

Safety Data Sheet

According to Regulation (EC) No. 1272/2008 (CLP), as amended by UK Regulations SI 2019/720 and SI 2020/1567), and (EC) No. 1907/2006 (REACH), as amended by UK REACH Regulations SI 2019/758 and SI 2020/1577

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Felimazole 5 mg/mL oral solution for cats

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

1.1 Product identifier

Product Name: Felimazole 5 mg/mL oral solution for cats

Synonyms: Not applicable

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

Relevant identified uses: VETERINARY USE: Antithyroid drug for cats.

Uses advised against: Not for human use.

Reasons why uses advised against: Veterinary product.

1.3 Details of the manufacturer/supplier of the safety data sheet

Supplier:

United Kingdom

Dechra Ltd

Snaygill Industrial Estate Keighley Road

Skipton, North Yorkshire BD23 2RW

+44 (0) 1756 791311

1.4 Emergency telephone number:

United Kingdom

Dechra Ltd

+44 (0) 1756 791311 (Normal Business hours)

SECTION 2: Hazard(s) identification

2.1 Classification of the substance or mixture:

Classification according to Regulation (EC) No. 1272/2008 (CLP), as amended for Great Britain in UK Regulations SI 2019/720 and SI 2020/1567:

The substance is not classified as hazardous according to the Globally Harmonized System (GHS).

Hazard-determining components of labeling: None

Additional Information: None

2.2 Label elements

Labelling according to Regulation (EC) No. 1272/2008 (CLP), as amended for Great Britain in UK Regulations SI 2019/720 and SI 2020/1567:

Hazard pictograms: None

Signal word: None

Hazard statements: None

Precautionary statements:

P102 Keep out of reach of children

2.3 Other hazards: None known

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SECTION 3: Composition/information on ingredients

3.1 **Substance:** Not applicable.

3.2 **Mixture:**

Identification	REACH Registration No.	Name	Classification according to Regulation (EC) No. 1272/2008 (CLP), as amended for Great Britain in UK Regulations SI 2019/720 and SI 2020/1567	Weight %
CAS number: 585-88-6 EC number: Not Applicable	–	Maltitol liquid	Not classified;	50-60
CAS number: 56-81-5 EC number: 200-289-5	–	Glycerol	Not classified;	30-40
CAS number: 77-92-9 EC number: 201-069-1	–	Citric acid	Eye Irrit. 2; H319 STOT SE 3 (RI); H335	<5
CAS number: 6155-57-3 EC number: Not Applicable	–	Saccharin sodium	Not classified;	<1
CAS number: 60-56-0 EC number: 200-482-4	–	Thiamazole	Acute Tox. 4 (Oral); H302 Skin Sens. 1; H317 Eye Irrit. 2; H319 Repr. 2; H361	0.5
CAS number: 10028-24-7 EC number: Not Applicable	–	Disodium dihydrate hydrogen phosphate	Eye Irrit. 2; H319	<0.5
CAS number: 99-76-3 EC number: 202-785-7	–	Methyl parahydroxybenzoate	Skin Irrit. 2; H315 STOT SE 3 (RI); H335 Eye Irrit. 2; H319	<0.5

Additional information:

None

Full Text of H and EUH statements: See section 16

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SECTION 4: First aid measures

4.1 Description of first aid measures

General notes:

Show this Safety Data Sheet to the doctor in attendance.

Following inhalation:

If inhaled, remove person to fresh air and place in a position comfortable for breathing. If respiratory symptoms develop or persist, seek medical advice/attention.

Following skin contact:

Wash affected area with plenty of soap and water. Remove contaminated clothing and laundry before reuse. If skin irritation develops or persists, seek medical advice/attention.

Following eye contact:

Immediately rinse eyes with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses. Continue to rinse for at least 15 minutes. If eye irritation develops or persists, seek medical advice/attention.

