

SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by
UK REACH Regulations SI 2019/758



PROLEAF BRASS

Version	Revision Date:	SDS Number:	Date of last issue: -
1.0	31.07.2023	50001961	Date of first issue: 18.07.2018

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

1.1 Product identifier

Product name PROLEAF BRASS

Other means of identification

Product code 50001961

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

Use of the Sub-
stance/Mixture : A fertilizer with micronutrients for use in agriculture

Recommended restrictions
on use : Use as recommended by the label.
For professional users only.

1.3 Details of the supplier of the safety data sheet

Supplier Address FMC Agro Limited
Rectors Lane, Pentre
Flintshire
CH5 2DH
United Kingdom

Telephone: + 44 1244 537370
E-mail address: SDS-Info@fmc.com .

1.4 Emergency telephone number

For leak, fire, spill or accident emergencies, call:
England and Wales: 44-870-8200418 (CHEMTREC)

Medical emergency:
England and Wales: 111
Scotland: 84 54 24 2424

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

**Classification (REGULATION (EC) No 1272/2008) as amended by GB-CLP Regulation, UK
SI 2019/720, and UK SI 2020/1567)**

Not a hazardous substance or mixture according to the Globally Harmonised System (GHS).

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2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008) as amended by GB-CLP Regulation, UK SI 2019/720, and UK SI 2020/1567)

Signal word : None

Hazard statements : None

Precautionary statements : **Prevention:**
P273 Avoid release to the environment.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.
Response:
P391 Collect spillage.

Additional Labelling

EUH208 Contains 1,2-benzisothiazol-3(2H)-one.
May produce an allergic reaction.

2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Components

Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
sulfur	7704-34-9 231-722-6 016-094-00-1 01-2119487295-27-0055	Skin Irrit. 2; H315	>= 1 - < 10
ethanediol	107-21-1 203-473-3 603-027-00-1	Acute Tox. 4; H302 STOT RE 2; H373 (Kidney)	>= 1 - < 10
zinc oxide	1314-13-2 215-222-5 030-013-00-7	Aquatic Acute 1; H400 Aquatic Chronic 1; H410 M-Factor (Acute aquatic toxicity): 1	>= 0.1 - < 0.25

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1,2-benzisothiazol-3(2H)-one	2634-33-5 220-120-9 613-088-00-6	M-Factor (Chronic aquatic toxicity): 10 Acute Tox. 4; H302 Skin Irrit. 2; H315 Eye Dam. 1; H318 Skin Sens. 1; H317 Aquatic Acute 1; H400 Aquatic Chronic 2; H411 M-Factor (Acute aquatic toxicity): 10 specific concentration limit Skin Sens. 1; H317 ≥ 0.05 %	≥ 0.0025 - < 0.025
Substances with a workplace exposure limit :			
Limestone	1317-65-3 215-279-6		≥ 1 - < 10

For explanation of abbreviations see section 16.

SECTION 4: First aid measures

4.1 Description of first aid measures

- General advice : Move out of dangerous area.
Consult a physician.
Show this safety data sheet to the doctor in attendance.
Do not leave the victim unattended.
- If inhaled : If unconscious, place in recovery position and seek medical advice.
If symptoms persist, call a physician.
- In case of skin contact : Immediate medical treatment is necessary as untreated wounds from corrosion of the skin heal slowly and with difficulty.
If on skin, rinse well with water.
If on clothes, remove clothes.
- In case of eye contact : Small amounts splashed into eyes can cause irreversible tissue damage and blindness.
In the case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
Continue rinsing eyes during transport to hospital.
Remove contact lenses.
Protect unharmed eye.
Keep eye wide open while rinsing.

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If eye irritation persists, consult a specialist.

If swallowed : Keep respiratory tract clear.
Do NOT induce vomiting.
Do not give milk or alcoholic beverages.
Never give anything by mouth to an unconscious person.
If symptoms persist, call a physician.
Take victim immediately to hospital.

4.2 Most important symptoms and effects, both acute and delayed

Risks : None known.

4.3 Indication of any immediate medical attention and special treatment needed

Treatment : Treat symptomatically.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media : Dry chemical, CO₂, water spray or regular foam.
Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

Unsuitable extinguishing media : High volume water jet

5.2 Special hazards arising from the substance or mixture

Specific hazards during fire-fighting : Do not allow run-off from fire fighting to enter drains or water courses.

Hazardous combustion products : Fire may produce irritating, corrosive and/or toxic gases.
Ammonia
Carbon oxides

5.3 Advice for firefighters

Special protective equipment for firefighters : Wear self-contained breathing apparatus for firefighting if necessary.

Further information : Collect contaminated fire extinguishing water separately. This must not be discharged into drains.
Fire residues and contaminated fire extinguishing water must be disposed of in accordance with local regulations.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions : Use personal protective equipment.
Mark the contaminated area with signs and prevent access to

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unauthorized personnel.
Only qualified personnel equipped with suitable protective
equipment may intervene.
For disposal considerations see section 13.

6.2 Environmental precautions

Environmental precautions : Prevent product from entering drains.
Prevent further leakage or spillage if safe to do so.
If the product contaminates rivers and lakes or drains inform
respective authorities.

