

SAFETY DATA SHEET

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



KWS PREMIX 450 (a)

Version	Revision Date:	SDS Number:	Date of last issue: -
1.1	18.10.2024	50001230	Date of first issue: 24.08.2020

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

1.1 Product identifier

Product name KWS PREMIX 450 (a)

Other means of identification

Product code 50001230

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

Use of the Sub-
stance/Mixture : Fertilizers

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

1.3 Manufacturer or supplier's details

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)**

Long-term (chronic) aquatic hazard, Cat- H411: Toxic to aquatic life with long lasting effects.

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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)

Hazard pictograms :



Hazard statements : H411 Toxic to aquatic life with long lasting effects.

Precautionary statements : **Prevention:**

P273 Avoid release to the environment.

Response:

P391 Collect spillage.

Disposal:

P501 Dispose of contents/ container to an approved waste disposal plant.

Additional Labelling

EUH208 Contains 3-hydroxy-2'-methyl-2-naphthanilide, 1,2-benzisothiazol-3(2H)-one, reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1). 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)
manganese carbonate	598-62-9 209-942-9	Aquatic Chronic 2; H411	>= 20 - < 25

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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 M-Factor (Chronic aquatic toxicity): 10	$\geq 2.5 - < 10$
ethanediol	107-21-1 203-473-3 603-027-00-1	Acute Tox. 4; H302 STOT RE 2; H373 (Kidney)	$\geq 1 - < 10$
sodium acrylate	7446-81-3 231-209-7	Aquatic Acute 1; H400 Aquatic Chronic 2; H411	$\geq 1 - < 2.5$
Humic acids, potassium salts	68514-28-3 271-030-1	Aquatic Chronic 3; H412	$\geq 1 - < 2.5$
3-hydroxy-2'-methyl-2-naphthanilide	135-61-5 205-205-0	Skin Sens. 1A; H317 Aquatic Chronic 2; H411	$\geq 0.025 - < 0.1$
1,2-benzisothiazol-3(2H)-one	2634-33-5 220-120-9 613-088-00-6	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 concentra- tion limit Skin Sens. 1A; H317 $\geq 0.036 \%$	$\geq 0.0025 - < 0.025$
reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1)	55965-84-9 613-167-00-5	Acute Tox. 3; H301 Acute Tox. 2; H330 Acute Tox. 2; H310 Skin Corr. 1C; H314 Eye Dam. 1; H318 Skin Sens. 1A; H317 Aquatic Acute 1; H400 Aquatic Chronic 1; H410	$\geq 0.0002 - < 0.0015$

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		<div>M-Factor (Acute aquatic toxicity): 100 M-Factor (Chronic aquatic toxicity): 100</div> <div>specific concentration limit Skin Corr. 1C; H314 ≥ 0.6 % Skin Irrit. 2; H315 0.06 - < 0.6 % Eye Irrit. 2; H319 0.06 - < 0.6 % Skin Sens. 1A; H317 ≥ 0.0015 % Eye Dam. 1; H318 ≥ 0.6 %</div>	
Substances with a workplace exposure limit :			
mica	12001-26-2		≥ 1 - < 10
titanium dioxide	13463-67-7 236-675-5		≥ 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.
Show this safety data sheet to the doctor in attendance.
Do not leave the victim unattended. |
| Protection of first-aiders | : First Aid responders should pay attention to self-protection and use the recommended protective clothing
Avoid inhalation, ingestion and contact with skin and eyes.
If potential for exposure exists refer to Section 8 for specific personal protective equipment. |
| If inhaled | : Move to fresh air.
If unconscious, place in recovery position and seek medical advice.
If symptoms persist, call a physician.
If experiencing any discomfort, immediately remove from ex- |

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posure. Light cases: Keep person under surveillance. Get medical attention immediately if symptoms develop. Serious cases: Get medical attention immediately or call for an ambulance.