Following ingestion:

If swallowed, DO NOT induce vomiting unless told to do so by a physician or poison control center. Rinse mouth with water. Never give anything by mouth to an unconscious person. If spontaneous vomiting occurs, place on the left side with head down to prevent aspiration of liquid into the lungs. If symptoms develop or persist, seek medical advice/attention.

Self-Protection of the first aider:

Take precautions to ensure your own safety before attempting rescue. Wear appropriate safety eyewear, gloves, protective clothing and respiratory protection to prevent exposure.

4.2 Most important symptoms and effects, both acute and delayed

Acute symptoms and effects:

No significant acute effects/symptoms.

Delayed symptoms and effects:

No significant acute effects/symptoms.

4.3 Indication of any immediate medical attention and special treatment needed

Specific treatment:

Not determined or not available.

Notes for the doctor:

Treat symptomatically.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media:

Use extinguishing media appropriate for surrounding materials and fire.

Unsuitable extinguishing media:

Do not use water jet.

5.2 Special hazards arising from the substance or mixture:

Thermal decomposition may produce irritating/toxic fumes/gases.

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5.3 Advice for firefighters

Personal protection equipment:

Fire-fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full-face piece operated in positive pressure mode.

Special precautions:

Avoid contact with skin, eyes, hair and clothing. Do not breathe fumes/gas/mists/aerosols/vapours/dusts. Move containers from fire area if safe to do so. Use water spray/fog for cooling fire exposed containers. Avoid unnecessary run-off of extinguishing media which may cause pollution.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures:

Evacuate unnecessary personnel. Ventilate area. Extinguish any sources of ignition. Wear recommended personal protective equipment (see Section 8). Avoid contact with skin, eyes and clothing. Avoid breathing mist, vapour, dust, fume and spray. Do not walk through spilled material. Wash thoroughly after handling.

6.2 Environmental precautions:

Prevent further leakage or spillage if safe to do so. Prevent from reaching drains, sewers and waterways. Discharge into the environment must be avoided.

6.3 Methods and material for containment and cleaning up:

Do not touch damaged containers or spilled material unless wearing appropriate personal protective clothing. Stop leak if you can do it without risk. Contain and collect spillage and place in suitable container for future disposal. Dispose of in accordance with all applicable regulations (see Section 13).

6.4 Reference to other sections:

For personal protective equipment see Section 8. For disposal see Section 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling:

Use appropriate personal protective equipment (see Section 8). Use only with adequate ventilation. Avoid breathing mist/vapor/spray/dust. Do not eat, drink, smoke, or use personal products when handling chemical substances. Avoid contact with skin, eyes and clothing. Wash affected areas thoroughly after handling. Keep away from incompatible materials (See Section 10). Keep containers tightly closed when not in use.

7.2 Conditions for safe storage, including any incompatibilities:

Store in cool, dry, well-ventilated location out of direct sunlight. Keep away from food and beverages. Protect from freezing and physical damage. Store away from heat, open flames and other sources of ignition. Keep container tightly sealed. Store away from incompatible materials (See Section 10).

7.3 Specific end use(s):

Refer to Section 1 (Recommended Use).

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SECTION 8: Exposure controls/personal protection



8.1 Control parameters

Only those substances with limit values have been included below.

Occupational Exposure limit values:

Country (Legal Basis)	Substance	Identifier	Permissible concentration
UK	Glycerol	56-81-5	8-Hour TWA: 10 mg/m ³
	Glycerol	56-81-5	15-Minute STEL: 30 mg/m ³ (calculated mist)

Biological limit values:

No biological limit values established for ingredients.

