10-4877700 | + 31 10 4877700 | Not Available |

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

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SECTION 2 Hazards identification

2.1. Classification of the substance or mixture

Classification according to regulation (EC) No 1272/2008 [CLP] and amendments ^[1]

Not Applicable

2.2. Label elements

| Hazard pictogram(s) | Not Applicable |
|---------------------|----------------|
| | |
| Signal word | Not Applicable |

Hazard statement(s)

Not Applicable

Supplementary statement(s)

| EUH208 | Contains 1,2-benzisothiazoline-3-one, 5-chloro-2-methyl-4-isothiazolin-3-one, eucalyptol. May produce an allergic reaction. |
|--------|---|
| EUH210 | Safety data sheet available on request. |

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

Not Applicable

Precautionary statement(s) Response

Not Applicable

Precautionary statement(s) Storage

Not Applicable

Precautionary statement(s) Disposal

Not Applicable

Material contains sodium xylenesulfonate, 1,2-benzisothiazoline-3-one, eucalyptol, 5-chloro-2-methyl-4-isothiazolin-3-one.

2.3. Other hazards

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

SECTION 3 Composition / information on ingredients

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. 1300-72-7 2.215-090-9 3.Not Available 4.Not Available | 1-5 | sodium xylenesulfonate | Skin Corrosion/Irritation Category 2, Serious Eye Damage/Eye Irritation Category 2, Specific Target Organ Toxicity - Single Exposure (Respiratory Tract Irritation) Category 3; H315, H319, H335 [1] | Not Available Acute M factor: Not Available Chronic M factor: Not | Not Available |

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| 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 |
|---|----------------|--|---|--|---|
| | | | | Available | |
| 1. 2634-33-5 2.220-120-9 3.613-088-00-6 4.Not Available | 0.01-0.1 | 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] | Skin Sens. 1; H317: C ≥ 0,05 % Acute M factor: 10 Chronic M factor: 1 | Not Available |
| 1. 26172-55-4 2.247-500-7 3.613-167-00-5 4.Not Available | 0.001- 0.01 | 5-chloro-2-methyl- 4-isothiazolin-3-one | Acute Toxicity (Oral) Category 3, Acute Toxicity (Dermal) Category 2, Skin Corrosion/Irritation Category 1C, Sensitisation (Skin) Category 1A, Serious Eye Damage/Eye Irritation Category 1, Acute Toxicity (Inhalation) Category 2, Hazardous to the Aquatic Environment Acute Hazard Category 1, Hazardous to the Aquatic Environment Long-Term Hazard Category 1; H301, H310, H314, H317, H318, H330, H400, H410 [2] | Not Available Acute M factor: 10 Chronic M factor: Not Available | Not Available |
| 1. 470-82-6 2.207-431-5 3.Not Available 4.Not Available | 0.01-0.1 | <u>eucalyptol</u> | Flammable Liquids Category 3, Skin Corrosion/Irritation Category 2, Sensitisation (Skin) Category 1, Serious Eye Damage/Eye Irritation Category 1, Specific Target Organ Toxicity - Single Exposure (Respiratory Tract Irritation) Category 3, Specific Target Organ Toxicity - Single Exposure (Narcotic Effects) Category 3, Hazardous to the Aquatic Environment Long-Term Hazard Category 3; H226, H315, H317, H318, H335, H336, H412, EUH019 [1] | Not Available Acute M factor: Not Available Chronic M factor: Not Available | Not Available |
| Legend: | | • | assification drawn from Regulation (EU) No 1272/2008 - Ani ubstance identified as having endocrine disrupting propertie | | sification drawn from |

SECTION 4 First aid measures

4.1. Description of first aid measures

| Eye Contact | If this product comes in contact with eyes: ► Wash out immediately with water. ► If irritation continues, seek medical attention. ► Removal of contact lenses after an eye injury should only be undertaken by skilled personnel. |
|--------------|--|
| Skin Contact | If skin contact occurs: Immediately remove all contaminated clothing, including footwear. Flush skin and hair with running water (and soap if available). Seek medical attention in event of irritation. |
| Inhalation | If fumes, aerosols or combustion products are inhaled remove from contaminated area. Other measures are usually unnecessary. |
| Ingestion | 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

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

Avoid contamination with oxidising agents i.e. nitrates, oxidising acids, chlorine bleaches, pool chlorine etc. as ignition may result

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5.3. Advice for firefighters