6.3 Methods and material for containment and cleaning up

Methods for cleaning up : Soak up with inert absorbent material (e.g. sand, silica gel,
acid binder, universal binder, sawdust).
Keep in suitable, closed containers for disposal.

6.4 Reference to other sections

See sections: 7, 8, 11, 12 and 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Advice on safe handling : Do not breathe vapours/dust.
Avoid exposure - obtain special instructions before use.
Avoid contact with skin and eyes.
For personal protection see section 8.
Smoking, eating and drinking should be prohibited in the ap-
plication area.
To avoid spills during handling keep bottle on a metal tray.
Dispose of rinse water in accordance with local and national
regulations.

Advice on protection against : Normal measures for preventive fire protection.
fire and explosion

Hygiene measures : When using do not eat or drink. When using do not smoke.
Wash hands before breaks and at the end of workday.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage : Keep container tightly closed in a dry and well-ventilated
areas and containers place. Containers which are opened must be carefully re-
sealed and kept upright to prevent leakage. Observe label
precautions. Electrical installations / working materials must
comply with the technological safety standards.

Further information on stor- : No decomposition if stored and applied as directed.
age stability

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7.3 Specific end use(s)

Specific use(s) : Fertilizers

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational Exposure Limits

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
Limestone	1317-65-3	TWA (inhalable dust)	10 mg/m3	GB EH40
Further information	For the purposes of these limits, respirable dust and inhalable dust are those fractions of airborne dust which will be collected when sampling is undertaken in accordance with the methods described in MDHS14/4 General methods for sampling and gravimetric analysis or respirable, thoracic and inhalable aerosols., The COSHH definition of a substance hazardous to health includes dust of any kind when present at a concentration in air equal to or greater than 10 mg.m-3 8-hour TWA of inhalable dust or 4 mg.m-3 8-hour TWA of respirable dust. This means that any dust will be subject to COSHH if people are exposed to dust above these levels. Some dusts have been assigned specific WELs and exposure to these must comply with the appropriate limits., Most industrial dusts contain particles of a wide range of sizes. The behaviour, deposition and fate of any particular particle after entry into the human respiratory system, and the body response that it elicits, depend on the nature and size of the particle. HSE distinguishes two size fractions for limit-setting purposes termed 'inhalable' and 'respirable'. Inhalable dust approximates to the fraction of airborne material that enters the nose and mouth during breathing and is therefore available for deposition in the respiratory tract. Respirable dust approximates to the fraction that penetrates to the gas exchange region of the lung. Fuller definitions and explanatory material are given in MDHS14/4., Where dusts contain components that have their own assigned WEL, all the relevant limits should be complied with., Where no specific short-term exposure limit is listed, a figure three times the long-term exposure limit should be used.			
		TWA (Respirable dust)	4 mg/m3	GB EH40
Further information	For the purposes of these limits, respirable dust and inhalable dust are those fractions of airborne dust which will be collected when sampling is undertaken in accordance with the methods described in MDHS14/4 General methods for sampling and gravimetric analysis or respirable, thoracic and inhalable aerosols., The COSHH definition of a substance hazardous to health includes dust of any kind when present at a concentration in air equal to or greater than 10 mg.m-3 8-hour TWA of inhalable dust or 4 mg.m-3 8-hour TWA of respirable dust. This means that any dust will be subject to COSHH if people are exposed to dust above these levels. Some dusts have been assigned specific WELs and exposure to these must comply with the appropriate limits., Most industrial dusts contain particles of a wide range of sizes. The behaviour, deposition and fate of any particular particle after entry into the human respiratory system, and the body response that it elicits, depend on the nature and size of the particle. HSE distinguishes two size fractions for limit-setting			

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	purposes termed 'inhalable' and 'respirable'. Inhalable dust approximates to the fraction of airborne material that enters the nose and mouth during breathing and is therefore available for deposition in the respiratory tract. Respirable dust approximates to the fraction that penetrates to the gas exchange region of the lung. Fuller definitions and explanatory material are given in MDHS14/4. Where dusts contain components that have their own assigned WEL, all the relevant limits should be complied with. Where no specific short-term exposure limit is listed, a figure three times the long-term exposure limit should be used.			
manganese carbonate	598-62-9	TWA (Inhalable)	0.2 mg/m ³ (Manganese)	GB EH40
		TWA (Respirable fraction)	0.05 mg/m ³ (Manganese)	GB EH40
		TWA (inhalable fraction)	0.2 mg/m ³ (Manganese)	2017/164/EU
Further information	Indicative			
		TWA (Respirable fraction)	0.05 mg/m ³ (Manganese)	2017/164/EU
Further information	Indicative			
ethanediol	107-21-1	TWA (Vapour)	20 ppm 52 mg/m ³	GB EH40
Further information	Can be absorbed through the skin. The assigned substances are those for which there are concerns that dermal absorption will lead to systemic toxicity.			
		TWA (particles)	10 mg/m ³	GB EH40
Further information	Can be absorbed through the skin. The assigned substances are those for which there are concerns that dermal absorption will lead to systemic toxicity.			
		STEL (Vapour)	40 ppm 104 mg/m ³	GB EH40
Further information	Can be absorbed through the skin. The assigned substances are those for which there are concerns that dermal absorption will lead to systemic toxicity.			
		STEL	40 ppm 104 mg/m ³	2000/39/EC
Further information	Identifies the possibility of significant uptake through the skin, Indicative			
		TWA	20 ppm 52 mg/m ³	2000/39/EC
Further information	Identifies the possibility of significant uptake through the skin, Indicative			