Derived No Effect Level (DNEL):

Ingredient Name: Glycerol

CAS #:56-81-5

Workers – Systemic Effects	Acute - Oral	Not determined or not applicable.
	Acute - Inhalation	No hazard identified
	Acute - Dermal	No hazard identified
	Chronic - Oral	Not determined or not applicable.
	Chronic - Inhalation	No hazard identified
	Chronic - Dermal	No hazard identified
Workers – Local Effects	Acute - Oral	Not determined or not applicable.
	Acute - Inhalation	No hazard identified
	Acute -Dermal	No hazard identified
	Chronic - Oral	Not determined or not applicable.
	Chronic - Inhalation	No hazard identified
	Chronic - Dermal	No hazard identified
General Population - Systemic Effects	Acute - Oral	No hazard identified
	Acute - Inhalation	No hazard identified
	Acute - Dermal	No hazard identified
	Chronic - Oral	No hazard identified
	Chronic - Inhalation	No hazard identified
	Chronic - Dermal	No hazard identified

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General Population - Local Effect	Acute - Oral	Not determined or not applicable.
	Acute - Inhalation	No hazard identified
	Acute - Dermal	No hazard identified
	Chronic - Oral	Not determined or not applicable.
	Chronic - Inhalation	No hazard identified
	Chronic - Dermal	No hazard identified

Ingredient Name: Methyl parahydroxybenzoate

CAS #: 99-76-3

Workers – Systemic Effects	Acute - Oral	Not determined or not applicable.
	Acute - Inhalation	No hazard identified
	Acute - Dermal	No hazard identified
	Chronic - Oral	Not determined or not applicable.
	Chronic - Inhalation	176.3 mg/m ³
	Chronic - Dermal	29.41 mg/kg bw/day
Workers – Local Effects	Acute - Oral	Not determined or not applicable.
	Acute - Inhalation	No hazard identified
	Acute - Dermal	No hazard identified
	Chronic - Oral	Not determined or not applicable.
	Chronic - Inhalation	No hazard identified
	Chronic - Dermal	No hazard identified
General Population - Systemic Effects	Acute - Oral	No hazard identified
	Acute - Inhalation	No hazard identified
	Acute - Dermal	No hazard identified
	Chronic - Oral	12.5 mg/kg bw/day
	Chronic - Inhalation	43.45 mg/m ³
	Chronic - Dermal	14.7 mg/kg bw/day
General Population - Local Effect	Acute - Oral	Not determined or not applicable.
	Acute - Inhalation	No hazard identified
	Acute - Dermal	No hazard identified
	Chronic - Oral	Not determined or not applicable.
	Chronic - Inhalation	No hazard identified
	Chronic - Dermal	No hazard identified

Ingredient Name: Saccharin sodium

CAS #: 6155-57-3

Workers – Systemic Effects	Acute - Oral	Not determined or not applicable.
	Acute - Inhalation	No hazard identified
	Acute - Dermal	No hazard identified
	Chronic - Oral	Not determined or not applicable.
	Chronic - Inhalation	1.4 mg/m ³
	Chronic - Dermal	0.4 mg/kg bw/day

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Workers – Local Effects	Acute - Oral	Not determined or not applicable.
	Acute - Inhalation	No hazard identified
	Acute -Dermal	No hazard identified
	Chronic - Oral	Not determined or not applicable.
	Chronic - Inhalation	No hazard identified
	Chronic - Dermal	No hazard identified
General Population - Systemic Effects	Acute - Oral	No hazard identified
	Acute - Inhalation	No hazard identified
	Acute - Dermal	No hazard identified
	Chronic - Oral	0.143 mg/kg bw/day
	Chronic - Inhalation	0.25 mg/m ³
	Chronic - Dermal	0.143 mg/kg bw/day
General Population - Local Effect	Acute - Oral	Not determined or not applicable.
	Acute - Inhalation	No hazard identified
	Acute - Dermal	No hazard identified
	Chronic - Oral	Not determined or not applicable.
	Chronic - Inhalation	No hazard identified
	Chronic - Dermal	No hazard identified