▶ 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 Fighting • Use fire fighting procedures suitable for surrounding area. DO NOT approach containers suspected to be hot. ▶ Cool fire exposed containers with water spray from a protected location. If safe to do so, remove containers from path of fire. carbon dioxide (CO2) Fire/Explosion Hazard other pyrolysis products typical of burning organic material. 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. Avoid breathing vapours and contact with skin and eyes. Control personal contact with the substance, by using protective equipment. Contain and absorb spill with sand, earth, inert material or vermiculite. Wipe up. Place in a suitable, labelled container for waste disposal. |
|--------------|---|
| Major Spills | 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 (HCI). Glutathione has also been used to inactivate the isothiazolinones. 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. If contamination of drains or waterways occurs, advise emergency services. After clean up operations, decontaminate and launder all protective clothing 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

| 7.11.11 recautions for sale in | anding |
|--------------------------------|---|
| Safe handling | Avoid all personal contact, including inhalation. Wear protective clothing when risk of exposure occurs. Use in a well-ventilated area. Avoid contact with moisture. Avoid contact with incompatible materials. When handling, DO NOT eat, drink or smoke. Keep containers securely sealed when not in use. DO NOT allow clothing wet with material to stay in contact with skin |
| Fire and explosion protection | See section 5 |
| Other information | |

7.2. Conditions for safe storage, including any incompatibilities

| Suitable container | Polyethylene or polypropylene container. Packing as recommended by manufacturer. Check all containers are clearly labelled and free from leaks. |
|--|---|
| Storage incompatibility | ► Avoid reaction with oxidising agents |
| Hazard categories in accordance with Regulation (EC) No 2012/18/EU (Seveso III) | Not Available |

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Qualifying quantity (tonnes) of dangerous substances as referred to in Article 3(10) for the application of

Not Available















- X Must not be stored together
- 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/m³ (Systemic, Chronic) Dermal 0.345 mg/kg bw/day (Systemic, Chronic) * Inhalation 0.0012 mg/m³ (Systemic, Chronic) * | 4.03 µg/L (Water (Fresh)) 1.1 µg/L (Water - Intermittent release) 0.403 µg/L (Water (Marine)) 49.9 µg/kg sediment dw (Sediment (Fresh Water)) 4.99 µg/kg sediment dw (Sediment (Marine)) 3 mg/kg soil dw (Soil) 1.03 mg/L (STP) | |
| 5-chloro-2-methyl-4- isothiazolin-3-one | Inhalation 0.02 mg/m³ (Local, Chronic) Inhalation 0.04 mg/m³ (Local, Acute) Oral 0.09 mg/kg bw/day (Systemic, Chronic) * Inhalation 0.02 mg/m³ (Local, Chronic) * Oral 0.11 mg/kg bw/day (Systemic, Acute) * Inhalation 0.04 mg/m³ (Local, Acute) * | 3.39 µg/L (Water (Fresh)) 3.39 µg/L (Water - Intermittent release) 3.39 µg/L (Water (Marine)) 0.027 mg/kg sediment dw (Sediment (Fresh Water)) 0.027 mg/kg sediment dw (Sediment (Marine)) 0.01 mg/kg soil dw (Soil) 0.23 mg/L (STP) | |
| eucalyptol | Dermal 2 mg/kg bw/day (Systemic, Chronic) Inhalation 7.05 mg/m³ (Systemic, Chronic) Dermal 1 mg/kg bw/day (Systemic, Chronic) * Inhalation 0.00174 mg/m³ (Systemic, Chronic) * Oral 600 mg/kg bw/day (Systemic, Chronic) * | 57 µg/L (Water (Fresh)) 0.57 mg/L (Water - Intermittent release) 5.7 µg/L (Water (Marine)) 1.425 mg/kg sediment dw (Sediment (Fresh Water)) 0.142 mg/kg sediment dw (Sediment (Marine)) 0.25 mg/kg soil dw (Soil) 10 mg/L (STP) 40 mg/kg food (Oral) | |

^{*} Values for General Population

Occupational Exposure Limits (OEL)

INGREDIENT DATA

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

Not Applicable

Emergency Limits

| Ingredient | TEEL-1 | TEEL-2 | TEEL-3 |
|--|-----------|-----------|----------|
| 5-chloro-2-methyl-4- isothiazolin-3-one | 0.6 mg/m3 | 6.6 mg/m3 | 40 mg/m3 |

| Ingredient | Original IDLH | Revised IDLH |
|--|---------------|---------------|
| sodium xylenesulfonate | Not Available | Not Available |
| 1,2-benzisothiazoline-3-one | Not Available | Not Available |
| 5-chloro-2-methyl-4- isothiazolin-3-one | Not Available | Not Available |

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| Ingredient | Original IDLH | Revised IDLH |
|------------|---------------|---------------|
| eucalyptol | Not Available | Not Available |

Occupational Exposure Banding

| Ingredient | Occupational Exposure Band Rating | Occupational Exposure Band Limit | |
|--|--|----------------------------------|--|
| sodium xylenesulfonate | E | ≤ 0.01 mg/m³ | |
| 1,2-benzisothiazoline-3-one | E | ≤ 0.01 mg/m³ | |
| 5-chloro-2-methyl-4- isothiazolin-3-one | Е | ≤ 0.01 mg/m³ | |
| eucalyptol | 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. 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.

Fragrance substance lacking human data, with respect to contact allergenicity in humans and used in high volumes according to industry information. Scientific Committee on Consumer Safety SCCS OPINION on Fragrance allergens in cosmetic products 2012

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

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.