Derived No Effect Level (DNEL):

Substance name	End Use	Exposure routes	Potential health effects	Value
1,2-benzisothiazol-3(2H)-one	Workers	Inhalation	Long-term systemic effects	6.81 mg/m ³
	Workers	Dermal	Long-term systemic effects	0.966 mg/kg
	Consumers	Inhalation	Long-term systemic effects	1.2 mg/m ³
	Consumers	Dermal	Long-term systemic effects	0.345 mg/kg

Predicted No Effect Concentration (PNEC):

Substance name	Environmental Compartment	Value
magnesium hydroxide	Fresh water	0.1 mg/l

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	Marine water	0.01 mg/l
	Fresh water sediment	0.082 mg/kg dry weight (d.w.)
	Marine sediment	0.0082 mg/kg dry weight (d.w.)
	Soil	0.0191 mg/kg dry weight (d.w.)
	Oral	66.67 mg/kg dry weight (d.w.)
1,2-benzisothiazol-3(2H)-one	Fresh water	0.00403 mg/l
	Marine water	0.000403 mg/l
	Sewage treatment plant	1.03 mg/l

8.2 Exposure controls

Personal protective equipment

- | | |
|--------------------------|---|
| Eye protection | : Eye wash bottle with pure water
Tightly fitting safety goggles
Wear face-shield and protective suit for abnormal processing problems. |
| Hand protection | |
| Material | : Wear chemical resistant gloves, such as barrier laminate, butyl rubber or nitrile rubber. |
| Remarks | : The suitability for a specific workplace should be discussed with the producers of the protective gloves. |
| Skin and body protection | : Impervious clothing
Choose body protection according to the amount and concentration of the dangerous substance at the work place. |
| Respiratory protection | : No personal respiratory protective equipment normally required. |
| Protective measures | : Plan first aid action before beginning work with this product.
Always have on hand a first-aid kit, together with proper instructions.
Ensure that eye flushing systems and safety showers are located close to the working place.
Wear suitable protective equipment. |

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

- | | |
|----------------|-------------------|
| Physical state | : liquid |
| Colour | : beige
opaque |
| Odour | : Faint odour |

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Odour Threshold	:	No data available
pH	:	9.0 - 11.5 Concentration: 100 %
Melting point/freezing point	:	No data available
Initial boiling point and boiling range	:	No data available
Flash point	:	No data available
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Vapour pressure	:	No data available
Relative vapour density	:	No data available
Relative density	:	No data available
Density	:	No data available
Bulk density	:	No data available
Solubility(ies)		
Water solubility	:	No data available
Solubility in other solvents	:	No data available
Partition coefficient: n-octanol/water	:	No data available
Auto-ignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity		
Viscosity, dynamic	:	No data available
Viscosity, kinematic	:	No data available
Explosive properties	:	No data available
Oxidizing properties	:	No data available

9.2 Other information

Particle size	:	Not applicable
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Particle Size Distribution : Not applicable

SECTION 10: Stability and reactivity

10.1 Reactivity

No decomposition if stored and applied as directed.

10.2 Chemical stability

No decomposition if stored and applied as directed.

10.3 Possibility of hazardous reactions

Hazardous reactions : No decomposition if stored and applied as directed.

10.4 Conditions to avoid

Conditions to avoid : Heat

10.5 Incompatible materials

Materials to avoid : Strong oxidizing agents
Strong acids

10.6 Hazardous decomposition products

Toxic fumes

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Acute toxicity

Not classified based on available information.

Product:

Acute oral toxicity : Acute toxicity estimate: > 2,000 mg/kg
Method: Calculation method

Components:

sulfur:

Acute oral toxicity : LD50 (Rat, male and female): > 2,000 mg/kg
Method: OECD Test Guideline 401

Acute inhalation toxicity : LC50 (Rat, male and female): > 5.43 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Method: OECD Test Guideline 403

Acute dermal toxicity : LD50 (Rat, male and female): > 2,000 mg/kg
Method: OECD Test Guideline 402

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ethanediol:

Acute inhalation toxicity : LC0 (Rat, male and female): > 2.5 mg/l
Exposure time: 6 h
Test atmosphere: dust/mist
Remarks: no mortality

Acute dermal toxicity : LD50 (Mouse, male and female): > 3,500 mg/kg

zinc oxide:

Acute oral toxicity : LD50 (Rat, male and female): > 2,000 mg/kg
Method: OECD Test Guideline 423

LD50 (Mouse, male and female): > 2,000 mg/kg
Method: OECD Test Guideline 401
Target Organs: Liver, Heart, spleen, Stomach, Pancreas
Symptoms: Damage
Remarks: mortality

Acute inhalation toxicity : LC0 (Rat, male and female): > 1.79 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Method: EPA OPP 81 - 3
Remarks: no mortality

Acute dermal toxicity : LD50 Dermal (Rat, male and female): > 2,000 mg/kg
Method: OECD Test Guideline 402

1,2-benzisothiazol-3(2H)-one:

Acute oral toxicity : LD50 (Rat, male and female): 490 mg/kg
Method: OECD Test Guideline 401

Acute dermal toxicity : LD50 (Rat, male and female): > 2,000 mg/kg
Method: OECD Test Guideline 402
Assessment: The substance or mixture has no acute dermal toxicity

Limestone:

Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg

Skin corrosion/irritation

Not classified based on available information.