Ingredient Name: Citric Acid

CAS #: 77-92-9

Workers - Systemic Effects	Acute - Oral	Not determined or not applicable.
	Acute - Inhalation	No hazard identified
	Acute - Dermal	No hazard identified
	Chronic - Oral	Not determined or not applicable.
	Chronic - Inhalation	No hazard identified
	Chronic - Dermal	No hazard identified
Workers - Local Effects	Acute - Oral	Not determined or not applicable.
	Acute - Inhalation	Hazard identified but no DNEL available
	Acute -Dermal	No hazard identified
	Chronic - Oral	Not determined or not applicable.
	Chronic - Inhalation	No hazard identified
	Chronic - Dermal	No hazard identified
General Population - Systemic Effects	Acute - Oral	No hazard identified
	Acute - Inhalation	No hazard identified
	Acute - Dermal	No hazard identified
	Chronic - Oral	No hazard identified
	Chronic - Inhalation	No hazard identified
	Chronic - Dermal	No hazard identified
General Population - Local Effect	Acute - Oral	Not determined or not applicable.
	Acute - Inhalation	Hazard identified but no DNEL available
	Acute - Dermal	No hazard identified
	Chronic - Oral	Not determined or not applicable.
	Chronic - Inhalation	No hazard identified
	Chronic - Dermal	No hazard identified

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Predicted No Effect Concentration (PNEC):

Ingredient Name: Glycerol

CAS #: 56-81-5

Environmental Protection Target	PNEC
Fresh water	No hazard identified
Freshwater sediments	No hazard identified
Marine water	No hazard identified
Marine sediments	No hazard identified
Microorganisms in sewage treatment	No hazard identified
Soil (agricultural)	No hazard identified
Air	No hazard identified
Oral (Secondary Poisoning)	No exposure expected

Ingredient Name: Methyl parahydroxybenzoate

CAS #: 99-76-3

Environmental Protection Target	PNEC
Fresh water	2.4 µg/L
Freshwater sediments	Not determined or not available.
Marine water	0.24 µg/L
Marine sediments	Not determined or not available.
Microorganisms in sewage treatment	2 mg/L
Soil (agricultural)	Not determined or not available.
Air	No hazard identified
Oral (Secondary Poisoning)	No exposure expected

Ingredient Name: Saccharin sodium

CAS #: 6155-57-3

Environmental Protection Target	PNEC
Fresh water	10 mg/L
Freshwater sediments	2060 mg/kg sediment dw
Marine water	1 mg/L
Marine sediments	206 mg/kg
Microorganisms in sewage treatment	No hazard identified
Soil (agricultural)	407 mg/kg soil dw
Air	No hazard identified
Oral (Secondary Poisoning)	No exposure expected

Ingredient Name: Citric acid

CAS #: 77-92-9

Environmental Protection Target	PNEC
Fresh water	No hazard identified
Freshwater sediments	No hazard identified
Marine water	No hazard identified
Marine sediments	No hazard identified

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Microorganisms in sewage treatment	No hazard identified
Soil (agricultural)	No hazard identified
Air	No hazard identified
Oral (Secondary Poisoning)	No hazard identified

Information on monitoring procedures:

Not determined or not applicable.

8.2 Exposure controls

Appropriate engineering controls:

Emergency eye wash stations and safety showers should be available in the immediate vicinity of use or handling. Provide adequate ventilation to maintain the airborne concentrations of vapor, mists, and/or dusts below the applicable workplace exposure limits, while observing recognized national standards (or equivalent).

Personal protection equipment

Eye and face protection:

Safety glasses or goggles. Use eye protection equipment that has been tested and approved by recognized national standards (or equivalent).

Skin and body protection:

Chemical resistant, impervious gloves approved by the appropriate standards. Gloves must be inspected prior to use. Avoid skin contact with used gloves. Appropriate techniques should be used to remove used gloves and contaminated clothing. Personal protective equipment for the body should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product. Ensure that all personal protective equipment is approved by recognized national standards (or equivalent).