8.2.1. Appropriate engineering controls

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.

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. 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.
- ► 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. 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

- ▶ Wear chemical protective gloves, e.g. PVC.
- ▶ Wear safety footwear or safety gumboots, e.g. Rubber

NOTE:

- ▶ The material may produce skin sensitisation in predisposed individuals. Care must be taken, when removing gloves and other protective equipment, to avoid all possible skin contact.
- Contaminated leather items, such as shoes, belts and watch-bands should be removed and destroyed.

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.

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.

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.

- Butvl rubber gloves
- · Nitrile rubber gloves (Note: Nitric acid penetrates nitrile gloves in a few minutes.)

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| Body protection | See Other protection below |
|------------------|--|
| Other protection | Overalls. P.V.C apron. Barrier cream. Skin cleansing cream. Eye wash unit. |

Respiratory protection

Type A Filter of sufficient capacity. (AS/NZS 1716 & 1715, EN 143:2000 & 149:2001, ANSI Z88 or national equivalent)

Selection of the Class and Type of respirator will depend upon the level of breathing zone contaminant and the chemical nature of the contaminant. Protection Factors (defined as the ratio of contaminant outside and inside the mask) may also be important.

| Required minimum protection factor | Maximum gas/vapour concentration present in air p.p.m. (by volume) | Half-face Respirator | Full-Face Respirator |
|------------------------------------|--|-------------------------|-------------------------|
| up to 10 | 1000 | A-AUS / Class1 | - |
| up to 50 | 1000 | - | A-AUS / Class 1 |
| up to 50 | 5000 | Airline * | - |
| up to 100 | 5000 | - | A-2 |
| up to 100 | 10000 | - | A-3 |
| 100+ | | | Airline** |

^{* -} Continuous Flow ** - Continuous-flow or positive pressure demand

A(All classes) = Organic vapours, B AUS or B1 = Acid gasses, B2 = Acid gas or hydrogen cyanide(HCN), B3 = Acid gas or hydrogen cyanide(HCN), E = Sulfur dioxide(SO2), G = Agricultural chemicals, K = Ammonia(NH3), Hg = Mercury, NO = Oxides of nitrogen, MB = Methyl bromide, AX = Low boiling point organic compounds(below 65 degC)

- ▶ Cartridge respirators should never be used for emergency ingress or in areas of unknown vapour concentrations or oxygen content.
- The wearer must be warned to leave the contaminated area immediately on detecting any odours through the respirator. The odour may indicate that the mask is not functioning properly, that the vapour concentration is too high, or that the mask is not properly fitted. Because of these limitations, only restricted use of cartridge respirators is considered appropriate.
- Cartridge performance is affected by humidity. Cartridges should be changed after 2 hr of continuous use unless it is determined that the humidity is less than 75%, in which case, cartridges can be used for 4 hr. Used cartridges should be discarded daily, regardless of the length of time used

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 | Off-whit liquid | | |
|--|-----------------|---|----------------|
| | | | |
| Physical state | Liquid | Relative density (Water = 1) | 1.0 |
| Odour | Not Available | Partition coefficient n- octanol / water | Not Available |
| Odour threshold | Not Available | Auto-ignition temperature (°C) | Not Applicable |
| pH (as supplied) | ~8 | Decomposition temperature (°C) | Not Applicable |
| Melting point / freezing point (°C) | 0 | 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 | 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 |
| Nanoform Solubility | Not Available | Nanoform Particle | Not Available |

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| | | Characteristics | |
|---------------|---------------|-----------------|--|
| 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. 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

| 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. Isothiazolinones are moderately to highly toxic by oral administration. The major signs of toxicity were severe gastric irritation, lethargy, and ataxia |
| | Skin contact is not thought to have harmful health effects (as classified under EC Directives); the material may still produce health damage following entry through wounds, lesions or abrasions. |
| Skin Contact | Limited evidence exists, or practical experience predicts, that the material either produces inflammation of the skin in a substantial number of individuals following direct contact, and/or produces significant inflammation when applied to the healthy intact skin of animals, for up to four hours, such inflammation being present twenty-four hours or more after the end of the exposure period. Skin irritation may also be present after prolonged or repeated exposure; this may result in a form of contact dermatitis (nonallergic). The dermatitis is often characterised by skin redness (erythema) and swelling (oedema) which may progress to blistering (vesiculation), scaling and thickening of the epidermis. At the microscopic level there may be intercellular oedema of the spongy layer of the skin (spongiosis) and intracellular oedema of the epidermis. 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. 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. |
| Еуе | Although the liquid is not thought to be an irritant (as classified by EC Directives), direct contact with the eye may produce transient discomfort characterised by tearing or conjunctival redness (as with windburn). 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 | Practical experience shows that skin contact with the material is capable either of inducing a sensitisation reaction in a substantial number of individuals, and/or of producing a positive response in experimental animals. Substances that can cause occupational asthma (also known as asthmagens and respiratory sensitisers) can induce a state of specific airway hyper-responsiveness via an immunological, irritant or other mechanism. Once the airways have become hyper-responsive, further exposure to the substance, sometimes even to tiny quantities, may cause respiratory symptoms. These symptoms can range in severity from a runny nose to asthma. Not all workers who are exposed to a sensitiser will become hyper-responsive and it is impossible to identify in advance who are likely to become hyper-responsive. |

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Substances than can cuase occupational asthma should be distinguished from substances which may trigger the symptoms of asthma in people with pre-existing air-way hyper-responsiveness. The latter substances are not classified as asthmagens or respiratory sensitisers

Wherever it is reasonably practicable, exposure to substances that can cuase occupational asthma should be prevented. 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.