Product:

Remarks : Extremely corrosive and destructive to tissue.

Components:

sulfur:

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Species : Rabbit
Method : OECD Test Guideline 404
Result : Skin irritation

ethanediol:

Species : Rabbit
Result : No skin irritation

zinc oxide:

Species : reconstructed human epidermis (RhE)
Method : OECD Test Guideline 431
Result : No skin irritation

1,2-benzisothiazol-3(2H)-one:

Species : Rabbit
Exposure time : 72 h
Method : OECD Test Guideline 404
Result : No skin irritation

Limestone:

Result : No skin irritation

Serious eye damage/eye irritation

Not classified based on available information.

Product:

Remarks : May cause irreversible eye damage.

Components:

sulfur:

Species : Rabbit
Method : OECD Test Guideline 405
Result : No eye irritation

ethanediol:

Species : Rabbit
Result : No eye irritation

zinc oxide:

Species : Rabbit
Method : OECD Test Guideline 405
Result : No eye irritation

1,2-benzisothiazol-3(2H)-one:

Species : Bovine cornea
Method : OECD Test Guideline 437

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Result	:	No eye irritation
Species	:	Rabbit
Method	:	EPA OPP 81-4
Result	:	Irreversible effects on the eye

Limestone:

Result	:	No eye irritation
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Respiratory or skin sensitisation

Skin sensitisation

Not classified based on available information.

Respiratory sensitisation

Not classified based on available information.

Components:

sulfur:

Test Type	:	Magnussen-Kligman test
Species	:	Guinea pig
Method	:	OECD Test Guideline 406
Result	:	Does not cause skin sensitisation.

ethanediol:

Test Type	:	Maximisation Test
Species	:	Guinea pig
Result	:	Does not cause skin sensitisation.

zinc oxide:

Test Type	:	Maximisation Test
Species	:	Guinea pig
Method	:	OECD Test Guideline 406
Result	:	Does not cause skin sensitisation.

Test Type	:	Maximisation Test
Species	:	Guinea pig
Method	:	OECD Test Guideline 406
Result	:	Substance is not considered to be potential skin sensitiser.

1,2-benzisothiazol-3(2H)-one:

Test Type	:	Maximisation Test
Species	:	Guinea pig
Method	:	OECD Test Guideline 406
Result	:	May cause sensitisation by skin contact.

Species	:	Guinea pig
Method	:	FIFRA 81.06
Result	:	May cause sensitisation by skin contact.

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Germ cell mutagenicity

Not classified based on available information.

Components:

sulfur:

Genotoxicity in vitro	:	Test Type: reverse mutation assay Method: OECD Test Guideline 471 Result: negative Test Type: Chromosome aberration test in vitro Test system: Chinese hamster ovary cells Method: OECD Test Guideline 473 Result: negative
Genotoxicity in vivo	:	Test Type: Micronucleus test Species: Mouse (male and female) Method: OECD Test Guideline 474 Result: negative
Germ cell mutagenicity- Assessment	:	Weight of evidence does not support classification as a germ cell mutagen.

ethanediol:

Genotoxicity in vitro	:	Test Type: reverse mutation assay Method: OPPTS 870.5100 Result: negative
Genotoxicity in vivo	:	Test Type: dominant lethal test Species: Rat Application Route: Oral Result: negative

zinc oxide:

Genotoxicity in vitro	:	Test Type: reverse mutation assay Method: Mutagenicity (Salmonella typhimurium - reverse mutation assay) Result: negative Test Type: In vitro mammalian cell gene mutation test Method: OECD Test Guideline 476 Result: equivocal Test Type: Chromosome aberration test in vitro Test system: Chinese hamster fibroblasts Method: OECD Test Guideline 473 Result: negative Test Type: Chromosome aberration test in vitro Test system: Human lymphocytes
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Result: positive

Test Type: Micronucleus test
Test system: Human epithelioid cells
Method: OECD Test Guideline 487
Result: negative

Test Type: Micronucleus test
Test system: Human lymphocytes
Result: positive

Genotoxicity in vivo : Test Type: In vivo micronucleus test
Species: Mouse (male)
Application Route: Intraperitoneal injection
Method: OECD Test Guideline 474
Result: negative

1,2-benzisothiazol-3(2H)-one:

Genotoxicity in vitro : Test Type: gene mutation test
Test system: mouse lymphoma cells
Metabolic activation: with and without metabolic activation
Method: OECD Test Guideline 476
Result: negative

Test Type: Ames test
Method: OECD Test Guideline 471
Result: negative

Test Type: Chromosome aberration test in vitro
Method: OECD Test Guideline 473
Result: positive

Genotoxicity in vivo : Test Type: unscheduled DNA synthesis assay
Species: Rat (male)
Cell type: Liver cells
Application Route: Ingestion
Exposure time: 4 h
Method: OECD Test Guideline 486
Result: negative

Test Type: Micronucleus test
Species: Mouse
Application Route: Oral
Method: OECD Test Guideline 474
Result: negative

Germ cell mutagenicity- Assessment : Weight of evidence does not support classification as a germ cell mutagen.