Respiratory protection:

If engineering controls do not maintain airborne concentrations below the applicable workplace exposure limits, or to an acceptable level (if exposure limits have not been established), a respirator approved by recognized national standards (or equivalent) must be worn.

General hygienic measures:

When handling chemical products, do not eat, drink or smoke. Wash hands after handling, before breaks, and at the end of the workday. Avoid contact with skin, eyes and clothing. Wash contaminated clothing before reuse. Perform routine housekeeping.

Environmental exposure controls:

Emissions from ventilation or work process equipment should be checked to ensure they comply with the requirements of environmental protection legislation.

Product (substance / mixture) related measures to prevent exposure:	Not determined or not applicable.
Instruction measures to prevent exposure:	Not determined or not applicable.
Organisational measures to prevent exposure:	Not determined or not applicable.
Technical measures to prevent exposure:	Not determined or not applicable.

Risk management measures to control exposure:

Not determined or not applicable.

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SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance	Liquid
Colour	Clear, light yellow to yellowish-brown
Odour/Odour threshold	Honey
pH	4,0 – 5,5
Melting point/freezing point	Not determined or not available.
Initial boiling point/range	Not determined or not available.
Flash point (closed cup)	Not determined or not available.
Evaporation rate	Not determined or not available.
Flammability (solid, gas)	Not determined or not available.
Upper flammability/explosive limit	Not determined or not available.
Lower flammability/explosive limit	Not determined or not available.
Vapour pressure	Not determined or not available.
Vapour density	Not determined or not available.
Density	Not determined or not available.
Relative density	1,25
Solubilities	Mixes with water.
Partition coefficient (n-octanol/water)	Not determined or not available.
Auto/Self-ignition temperature	Not determined or not available.
Decomposition temperature	Not determined or not available.
Dynamic viscosity	Not determined or not available.
Kinematic viscosity	Not determined or not available.
Explosive properties	Not determined or not available.
Oxidizing properties	Not determined or not available.

9.2 Other information:

Explosives	No data available/Not applicable
Flammable gases	No data available/Not applicable
Aerosols	No data available/Not applicable
Oxidizing gases	No data available/Not applicable
Gases under pressure	No data available/Not applicable
Flammable liquids	No data available/Not applicable
Flammable solids	No data available/Not applicable
Self-reactive substances and mixtures	No data available/Not applicable
Pyrophoric liquids	No data available/Not applicable
Pyrophoric solids	No data available/Not applicable
Self-heating substances and mixtures	No data available/Not applicable
Substances and mixtures, which emit flammable gases in contact with water	No data available/Not applicable

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Oxidizing liquids	No data available/Not applicable
Oxidizing solids	No data available/Not applicable
Organic peroxides	No data available/Not applicable
Corrosive to metals	No data available/Not applicable
Desensitized explosives	No data available/Not applicable

SECTION 10: Stability and reactivity

10.1 Reactivity:

Not reactive under recommended handling and storage conditions.

10.2 Chemical stability:

Stable under recommended handling and storage conditions.

10.3 Possibility of hazardous reactions:

Hazardous reactions are not anticipated under recommended conditions of handling and storage.

10.4 Conditions to avoid:

Extreme heat, open flames, hot surfaces, sparks, ignition sources and incompatible materials.

10.5 Incompatible materials:

Strong oxidizing agents.

10.6 Hazardous decomposition products:

Under normal conditions of storage and use, hazardous decomposition products should not be produced.

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Acute toxicity

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

Product data: No data available.

Substance data:

Name	Route	Result
Thiamazole	oral	LD50 Rat: 860 mg/kg
Glycerol	oral	LD50 Rat: 27.200 mg/kg
	dermal	LD50 Guinea Pig: 56.750 mg/kg
	inhalation	LC50 Rat: > 5850 mg/m ³ (4 hr [Aerosol])
Methyl parahydroxybenzoate	oral	LD50 Rat: 2100 mg/kg
Maltitol liquid	oral	LD50 Mouse: >5000 mg/kg
Disodium dihydrate hydrogen phosphate	oral	LD50 Rat: 12.900 mg/kg
Saccharin sodium	oral	LD50 Rat: 8820 mg/kg
	dermal	LD50 Rabbit: >5000 mg/kg
Citric acid	oral	LD50 Mouse: 5400 mg/kg
	dermal	LD50 Rat: > 2000 mg/kg

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Skin corrosion/irritation

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

Product data: No data available.