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.

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.

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.

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.

| | TOXICITY | IRRITATION | | |
|--------------------------|--|---|--|--|
| GAMAZYME FRESH | Not Available | Not Available | | |
| | TOXICITY | IRRITATION | | |
| sodium xylenesulfonate | Oral (Rat) LD50: >10 mg/kg ^[2] | Eye: adverse effect observed (irritating) ^[1] | | |
| | | Skin: no adverse effect observed (not irritating) ^[1] | | |
| | TOXICITY | IRRITATION | | |
| 1,2-benzisothiazoline-3- | dermal (rat) LD50: >2000 mg/kg ^[1] | Eye: adverse effect observed (irreversible damage) ^[1] | | |
| 55 | Oral (Rat) LD50: 454 mg/kg ^[1] | Skin: no adverse effect observed (not irritating) $^{[1]}$ | | |
| | TOXICITY | IRRITATION | | |
| 5-chloro-2-methyl-4- | dermal (rat) LD50: >1008 mg/kg ^[2] | Eye: adverse effect observed (irreversible damage) ^[1] | | |
| isothiazolin-3-one | Inhalation (Rat) LC50: 1.23 mg/l4h ^[2] | Skin: adverse effect observed (corrosive) ^[1] | | |
| | Oral (Rat) LD50: 53 mg/kg ^[2] | Skin: adverse effect observed (irritating) ^[1] | | |
| | TOXICITY | IRRITATION | | |
| eucalyptol | dermal (rat) LD50: >2000 mg/kg ^[1] | Eye: no adverse effect observed (not irritating) ^[1] | | |
| | Oral (Rat) LD50: 2480 mg/kg ^[2] | Skin: no adverse effect observed (not irritating) ^[1] | | |
| Legend: | Nalue 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 | | | |

SODIUM XYLENESULFONATE

Toxicological data are available and well documented for representative toluenesulfonates, xylenesulfonates and cumenesulfonates (including sodium, potassium, ammonium and calcium salts). These data demonstrate that hydrotropes have a low order of acute toxicity by all relevant routes (LC50s range from 100s to 1000s mg/kg), are not genotoxic *in vitro* or *in vivo*, show no evidence of a carcinogenic response (or any other systemic toxicity) in 2-year dermal exposure studies, and failed to induce developmental, teratogenic or fertility (sex organ) effects.

Adverse effects after repeated long term dosing of hydrotropes to animals included epidermal hyperplasia at the site of application in dermal studies, and decreased relative spleen weight in females in oral studies. The critical adverse effect and corresponding systemic NOAEL is 763 mg a.i./kg bw based upon decreased relative spleen weight in female rats in a 90-day oral study. The NOAEL for local effects, based on epidermal hyperplasia at the site of application, was 440 mg a.i./kg bw for mice in 90-day dermal studies.

Hydrotropes can be classified as a negligible-to-slight irritant to skin and a slight-to-moderate irritant to eyes. The irritation potential of aqueous solutions of hydrotropes depends on concentration, and the irritation is lessened with rinsing. Hydrotropes are not considered to be skin sensitisers.

HERA Report (Hydrotropes) September 2005

Hydrotropes in this category were assessed for mutagen/ genotoxic potential in a variety of assays including the mouse micronucleus, Ames, mouse lymphoma, sister chromatid exchange and chromosome aberration assays. No positive results were seen in vitro or in vivo in any of the studies.

1,2-BENZISOTHIAZOLINE-3-ONE

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

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GAMAZYME FRESH

metabolite. Ring opening has also been observed in benzothiazoles. For instance, benzothiazole itself is converted to S-

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. 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.

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.

Considered to be the major sensitiser in Kathon CG (1) (1). Bruze et al - Contact Dermatitis 20: 219-39, 1989 Exposure to the material may result in a possible risk of irreversible effects. The material may produce mutagenic effects in man. This concern is raised, generally, on the basis of

appropriate studies with similar materials using mammalian somatic cells in vivo. Such findings are often supported by positive results from in vitro mutagenicity studies.