- | | | |
|-------------------------|---|--|
| In case of skin contact | : | Take off all contaminated clothing immediately.
Wash contaminated clothing before re-use.
Wash off immediately with plenty of water for at least 15 minutes.
Get medical attention immediately if irritation develops and persists. |
| In case of eye contact | : | Flush eyes with water as a precaution.
Remove contact lenses.
Protect unharmed eye.
Keep eye wide open while rinsing.
If eye irritation persists, consult a specialist. |
| If swallowed | : | Do not induce vomiting without medical advice.
Keep respiratory tract clear.
Do not give milk or alcoholic beverages.
Never give anything by mouth to an unconscious person.
If symptoms persist, call a physician. |

4.2 Most important symptoms and effects, both acute and delayed

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, CO ₂ , 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
Do not spread spilled material with high-pressure water streams. |

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.
Carbon oxides |

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5.3 Advice for firefighters

- Special protective equipment for firefighters : Firefighters should wear protective clothing and self-contained breathing apparatus.
- 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 : If it can be safely done, stop the leak.
Ensure adequate ventilation.
Use personal protective equipment.
Never return spills in original containers for re-use.
Mark the contaminated area with signs and prevent access to 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.
For personal protection see section 8.
Smoking, eating and drinking should be prohibited in the application area.
Dispose of rinse water in accordance with local and national regulations.

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

Hygiene measures : Wash hands before breaks and at the end of workday.

7.2 Conditions for safe storage, including any incompatibilities

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

Further information on storage stability : No decomposition if stored and applied as directed.

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
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			
mica	12001-26-2	TWA (Inhalable)	10 mg/m ³	GB EH40
		TWA (Respirable fraction)	0.8 mg/m ³	GB EH40
ethanediol	107-21-1	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.			
		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.			
		STEL (Vapour)	40 ppm	GB EH40

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			104 mg/m3	
	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	20 ppm 52 mg/m3	2000/39/EC
	Further information: Identifies the possibility of significant uptake through the skin, Indicative			
		STEL	40 ppm 104 mg/m3	2000/39/EC
	Further information: Identifies the possibility of significant uptake through the skin, Indicative			
titanium dioxide	13463-67-7	TWA (inhalable dust)	10 mg/m3	GB EH40
		TWA (Respirable dust)	4 mg/m3	GB EH40

Derived No Effect Level (DNEL)

Substance name	End Use	Exposure routes	Potential health effects	Value
3-hydroxy-N-(o-tolyl)-4-[(2,4,5-trichlorophenyl)azo]naphthalene-2-carboxamide	Workers	Inhalation	Long-term systemic effects	49 mg/m3
	Workers	Dermal	Long-term systemic effects	42 mg/kg
	Consumers	Dermal	Long-term systemic effects	25 mg/kg
	Consumers	Oral	Long-term systemic effects	25 mg/kg
1,2-benzisothiazol-3(2H)-one	Workers	Inhalation	Long-term systemic effects	6.81 mg/m3
	Workers	Dermal	Long-term systemic effects	0.966 mg/kg
	Consumers	Inhalation	Long-term systemic effects	1.2 mg/m3
	Consumers	Dermal	Long-term systemic effects	0.345 mg/kg
reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1)	Workers	Inhalation	Long-term local effects	0.02 mg/m3
	Workers	Inhalation	Acute local effects	0.04 mg/m3
	Consumers	Inhalation	Long-term local effects	0.02 mg/m3
	Consumers	Inhalation	Acute local effects	0.04 mg/m3
	Consumers	Oral	Long-term systemic effects	0.09 mg/kg

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	Consumers	Oral	Acute systemic effects	0.11 mg/kg
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Predicted No Effect Concentration (PNEC)

Substance name	Environmental Compartment	Value
manganese carbonate	Fresh water	0.0084 mg/l
	Intermittent use/release	0.011 mg/l
	Marine water	840 ng/l
	Sewage treatment plant	100 mg/l
	Fresh water sediment	8.18 mg/kg dry weight (d.w.)
	Marine sediment	0.810 mg/kg dry weight (d.w.)
	Soil	8.15 mg/kg dry weight (d.w.)
ethanediol	Fresh water	10 mg/l
	Marine water	1 mg/l
	Sewage treatment plant	199.5 mg/l
	Fresh water sediment	37 mg/kg dry weight (d.w.)
	Marine sediment	3.7 mg/kg dry weight (d.w.)
	Soil	1.53 mg/kg dry weight (d.w.)
Humic acids, potassium salts	Fresh water	0.077 mg/l
	Marine water	
	Fresh water sediment	
	Marine sediment	
	Soil	
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
	Fresh water sediment	0.0499 mg/l
	Marine sediment	0.00499 mg/l
reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1)	Fresh water	0.00339 mg/l
	Intermittent use/release	0.00339 mg/l
	Marine water	0.00339 mg/l
	Sewage treatment plant	0.23 mg/l
	Fresh water sediment	0.027 mg/kg
	Marine sediment	0.027 mg/kg