Substance data:

Name	Result
Methyl parahydroxybenzoate	Causes skin irritation.

Serious eye damage/irritation

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

Product data: No data available.

Substance data:

Name	Result
Thiamazole	Causes serious eye irritation.
Methyl parahydroxybenzoate	Causes serious eye irritation.
Disodium dihydrate hydrogen phosphate	Causes serious eye irritation.
Citric acid	Causes serious eye irritation.

Respiratory or skin sensitization

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

Product data: No data available.

Substance data:

Name	Result
Methyl parahydroxybenzoate	Causes skin irritation.

No data available.

Carcinogenicity

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

Product data: No data available.

Substance data: No data available.

International Agency for Research on Cancer (IARC):

Name	Classification
Thiamazole	Group 3
Saccharin sodium	Group 3

Germ cell mutagenicity

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

Product data: No data available.

Substance data: No data available.

Reproductive Toxicity

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

Product data: No data available.

Substance data:

Name	Result
Thiamazole	Suspected of damaging fertility or the unborn child.

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Specific target organ toxicity (single exposure)

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

Product data: No data available.

Substance data:

Name	Result
Methyl parahydroxybenzoate	May cause respiratory irritation.
Citric acid	May cause respiratory irritation.

Specific target organ toxicity (repeated exposure)

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

Product data: No data available.

Substance data: No data available.

Aspiration toxicity

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

Product data: No data available.

Substance data: No data available.

Information on likely routes of exposure:

Ingestion.

Symptoms related to the physical, chemical and toxicological characteristics:

No significant acute or delayed effects/symptoms.

Other information:

No data available.

SECTION 12: Ecological information

12.1 Toxicity

Acute (short-term) toxicity

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

Product data: No data available.

Substance data:

Name	Result
Glycerol	Fish LC50 <i>Oncorhynchus mykiss</i> : 54,000 mg/L (96 hr)
	Aquatic Invertebrates LC50 <i>Daphnia magna</i> : 1955 mg/L (48 hr)
Methyl parahydroxybenzoate	Fish LC50 <i>Oryzias latipes</i> : 59.5 mg/L (96 hr)
	Aquatic Plants EC50 <i>Pseudokirchneriella subcapitata</i> (algae): 91 mg/L (72 hr [growth rate])
	Aquatic Invertebrates EC50 <i>Daphnia magna</i> : 11.2 mg/L (48 hr [mobility])
Maltitol liquid	Fish LC50 <i>Oryzias latipes</i> : >1050 mg/L (96 hr)
	Aquatic Invertebrates EC50 <i>Daphnia magna</i> : >1020 mg/L (48 hr [mobility])
	Aquatic Plants EC50 <i>Raphidocelis subcapitata</i> : >1040 mg/L (72 hr [growth rate])

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Name	Result
Saccharin sodium	Fish LC50 Danio rerio: >400 mg/L (96 hr [Read-across substance data])
	Aquatic Invertebrates EC50 Daphnia magna: >100 mg/L (48 hr [mobility & inhibition, Read-across substance data])
	Aquatic Plants EC50 Raphidocelis subcapitata: >100 mg/L (72 hr [growth rate, Read-across substance data])
Citric acid	Fish LC50 Pimephales promelas: >100 mg/L (96 hr)
	Aquatic Invertebrates EC50 Dreissena polymorpha: >50 mg/L (48 hr [attachment to substrate])

Chronic (long-term) toxicity

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

Product data: No data available.