The European Union has reclassified several formaldehyde-releasing agents (FRAs) such as methylenedimorpholine (MBM), oxazolidine (MBO) and hydroxypropylamine (HPT) as category 1B carcinogens. Previously, formaldehyde itself was classed as a carcinogen - but formaldehyde-releasing agents were not. This is no longer the case. Based on this regulation, formulations for which the maximum theoretical concentration of releasable formaldehyde is more than > 1000 ppm (>0.1%), have to be labelled as carcinogenic

Water mix metalworking fluids are subject to contamination by bacteria and fungi, and the control of this is an essential part of good fluid maintenance. The use of preservatives both within the formulation and tank-side treatment plays a significant contribution in the protection of potentially harmful microbes that could cause health problems for workers.

A large proportion of bactericides on the market today are classed as formaldehyde releasing biocides which means that under specific conditions they release small amounts of formaldehyde - this is their mode of action in the presence of bacteria. Although they are effective as a biocide their use may become restricted or unfavourable due to potential changes in legislation. A decision by the ECHA (European Chemicals Agency) was made to re-classify formaldehyde as a category 1b H350 carcinogen and category 2 mutagen in June 2015.

It has also been proposed by the ECHA Risk Assessment Committee (RAC) that formaldehyde release biocides should be classified the same as formaldehyde because formaldehyde is released when these substances come into contact under favorable conditions (i.e. interaction with microorganisms).

Formaldehyde generators (releasers) are often used as preservatives (antimicrobials, biocides, microbiocides). Formaldehyde may be generated following hydrolysis.

The material may be irritating to the eye, with prolonged contact causing inflammation. Repeated or prolonged exposure to irritants may produce conjunctivitis.

The material may cause 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) and swelling epidermis. Histologically there may be intercellular oedema of the spongy layer (spongiosis) and intracellular oedema of the epidermis.

EUCALYPTOL

The chemical category designated terpenoid hydrocarbons includes three simple C10 isomeric monocyclic terpene hydrocarbons (d-limonene, dl-limonene, and terpinolene) two simple C10 acyclic terpene hydrocarbons (beta-myrcene and dihydromyrcene) and mixtures composed primarily of d-limonene, dl-limonene (dipentene), terpinolene, myrcene, and alphaand beta-pinene Monoterpene hydrocarbons are mainly released by coniferous woodland such as pine trees, cedars, redwood and firs. To a lesser extent, they are also produced and released by deciduous plants. They are common components of traditional foods occurring in essentially all fruits and vegetables.

Members of this chemical category are of very low acute toxicity

Studies of terpene hydrocarbons indicate that they are rapidly absorbed, distributed, metabolised and excreted. The principal metabolic pathway involves side chain oxidation to yield monocyclic terpene alcohols and carboxylic acids. These metabolites are mainly conjugated with glucuronic acid and excreted in the urine, or to a lesser extent in the feces. A secondary pathway involves epoxidation of either the exocyclic or endocyclic double bond yielding an epoxide that is subsequently detoxicated via formation of the corresponding diol or conjugation with glutathione. Although some species- and sex-specific differences exist, studies for d-limonene and beta-myrcene indicate that the monoterpene hydrocarbons in this chemical category will participate in common pathways of absorption, distribution, metabolism and excretion.

Genotoxicity: Based on the results of this in vivo genotoxicity assay and the numerous in vitro genotoxicity assays, it is unlikely that any of these materials would exhibit a significant genotoxic potential in vivo.

Carcinogenicity: Under the conditions of 2-year gavage studies, conducted by NTP, there was clear evidence of carcinogenic activity of d-limonene for male F344/N rats as shown by increased incidences in tubular cell hyperplasia, adenomas, and adenocarcinomas of the kidney.

d-Limonene is readily absorbed by inhalation and ingestion. Dermal absorption is reported to be lower than by the inhalation route. d-Limonene is rapidly distributed to different tissues in the body, readily metabolised and eliminated primarily through the

Limonene exhibits low acute toxicity by all three routes in animals. Limonene is a skin irritant in both experimental animals and humans. Limited data are available on the potential to cause eve and respiratory irritation. Autooxidised products of d-limonene have the potential to be skin sensitisers. Limited data are available in humans on the potential to cause respiratory sensitisation. Adverse reactions to fragrances in perfumes and in fragranced cosmetic products include allergic contact dermatitis, irritant contact dermatitis, photosensitivity, immediate contact reactions (contact urticaria), and pigmented contact dermatitis. Airborne and connubial contact dermatitis occur.

5-CHLORO-2-METHYL-4-

ISOTHIAZOLIN-3-ONE

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Intolerance to perfumes, by inhalation, may occur if the perfume contains a sensitising principal. Symptoms may vary from general illness, coughing, phlegm, wheezing, chest-tightness, headache, exertional dyspnoea, acute respiratory illness, hayfever, and other respiratory diseases (including asthma). Perfumes can induce hyper-reactivity of the respiratory tract without producing an IgE-mediated allergy or demonstrable respiratory obstruction. This was shown by placebo-controlled challenges of nine patients to "perfume mix". The same patients were also subject to perfume provocation, with or without a carbon filter mask, to ascertain whether breathing through a filter with active carbon would prevent symptoms. The patients breathed through the mouth, during the provocations, as a nose clamp was used to prevent nasal inhalation.