Carcinogenicity

Not classified based on available information.

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Components:

ethanediol:

Species	:	Mouse
Application Route	:	Oral
Exposure time	:	24 month(s)
Result	:	negative

zinc oxide:

Species	:	Mouse, male and female
Application Route	:	Oral
Exposure time	:	1 year
Dose	:	4400, 22000 mg/l
NOAEL	:	> 22,000 mg/l
Result	:	negative
Remarks	:	Based on data from similar materials

Carcinogenicity - Assessment	:	Animal testing did not show any carcinogenic effects.
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Reproductive toxicity

Not classified based on available information.

Components:

zinc oxide:

Effects on fertility	:	Test Type: Two-generation study Species: Rat, male and female Application Route: Oral Dose: 7.5, 15, 30mg/kg bw/day Frequency of Treatment: 7 days/week General Toxicity - Parent: LOAEL: 7.5 mg/kg body weight General Toxicity F1: LOAEL: 30 mg/kg body weight Method: OECD Test Guideline 416 Result: negative Remarks: Based on data from similar materials
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	:	Test Type: one-generation reproductive toxicity Species: Rat, male Application Route: Oral Dose: 4,000 milligram per liter Frequency of Treatment: 32 daily General Toxicity - Parent: LOAEL: 4,000 mg/l General Toxicity F1: LOAEL: 4,000 mg/l Symptoms: Reduced fertility Target Organs: male reproductive organs Result: positive Remarks: Based on data from similar materials
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Effects on foetal development	:	Species: Rat Application Route: inhalation (dust/mist/fume) Dose: .0003, 0.002, 0.008 milligram per liter
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Duration of Single Treatment: 14 d
General Toxicity Maternal: LOAEC: 0.008 mg/l
Developmental Toxicity: NOAEC: 0.008 mg/l
Embryo-foetal toxicity: NOAEC Mating/Fertility: 0.008 mg/l
Method: OECD Test Guideline 414
Result: negative

Reproductive toxicity - Assessment : Some evidence of adverse effects on sexual function and fertility, and/or on development, based on animal experiments.

1,2-benzisothiazol-3(2H)-one:

Effects on fertility : Species: Rat, male
Application Route: Ingestion
General Toxicity - Parent: NOAEL: 18.5 mg/kg body weight
General Toxicity F1: NOAEL: 48 mg/kg body weight
Fertility: NOAEL: 112 mg/kg bw/day
Symptoms: No effects on reproduction parameters
Method: OPPTS 870.3800
Result: negative

Reproductive toxicity - Assessment : Weight of evidence does not support classification for reproductive toxicity

STOT - single exposure

Not classified based on available information.

Components:

Limestone:

Assessment : The substance or mixture is not classified as specific target organ toxicant, single exposure.

STOT - repeated exposure

Not classified based on available information.

Components:

sulfur:

Assessment : The substance or mixture is not classified as specific target organ toxicant, repeated exposure.

ethanediol:

Exposure routes : Oral
Target Organs : Kidney
Assessment : The substance or mixture is classified as specific target organ toxicant, repeated exposure, category 2.

zinc oxide:

Exposure routes : Oral
Target Organs : Central nervous system, Reproductive organs

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Assessment : The substance or mixture is classified as specific target organ toxicant, repeated exposure, category 2.

1,2-benzisothiazol-3(2H)-one:

Assessment : The substance or mixture is not classified as specific target organ toxicant, repeated exposure.

Limestone:

Assessment : The substance or mixture is not classified as specific target organ toxicant, repeated exposure.

Repeated dose toxicity

Components:

sulfur:

Species : Rat, male and female
NOAEL : 1,000 mg/kg
Application Route : Oral
Exposure time : 90 d
Method : OECD Test Guideline 408

Species : Rat, male and female
NOAEL : 400 - 1,000 mg/kg
Application Route : Dermal
Exposure time : 28 d
Method : OECD Test Guideline 410

ethanediol:

Species : Rat
NOAEL : 150 mg/kg
Application Route : Oral
Exposure time : 12 months

Species : Dog
NOAEL : > 2,200 - < 4,400 mg/kg
Application Route : Dermal
Exposure time : 4 weeks
Method : OECD Test Guideline 410

zinc oxide:

Species : Rat, male and female
NOAEL : 31.52 mg/kg
LOAEL : 127.52 mg/kg
Application Route : Oral
Exposure time : 13 weeks
Dose : 0, 31.52, 127.52 mg/kg
Method : OECD Test Guideline 408
Target Organs : Pancreas
Symptoms : Necrosis

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Remarks : Based on data from similar materials

Species : Mouse, male and female
NOEL : 3000 ppm
Application Route : Oral
Exposure time : 13 weeks
Dose : 0, 300, 3000, 30000 ppm
Method : OECD Test Guideline 408
Remarks : Based on data from similar materials