Substance data:

Name	Result
Methyl parahydroxybenzoate	Aquatic Invertebrates EC50 Daphnia magna: 5.32 mg/L (21 d [reproduction])
Saccharin sodium	Fish NOEC Fish: 307.146 mg/L (28 d [mortality, QSAR substance data])
	Aquatic Invertebrates NOEC Daphnia magna: 119.839 mg/L (21 d [immobilisation, Neutral Organic SAR])

12.2 Persistence and degradability

Product data: No data available.

Substance data:

Name	Result
Glycerol	The substance is readily biodegradable. 94% degradation, measured by TOC removal, after 24 hr.
Methyl parahydroxybenzoate	The substance is readily biodegradable. 89% degradation, measured by CO2 evolution, after 28 days.
Maltitol liquid	The substance is readily biodegradable. $\geq 73 \leq 81\%$ degradation in water, measured by CO2 evolution, after 28 days.
Disodium dihydrate hydrogen phosphate	Persistence assessment based on biodegradability is not relevant for inorganic compounds such as this substance.
Saccharin sodium	The substance is inherently biodegradable. 53.6% degradation in water, measured by BOD and ThOD, after 28 days (Read-across substance data).
Citric acid	The substance is readily biodegradable. 97% degradation measured by CO2 evolution, after 28 days.

12.3 Bioaccumulative potential

Product data: No data available.

Substance data:

Name	Result
Thiamazole	The substance is not expected to bioaccumulate (log Kow=-0.34).
Glycerol	The substance has a low potential for bioaccumulation based on log Kow ≤ 3 .
Methyl parahydroxybenzoate	The substance has a low potential for bioaccumulation. Estimated BCF: 6.4[QSAR]

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Name	Result
Maltitol liquid	The substance is not expected to bioaccumulate (log Pow= -3.87 at 24 °C).
Disodium dihydrate hydrogen phosphate	Bioaccumulation assessment using a classic BCF assessment is not considered relevant for inorganic compounds such as this substance.
Saccharin sodium	The substance is not expected to bioaccumulate (BCF=3.162 L/kg, basis-whole body w.w., at 25 °C, Read-across substance data).
Citric acid	The substance has low potential for bioaccumulation (BCF: 3.2 L/kg).

12.4 Mobility in soil

Product data: No data available.

Substance data:

Name	Result
Methyl parahydroxybenzoate	The substance has a low potential for adsorption to soil and sediment. Koc at 20 °C: 280
Maltitol liquid	The substance is mobile, therefore, adsorption to soil is not expected (Koc=69).
Disodium dihydrate hydrogen phosphate	Mobility in soil assessment based on KOC/Kd values are not relevant for inorganic compounds such as this substance.
Saccharin sodium	The substance is slightly mobile, therefore, slight adsorption to soil is expected (log Koc= 3.307 dimensionless at 25 °C, Read-across substance data).

12.5 Results of PBT and vPvB assessment

Product data:

PBT assessment: This product does not contain any substances that are assessed to be a PBT.

vPvB assessment: This product does not contain any substances that are assessed to be a vPvB.

Substance data:

PBT assessment:

Glycerol	The substance is not PBT.
Methyl parahydroxybenzoate	The substance is not PBT.
Maltitol liquid	The substance is not PBT.
Disodium dihydrate hydrogen phosphate	PBT assessment does not apply to inorganic compounds such as this substance.
Citric acid	The substance is not PBT

vPvB assessment:

Glycerol	The substance is not vPvB.
Methyl parahydroxybenzoate	The substance is not vPvB.
Maltitol liquid	The substance is not vPvB.
Disodium dihydrate hydrogen phosphate	vPvB assessment does not apply to inorganic compounds such as this substance.
Citric acid	The substance is not vPvB

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12.6 **Other adverse effects:** No data available.

12.7 **Hazard to the ozone layer**

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

Product data: No data available.

Substance data: No data available.