Fragrance allergens act as haptens, i.e. low molecular weight chemicals that are immunogenic only when attached to a carrier protein. However, not all sensitising fragrance chemicals are directly reactive, but require previous activation. A **prehapten** is a chemical that itself is non- or low-sensitising, but that is transformed into a hapten outside the skin by simple chemical transformation (air oxidation, photoactivation) and without the requirement of specific enzymatic systems.

In the case of prehaptens, it is possible to prevent activation outside the body to a certain extent by different measures, e.g. prevention of air exposure during handling and storage of the ingredients and the final product, and by the addition of suitable antioxidants. When antioxidants are used, care should be taken that they will not be activated themselves and thereby form new sensitisers

Prehaptens

Most terpenes with oxidisable allylic positions can be expected to autoxidise on air exposure due to their inherent properties. Depending on the stability of the oxidation products that are formed, a difference in the sensitisation potency of the oxidised terpenes can be seen

Autoxidation is a free radical chain reaction in which hydrogen atom abstraction in combination with addition of oxygen forms peroxyl radicals. The reaction shows selectivity for positions where stable radicals can be formed. So far, all fragrance substances that have been investigated with regard to the influence of autoxidation on the allergenic potential, including identification of formed oxidation products, have oxidisable allylic positions that are able to form hydroperoxides and/or hydrogen peroxide as primary oxidation products upon air exposure.

GAMAZYME FRESH & 1,2-BENZISOTHIAZOLINE-3-ONE & 5-CHLORO-2-METHYL-4-ISOTHIAZOLIN-3-ONE & EUCALYPTOL 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. 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.

for alkyl sulfates; alkane sulfonates and alpha-olefin sulfonates

Most chemicals of this category are not defined substances, but mixtures of homologues with different alkyl chain lengths. Alphaolefin sulfonates are mixtures of alkene sulfonate and hydroxyl alkane sulfonates with the sulfonate group in the terminal position and the double bond, or hydroxyl group, located at a position in the vicinity of the sulfonate group.

Common physical and/or biological pathways result in structurally similar breakdown products, and are, together with the surfactant properties, responsible for similar environmental behavior and essentially identical hazard profiles with regard to human health.

Acute toxicity: These substances are well absorbed after ingestion; penetration through the skin is however poor. After absorption, these chemicals are distributed mainly to the liver.

Acute oral LD50 values of alkyl sulfates in rats and/or mice were (in mg/kg):

C10-; 290-580

C10-16-, and C12-; 1000-2000

C12-14, C12-15, C12-16, C12-18 and C16-18-; >2000

C14-18, C16-18-; >5000

The clinical signs observed were non-specific (piloerection, lethargy, decreased motor activity and respiratory rate, diarrhoea). At necropsy the major findings were irritation of the gastrointestinal tract and anemia of inner organs.

Based on limited data, the acute oral LD50 values of alkane sulfonates and alpha-olefin sulfonates of comparable chain lengths are assumed to be in the same range.

The counter ion does not appear to influence the toxicity in a substantial way.

GAMAZYME FRESH & SODIUM XYLENESULFONATE

Acute dermal LD50 values of alkyl sulfates in rabbits (mg/ kg):

C12-; 200

C12-13 and C10-16-;>500

Apart from moderate to severe skin irritation, clinical signs included tremor, tonic-clonic convulsions, respiratory failure, and body weight loss in the study with the C12- alkyl sulfate and decreased body weights after administration of the C10-16- alkyl sulfates. No data are available for alkane sulfonates but due to a comparable metabolism and effect concentrations in long-term studies effect concentrations are expected to be in the same range as found for alkyl sulfates.

There are no data available for acute inhalation toxicity of alkyl sulfates, alkane sulfonates or alpha-olefin sulfonates.

In skin irritation tests using rabbits (aqueous solutions, OECD TG 404):

C8-14 and C8-16 (30%), C12-14 (90%), C14-18 (60%)- corrosive

Under occlusive conditions:

C12, and C12-14 (25%), C12-15-, C13-15 and C15-16 (5-7%) - moderate to strong irritants

Comparative studies investigating skin effects like transepidermal water loss, epidermal electrical conductance, skin swelling, extraction of amino acids and proteins or development of erythema in human volunteers consistently showed a maximum of effects with C12-alkyl sulfate, sodium; this salt is routinely used as a positive internal control giving borderline irritant reactions in skin irritation studies performed on humans. As the most irritant alkyl sulfate it can be concluded that in humans 20% is the threshold concentration for irritative effects of alkyl sulfates in general.

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SODIUM
XYLENESULFONATE & 5CHLORO-2-METHYL-4ISOTHIAZOLIN-3-ONE &
EUCALYPTOL

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.

SODIUM
XYLENESULFONATE &
1,2-BENZISOTHIAZOLINE3-ONE & 5-CHLORO-2METHYL-4-ISOTHIAZOLIN3-ONE

No significant acute toxicological data identified in literature search.