Species : Rat, male
LOAEL : 0.0045 mg/l
Application Route : inhalation (dust/mist/fume)
Exposure time : 3 months
Dose : 0.0003, 0.0015, 0.004mg/l
Method : OECD Test Guideline 413
Target Organs : Lungs
Remarks : mortality

Species : Rat, male and female
LOAEL : 75 mg/kg bw/day
Application Route : Dermal
Exposure time : 28d
Dose : 0, 75, 180, 360 mg/kg bw/day
Method : OECD Test Guideline 410

1,2-benzisothiazol-3(2H)-one:

Species : Rat, male and female
NOAEL : 15 mg/kg
Application Route : Ingestion
Exposure time : 28 d
Method : OECD Test Guideline 407
Symptoms : Irritation

Species : Rat, male and female
NOAEL : 69 mg/kg
Application Route : Ingestion
Exposure time : 90 d
Symptoms : Irritation, Reduced body weight

Aspiration toxicity

Not classified based on available information.

Experience with human exposure

Components:

zinc oxide:

Inhalation : Symptoms: Fatigue, Sweating, bitter taste, chills, dry mouth, flu-like symptoms

Ingestion : Symptoms: Gastrointestinal discomfort

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Further information

Product:

Remarks : No data available

SECTION 12: Ecological information

12.1 Toxicity

Components:

sulfur:

Toxicity to fish	:	LC0 (Oncorhynchus mykiss (rainbow trout)): > 0.005 mg/l Exposure time: 96 h Method: OECD Test Guideline 203
Toxicity to daphnia and other aquatic invertebrates	:	NOEC (Daphnia magna Straus): > 0.005 mg/l Exposure time: 48 h Method: OECD Test Guideline 202
Toxicity to algae/aquatic plants	:	NOEC (algae): > 0.005 mg/l Exposure time: 72 h Method: OECD Test Guideline 201 Remarks: No toxicity at the limit of solubility
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	:	NOEC: > 0.0025 mg/l Exposure time: 21 d Species: Daphnia magna (Water flea) Method: OECD Test Guideline 211 Remarks: No toxicity at the limit of solubility
Toxicity to soil dwelling organisms	:	NOEC: > 1,000 mg/kg Exposure time: 14 d Species: Eisenia fetida (earthworms) Method: OECD Test Guideline 207
Plant toxicity	:	NOEC: 25.2 kg/ha Exposure time: 14 d Species: Avena sativa (oats) Method: OECD Test Guideline 208
Toxicity to terrestrial organisms	:	NOEC: > 1400 - < 1900 kg/ha Exposure time: 60 d Species: Typhlodromus pyri LD50: > 2,000 mg/kg Exposure time: 15 d Species: Coturnix japonica (Japanese quail)

ethanediol:

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Toxicity to fish	:	LC50 (Pimephales promelas (fathead minnow)): > 72,860 mg/l Exposure time: 96 h
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia magna (Water flea)): > 100 mg/l Exposure time: 48 h Method: OECD Test Guideline 202
Toxicity to algae/aquatic plants	:	IC50 (Pseudokirchneriella subcapitata (green algae)): 10,940 mg/l Exposure time: 96 h
Toxicity to microorganisms	:	(activated sludge): > 1,995 mg/l Exposure time: 30 min Method: ISO 8192
Toxicity to fish (Chronic toxicity)	:	1,500 mg/l Exposure time: 28 d Species: Menidia peninsulae (tidewater silverside)
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	:	33,911 mg/l Exposure time: 21 d Species: Daphnia magna (Water flea)

zinc oxide:

Toxicity to fish	:	LC50 (Danio rerio (zebra fish)): 1.55 mg/l Exposure time: 96 h Test Type: static test
Toxicity to daphnia and other aquatic invertebrates	:	LC50 (Daphnia magna (Water flea)): 0.76 mg/l Exposure time: 48 h Method: OECD Test Guideline 202 LC50 : 0.37 mg/l Exposure time: 96 h Test Type: static test EC50 : 0.14 mg/l Exposure time: 24 h Test Type: static test EC50 : 0.072 mg/l Exposure time: 96 h Test Type: static test
Toxicity to algae/aquatic plants	:	IC50 (Pseudokirchneriella subcapitata (algae)): 0.044 mg/l Exposure time: 72 h Method: OECD Test Guideline 201 NOEC (Pseudokirchneriella subcapitata (algae)): 0.024 mg/l Exposure time: 3 d Method: OECD Test Guideline 201

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IC50 (Skeletonema costatum (marine diatom)): 1.23 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 201

IC50 : 3.28 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 201

NOEC (Dunaliella tertiolecta (marine algae)): 0.01 mg/l
Exposure time: 4 d
Test Type: static test

EC50 (Dunaliella tertiolecta (marine algae)): 0.65 mg/l
Exposure time: 4 d
Test Type: static test

(Chlorella vulgaris (Fresh water algae)): 1.16 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

EC50 (Anabaena flos-aquae (cyanobacterium)): 0.3 mg/l
Exposure time: 96 h
Test Type: static test