SECTION 13: Disposal considerations

13.1 **Waste treatment methods**

13.1.1 **Product / Packaging disposal:**

Dispose of in accordance with all applicable local, regional, state and federal regulations.

Waste codes / waste designations according to LoW: Not determined or not available.

13.1.2 **Waste treatment-relevant information:** Not determined or not available.

13.1.3 **Sewage disposal-relevant information:** Not determined or not available.

13.1.4 **Other disposal recommendations:**

It is the responsibility of the waste generator to properly characterize all waste materials according to applicable regulatory entities.

SECTION 14: Transport information

International Carriage of Dangerous Goods by Road/Rail (ADR/RID)

UN number	Not regulated
UN proper shipping name	Not regulated
UN transport hazard class(es)	None
Packing group	None
Environmental hazards	None
Special precautions for user	None
Additional Information	None

International Carriage of Dangerous Goods by Inland Waterways (ADN)

UN number	Not regulated
UN proper shipping name	Not regulated
UN transport hazard class(es)	None
Packing group	None
Environmental hazards	None
Special precautions for user	None
Additional Information	None

Safety Data Sheet

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International Maritime Dangerous Goods (IMDG)

UN number	Not regulated
UN proper shipping name	Not regulated
UN transport hazard class(es)	None
Packing group	None
Environmental hazards	None
Special precautions for user	None
Additional Information	None

International Air Transport Association Dangerous Goods Regulations (IATA-DGR)

UN number	Not regulated
UN proper shipping name	Not regulated
UN transport hazard class(es)	None
Packing group	None
Environmental hazards	None
Special precautions for user	None
Additional Information	None

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

Bulk Name	None
Ship type	None
Pollution category	None

SECTION 15: Regulatory information

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

United Kingdom regulations

UK REACH SVHC Candidate list: None of the ingredients are listed.

UK REACH SVHC Authorisation List: None of the ingredients are listed.

UK REACH Restriction List:

60-56-0	Thiamazole	Listed
99-76-3	Methyl parahydroxybenzoate	Not Listed
585-88-6	Maltitol liquid	Not Listed
10028-24-7	Disodium dihydrate hydrogen phosphate	Not Listed
13472-35-0	Phosphoric acid, sodium salt, hydrate (1:1:2)	Not Listed
6155-57-3	Saccharin sodium	Not Listed
77-92-9	Citric acid	Not Listed

Safety Data Sheet

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15.2 Chemical Safety Assessment

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

SECTION 16: Other information

Abbreviations and Acronyms: None

Summary of classification(s) in section 3:

Eye Irrit. 2 Eye	Eye Irritation, category 2
STOT SE 3 (RI)	Specific target organ toxicity - single exposure, category 3, respiratory tract irritation
Acute Tox. 4 (Oral)	Acute toxicity (oral), category 4
Skin Sens. 1	Skin sensitization, category 1
Repr. 2	Reproductive toxicity, category 2
Skin Irrit. 2	Skin irritation, category 2

Summary of hazard statements in section 3:

H319	Causes serious eye irritation
H335	May cause respiratory irritation
H302	Harmful if swallowed
H317	May cause an allergic skin reaction
H361	Suspected of damaging fertility or the unborn child
H315	Causes skin irritation

Disclaimer:

This product has been classified in accordance with EC No. 1272/2008 (CLP), as amended by UK Regulations SI 2019/720 and SI 2020/1567), and (EC) No. 1907/2006 (REACH), as amended by UK REACH Regulations SI 2019/758 and SI 2020/1577. The information provided in this SDS is correct, to the best of our knowledge, based on information available. The information given is designed only as a guidance for safe handling, use, storage, transportation, and disposal and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials, unless specified in the text. The responsibility to provide a safe workplace remains with the user.

Initial preparation date: 2024.02.19

Revision notes:

Revision Date	Notes
2024-02-19	Version 1

End of Safety Data Sheet