1,2-BENZISOTHIAZOLINE-3-ONE & 5-CHLORO-2-METHYL-4-ISOTHIAZOLIN-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. 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.

| Acute Toxicity | × | Carcinogenicity | × |
|--------------------------------------|---|--------------------------|---|
| Skin Irritation/Corrosion | × | Reproductivity | × |
| 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

| | Endpoint | Test Duration (hr) | Species | Value | Source | |
|--------------------------|------------------|--------------------|-------------------------------|------------------|------------------|--|
| GAMAZYME FRESH | Not Available | Not Available | Not Available | Not Available | Not Available | |
| | Endpoint | Test Duration (hr) | Species | Value | Source | |
| sodium xylenesulfonate | EC50 | 72h | Algae or other aquatic plants | ~252mg/l | 2 | |
| | EC50 | 48h | Crustacea | >400mg/l | 1 | |
| | NOEC(ECx) | 72h | Algae or other aquatic plants | 40mg/l | 2 | |
| | EC50 | 96h | Algae or other aquatic plants | >=230mg/l | 2 | |
| 1,2-benzisothiazoline-3- | Endpoint | Test Duration (hr) | Species | Value | Source | |
| one | EC50 | 72h | Algae or other aquatic plants | 0.07mg/L | 2 | |

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| | EC50 | 48h | Crustacea | 0.097mg/L | 4 |
|--|---------------|--------------------|--|---------------------|------------|
| | LC50 | 96h | Fish | | 4 |
| | NOEC(ECx) 72h | | Algae or other aquatic plants | 0.04mg/L | 2 |
| | Endpoint | Test Duration (hr) | Species | Value | Sourc |
| | EC50 | 72h | Algae or other aquatic plants | 0.018- 0.026mg/L | 4 |
| | EC50 | 48h | Crustacea | 4.71mg/l | 1 |
| 5-chloro-2-methyl-4- isothiazolin-3-one | LC50 | 96h | Fish | 0.13- 0.31mg/L | 4 |
| | NOEC(ECx) | 504h | Crustacea 0.172 | | 1 |
| | EC50 | 96h | Algae or other aquatic plants | 0.03- 0.13mg/L | 4 |
| | Endpoint | Test Duration (hr) | Species | Value | Sourc |
| | EC50 | 72h | Algae or other aquatic plants | >74mg/l | 2 |
| | EC50 | 48h | Crustacea | >100mg/l | 2 |
| eucalyptol | LC50 | 96h | Fish | 57mg/l | 2 |
| | EC50 | 96h | Algae or other aquatic plants | >74mg/l | 2 |
| | NOEC(ECx) | 96h | Algae or other aquatic plants | 9.1mg/l | 2 |
| Legend: | | | CHA Registered Substances - Ecotoxicologic 5. ECETOC Aquatic Hazard Assessment Da | • | atic Toxic |

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 |
|--|-------------------------|------------------|
| 5-chloro-2-methyl-4-isothiazolin-3-one | HIGH | HIGH |
| eucalyptol | HIGH | HIGH |

12.3. Bioaccumulative potential

| Ingredient | Bioaccumulation | | | |
|--|-----------------------|--|--|--|
| 5-chloro-2-methyl-4- isothiazolin-3-one | LOW (LogKOW = 0.0444) | | | |
| eucalyptol | LOW (LogKOW = 2.74) | | | |

12.4. Mobility in soil

| Ingredient | Mobility |
|--|-----------------------|
| 5-chloro-2-methyl-4- isothiazolin-3-one | LOW (Log KOC = 45.15) |
| eucalyptol | LOW (Log KOC = 106.7) |

12.5. Results of PBT and vPvB assessment

| | P | В | Т | | | | |
|-------------------------|-------------------------|---------------|---------------|--|--|--|--|
| Relevant available data | Not Available | Not Available | Not Available | | | | |
| PBT | × | × | × | | | | |
| vPvB | × | × | × | | | | |
| PBT Criteria fulfilled? | PBT Criteria fulfilled? | | | | | | |
| vPvB | No | | | | | | |

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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 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

- ▶ Containers may still present a chemical hazard/ danger when empty.
- Return to supplier for reuse/ recycling if possible.

Otherwise:

- If container can not be cleaned sufficiently well to ensure that residuals do not remain or if the container cannot be used to store the same product, then puncture containers, to prevent re-use, and bury at an authorised landfill
- ▶ Where possible retain label warnings and SDS and observe all notices pertaining to the product.

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.

A Hierarchy of Controls seems to be common - the user should investigate:

- Reduction
- Reuse
- Recycling
- ▶ Disposal (if all else fails)

Product / Packaging disposal

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.

- ▶ 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.
- Where in doubt contact the responsible authority.
- 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).
- ▶ Decontaminate empty containers. Observe all label safeguards until containers are cleaned and destroyed.