EC50 : 0.69 mg/l
Exposure time: 3 d
Test Type: static test

EC50 (Phaeodactylum tricornutum): 1.12 mg/l
Exposure time: 24 h
Test Type: static test

M-Factor (Acute aquatic toxicity) : 1

Toxicity to microorganisms : EC50 (activated sludge): > 1,000 mg/l
Exposure time: 3 h
Method: OECD Test Guideline 209

EC50 (Tetrahymena pyriformis): 7.1 mg/l
Exposure time: 24 h
Test Type: Growth inhibition

Toxicity to fish (Chronic toxicity) : NOEC: 0.440 mg/l
Exposure time: 72 d
Species: Oncorhynchus mykiss (rainbow trout)
Test Type: flow-through test
Remarks: Based on data from similar materials

NOEC: 0.026 mg/l
Exposure time: 30 d
Species: Jordanella floridae (flagfish)
Method: OECD Test Guideline 210

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Remarks: Based on data from similar materials

NOEC: 0.530 mg/l
Exposure time: 1,095 d
Species: *Salvelinus fontinalis* (Brook trout)
Test Type: flow-through test
Remarks: Based on data from similar materials

NOEC: 0.056 mg/l
Exposure time: 116 d
Species: *Salmo trutta* (brown trout)
Method: OECD Test Guideline 210
Remarks: Based on data from similar materials

NOEC: 0.025 mg/l
Exposure time: 27 d
Species: Fish
Test Type: semi-static test
Remarks: Based on data from similar materials

NOEC: 0.078 mg/l
Exposure time: 248 d
Species: *Pimephales promelas* (fathead minnow)
Test Type: flow-through test
Remarks: Based on data from similar materials

NOEC: 0.050 mg/l
Exposure time: 155 d
Species: Fish
Test Type: flow-through test
Remarks: Based on data from similar materials

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : LOEC: 0.125 mg/l
Exposure time: 21 d
Species: *Daphnia magna* (Water flea)
Method: OECD Test Guideline 211

M-Factor (Chronic aquatic toxicity) : 10

Toxicity to soil dwelling organisms : NOEC: 750 mg/kg
Exposure time: 21 d
Species: *Eisenia fetida* (earthworms)

1,2-benzisothiazol-3(2H)-one:

Toxicity to fish : LC50 (*Cyprinodon variegatus* (sheepshead minnow)): 16.7 mg/l
Exposure time: 96 h
Test Type: static test

LC50 (*Oncorhynchus mykiss* (rainbow trout)): 2.15 mg/l
Exposure time: 96 h

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Method: OECD Test Guideline 203

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 2.9 mg/l
Exposure time: 48 h
Test Type: static test
Method: OECD Test Guideline 202

Toxicity to algae/aquatic plants : EC50 (Pseudokirchneriella subcapitata (green algae)): 0.070 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

NOEC (Pseudokirchneriella subcapitata (green algae)): 0.04 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

M-Factor (Acute aquatic toxicity) : 10

Toxicity to microorganisms : EC50 (activated sludge): 24 mg/l
Exposure time: 3 h
Test Type: Respiration inhibition
Method: OECD Test Guideline 209

EC50 (activated sludge): 12.8 mg/l
Exposure time: 3 h
Test Type: Respiration inhibition
Method: OECD Test Guideline 209

Limestone:

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): 10,000 mg/l
Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): > 1,000 mg/l
Exposure time: 48 h

Toxicity to algae/aquatic plants : EC50 (Desmodesmus subspicatus (green algae)): > 200 mg/l
Exposure time: 72 h

12.2 Persistence and degradability

Components:

sulfur:

Biodegradability : Remarks: The methods for determining the biological degradability are not applicable to inorganic substances.

ethanediol:

Biodegradability : Result: Readily biodegradable.
Biodegradation: 90 - 100 %

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Exposure time: 10 d
Method: OECD Test Guideline 301A

1,2-benzisothiazol-3(2H)-one:

Biodegradability : Result: rapidly biodegradable
Method: OECD Test Guideline 301C

12.3 Bioaccumulative potential

Components:

ethanediol:

Partition coefficient: n-octanol/water : log Pow: -1.36

zinc oxide:

Bioaccumulation : Species: Oncorhynchus mykiss (rainbow trout)
Exposure time: 14 d
Bioconcentration factor (BCF): 2,060

1,2-benzisothiazol-3(2H)-one:

Bioaccumulation : Species: Lepomis macrochirus (Bluegill sunfish)
Exposure time: 56 d
Bioconcentration factor (BCF): 6.62
Method: OECD Test Guideline 305
Remarks: This substance is not considered to be persistent, bioaccumulating and toxic (PBT).

Partition coefficient: n-octanol/water : log Pow: 0.7 (20 °C)
pH: 7

log Pow: 0.99 (20 °C)
pH: 5

12.4 Mobility in soil

Components:

1,2-benzisothiazol-3(2H)-one:

Distribution among environmental compartments : Koc: 9.33 ml/g, log Koc: 0.97
Method: OECD Test Guideline 121
Remarks: Highly mobile in soils

12.5 Results of PBT and vPvB assessment

Product:

Assessment : This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

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12.6 Other adverse effects

Product:

Endocrine disrupting potential : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Additional ecological information : An environmental hazard cannot be excluded in the event of unprofessional handling or disposal.
Harmful to aquatic life.
Toxic to aquatic life with long lasting effects.

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product : The product should not be allowed to enter drains, water courses or the soil.
Do not contaminate ponds, waterways or ditches with chemical or used container.
Send to a licensed waste management company.

Contaminated packaging : Empty remaining contents.
Dispose of as unused product.
Do not re-use empty containers.

SECTION 14: Transport information

14.1 UN number

ADN	: Not regulated as a dangerous good
ADR	: Not regulated as a dangerous good
RID	: Not regulated as a dangerous good
IMDG	: Not regulated as a dangerous good
IATA	: Not regulated as a dangerous good

14.2 UN proper shipping name

ADN	: Not regulated as a dangerous good
ADR	: Not regulated as a dangerous good
RID	: Not regulated as a dangerous good
IMDG	: Not regulated as a dangerous good
IATA	: Not regulated as a dangerous good

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14.3 Transport hazard class(es)

ADN	:	Not regulated as a dangerous good
ADR	:	Not regulated as a dangerous good
RID	:	Not regulated as a dangerous good
IMDG	:	Not regulated as a dangerous good
IATA	:	Not regulated as a dangerous good

14.4 Packing group

ADN	:	Not regulated as a dangerous good
ADR	:	Not regulated as a dangerous good
RID	:	Not regulated as a dangerous good
IMDG	:	Not regulated as a dangerous good
IATA (Cargo)	:	Not regulated as a dangerous good
IATA (Passenger)	:	Not regulated as a dangerous good

14.5 Environmental hazards

Not regulated as a dangerous good

14.6 Special precautions for user

Not applicable

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

Not applicable for product as supplied.

SECTION 15: Regulatory information

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

Relevant EU provisions transposed through retained EU law

UK REACH List of restrictions (Annex 17)	:	Conditions of restriction for the following entries should be considered: Number on list 3 ethanediol (Number on list 3)
UK REACH Candidate list of substances of very high concern (SVHC) for Authorisation	:	Not applicable
The Persistent Organic Pollutants Regulations (retained Regulation (EU) 2019/1021 as amended for Great Britain)	:	Not applicable
Regulation (EC) No 1005/2009 on substances that deplete the ozone layer	:	Not applicable
UK REACH List of substances subject to authorisation (Annex XIV)	:	Not applicable

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Control of Major Accident Hazards Regulations 2015 (COMAH) E2 ENVIRONMENTAL HAZARDS
E2

Other regulations:

The components of this product are reported in the following inventories:

TCSI	:	Not in compliance with the inventory
TSCA	:	Product contains substance(s) not listed on TSCA inventory.
AIIC	:	Not in compliance with the inventory
DSL	:	This product contains the following components that are not on the Canadian DSL nor NDSL. Boron calcium oxide, hydrate MAGNESIUM SUSPENSION 300 SULPHUR 800 ZINC 69 SUSPENSION emulsion of silicone dolomite Limestone CLASSIC 500G/L
ENCS	:	Not in compliance with the inventory
ISHL	:	Not in compliance with the inventory
KECI	:	Not in compliance with the inventory
PICCS	:	Not in compliance with the inventory
IECSC	:	Not in compliance with the inventory
NZIoC	:	Not in compliance with the inventory
TECI	:	Not in compliance with the inventory

15.2 Chemical safety assessment

A chemical safety assessment is not required for this product (mixture).

SECTION 16: Other information

Full text of H-Statements

H302	:	Harmful if swallowed.
H315	:	Causes skin irritation.
H317	:	May cause an allergic skin reaction.
H318	:	Causes serious eye damage.

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H373	: May cause damage to organs through prolonged or repeated exposure if swallowed.
H400	: Very toxic to aquatic life.
H410	: Very toxic to aquatic life with long lasting effects.
H411	: Toxic to aquatic life with long lasting effects.

Full text of other abbreviations

Acute Tox.	: Acute toxicity
Aquatic Acute	: Short-term (acute) aquatic hazard
Aquatic Chronic	: Long-term (chronic) aquatic hazard
Eye Dam.	: Serious eye damage
Skin Irrit.	: Skin irritation
Skin Sens.	: Skin sensitisation
STOT RE	: Specific target organ toxicity - repeated exposure
2000/39/EC	: Europe. Commission Directive 2000/39/EC establishing a first list of indicative occupational exposure limit values
2017/164/EU	: Europe. Commission Directive 2017/164/EU establishing a fourth list of indicative occupational exposure limit values
GB EH40	: UK. EH40 WEL - Workplace Exposure Limits
2000/39/EC / TWA	: Limit Value - eight hours
2000/39/EC / STEL	: Short term exposure limit
2017/164/EU / TWA	: Limit Value - eight hours
GB EH40 / TWA	: Long-term exposure limit (8-hour TWA reference period)
GB EH40 / STEL	: Short-term exposure limit (15-minute reference period)

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by Road; AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of very high concern; TCSI - Taiwan Chemical Substance Inventory; TECL -

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Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

Classification of the mixture:

Classification procedure:

Based on product data or assessment

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