Waste treatment options

Sewage disposal options

Not Available 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 | r or ID | Not Applicable | | | | | | | |
|---------------------------|-----------|---|---|----------------|--|--|--|--|--|
| 14.2. UN proper name | shipping | Not Applicable | Not Applicable | | | | | | |
| 14.3. Transport class(es) | hazard | Class Not Applicable Subsidiary Hazard Not Applicable | | | | | | | |
| 14.4. Packing gr | roup | Not Applicable | Not Applicable | | | | | | |
| 14.5. Environme | ental | Not Applicable | Not Applicable | | | | | | |
| 14.6. Special pro | ecautions | Hazard identification | Hazard identification (Kemler) Not Applicable | | | | | | |
| ioi usei | | Classification code | | Not Applicable | | | | | |
| | | Hazard Label | | Not Applicable | | | | | |
| | | | | | | | | | |

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| Special provisions | Not Applicable |
|-------------------------|------------------|
| Limited quantity | Not Applicable |
| Tunnel Restriction Code | Not Applicable |
| | Limited quantity |

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 | | |
| | ICAO/IATA Class | Not Applicable | |
| 14.3. Transport hazard class(es) | ICAO / IATA Subsidiary Hazard | Not Applicable | |
| 0:033(03) | ERG Code | Not Applicable | |
| 4.4. Packing group | Not Applicable | | |
| 14.5. Environmental hazard | Not Applicable | | |
| | Special provisions | | Not Applicable |
| | Cargo Only Packing Instructions | | Not Applicable |
| | Cargo Only Maximum Qty / Pack | | Not Applicable |
| 14.6. Special precautions for user | Passenger and Cargo Packing In | structions | Not Applicable |
| 101 4001 | 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 | | |
| | Classification code | Not Applicable | |
| | Special provisions | Not Applicable | |
| 14.6. Special precautions for user | 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

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Not Applicable

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

| Product name | Group |
|--|---------------|
| sodium xylenesulfonate | Not Available |
| 1,2-benzisothiazoline-3-one | Not Available |
| 5-chloro-2-methyl-4- isothiazolin-3-one | Not Available |
| eucalyptol | Not Available |

14.7.3. Transport in bulk in accordance with the IGC Code

| Product name | Ship Type |
|--|---------------|
| sodium xylenesulfonate | Not Available |
| 1,2-benzisothiazoline-3-one | Not Available |
| 5-chloro-2-methyl-4- isothiazolin-3-one | Not Available |
| eucalyptol | Not Available |

SECTION 15 Regulatory information

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

sodium xylenesulfonate is found on the following regulatory lists

Europe EC Inventory

European Union - European Inventory of Existing Commercial Chemical Substances (EINECS)

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

5-chloro-2-methyl-4-isothiazolin-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

eucalyptol is found on the following regulatory lists

Europe EC Inventory

European Union - European Inventory of Existing Commercial Chemical Substances (EINECS)

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

| manorial involves, otalao | |
|--|--|
| National Inventory | Status |
| Australia - AIIC / Australia Non-Industrial Use | Yes |
| Canada - DSL | Yes |
| Canada - NDSL | No (sodium xylenesulfonate; 1,2-benzisothiazoline-3-one; 5-chloro-2-methyl-4-isothiazolin-3-one; eucalyptol) |
| China - IECSC | Yes |
| Europe - EINEC / ELINCS / NLP | Yes |

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| National Inventory | Status |
|---------------------|---|
| Japan - ENCS | Yes |
| Korea - KECI | Yes |
| New Zealand - NZloC | Yes |
| Philippines - PICCS | Yes |
| USA - TSCA | Yes |
| Taiwan - TCSI | Yes |
| Mexico - INSQ | Yes |
| Vietnam - NCI | Yes |
| Russia - FBEPH | Yes |
| 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 | 26/07/2023 |
|---------------|------------|
| Initial Date | 27/08/2019 |

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

| H226 | Flammable liquid and vapour. |
|------|---|
| H301 | Toxic if swallowed. |
| H302 | Harmful if swallowed. |
| H310 | Fatal in contact with skin. |
| H314 | Causes severe skin burns and eye damage. |
| H315 | Causes skin irritation. |
| H317 | May cause an allergic skin reaction. |
| H318 | Causes serious eye damage. |
| H319 | Causes serious eye irritation. |
| H330 | Fatal if inhaled. |
| H335 | May cause respiratory irritation. |
| H336 | May cause drowsiness or dizziness. |
| H400 | Very toxic to aquatic life. |
| H410 | Very toxic to aquatic life with long lasting effects. |
| H412 | Harmful to aquatic life with long lasting effects. |

SDS Version Summary

| Version | Date of Update | Sections Updated |
|---------|-------------------|---|
| 1.16 | 26/07/2023 | Hazards identification - Classification, Ecological Information - Environmental, Firefighting measures - Fire Fighter (fire/explosion hazard), Composition / information on ingredients - Ingredients |

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. 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

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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
- 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]

| Classification according to regulation (EC) No 1272/2008 [CLP] and amendments | Classification Procedure |
|---|--------------------------|
| , EUH208 | Calculation method |
| , EUH210 | Calculation method |

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