8.2 Exposure controls

Personal protective equipment

Eye/face protection : Eye wash bottle with pure water
Tightly fitting safety goggles

Hand protection

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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	:	red
Odour	:	Barely perceptible
Odour Threshold	:	No data available
pH	:	7.5 - 9.5 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	:	1.48 - 1.54
Density	:	No data available
Bulk density	:	No data available
Solubility(ies)	:	
Water solubility	:	soluble
Solubility in other solvents	:	No data available
Partition coefficient: n-octanol/water	:	No data available

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Auto-ignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity	:	
Viscosity, dynamic	:	1,000 - 1,600 mPa,s
Viscosity, kinematic	:	No data available
Explosive properties	:	
	:	No data available
Oxidizing properties	:	Non-oxidizing

9.2 Other information

Particle Size Distribution	:	No data available
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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.
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10.4 Conditions to avoid

Conditions to avoid	:	Avoid extreme temperatures Heat Avoid formation of aerosol.
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10.5 Incompatible materials

Materials to avoid	:	Avoid strong acids, bases, and oxidizers
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10.6 Hazardous decomposition products

No decomposition if stored and applied as directed.
In case of fire hazardous decomposition products may be produced such as:
Toxic fumes
irritating gases

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Acute toxicity

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

Product:

Acute oral toxicity	:	Acute toxicity estimate: > 2,000 mg/kg Method: Calculation method
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Acute inhalation toxicity : Acute toxicity estimate: > 20 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Method: Calculation method

Acute dermal toxicity : Acute toxicity estimate: > 5,000 mg/kg
Method: Calculation method

Components:

manganese carbonate:

Acute oral toxicity : LD0 (Rat, female): > 2,000 mg/kg
Method: OECD Test Guideline 420
Remarks: no mortality

Acute inhalation toxicity : LC0 (Rat, male and female): > 5.35 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Method: OECD Test Guideline 403
Remarks: no mortality
Based on data from similar materials

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

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

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Humic acids, potassium salts:

Acute oral toxicity : LD50 (Rat, female): > 2,000 mg/kg
Method: Regulation (EC) No. 440/2008, Annex, B.1 tris

Acute dermal toxicity : LD50 (Rat, male and female): > 2,000 mg/kg
Method: Regulation (EC) No. 440/2008, Annex, B.3

3-hydroxy-2'-methyl-2-naphthanilide:

Acute oral toxicity : LD50 (Rat, female): > 5,000 mg/kg
Method: OECD Test Guideline 401
GLP: no
Remarks: No significant adverse effects were reported

Acute inhalation toxicity : Remarks: No data available

Acute dermal toxicity : Remarks: No data available

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

reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1):

Acute oral toxicity : LD50 Oral (Rat, female): 200 mg/kg
Method: OECD Test Guideline 423

Acute inhalation toxicity : LC50 (Rat, male and female): 0.33 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Method: OECD Test Guideline 403
Assessment: Corrosive to the respiratory tract.

Acute dermal toxicity : LD50 (Rabbit, male): 87 mg/kg

mica:

Acute oral toxicity : Remarks: No data available

titanium dioxide:

Acute oral toxicity : LD50 (Rat, male and female): > 2,000 mg/kg
Method: OECD Test Guideline 401
Assessment: The substance or mixture has no acute oral toxicity

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Acute inhalation toxicity : LC50 (Rat, male): 3.43 - 5.09 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Method: OECD Test Guideline 403
Assessment: The substance or mixture has no acute inhalation toxicity

Skin corrosion/irritation

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

Product:

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

Components:

manganese carbonate:

Species : Rabbit
Method : OECD Test Guideline 404
Result : No skin irritation

zinc oxide:

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

ethanediol:

Species : Rabbit
Result : No skin irritation

Humic acids, potassium salts:

Species : Rabbit
Method : Regulation (EC) No. 440/2008, Annex, B.4
Result : No skin irritation

3-hydroxy-2'-methyl-2-naphthanilide:

Species : Rabbit
Exposure time : 4 h
Method : Directive 67/548/EEC, Annex V, B.4.
Result : No skin irritation
GLP : yes

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

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

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reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1):

Method	: OECD Test Guideline 404
Result	: Corrosive after 1 to 4 hours of exposure

mica:

Remarks	: No data available
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titanium dioxide:

Species	: Rabbit
Method	: OECD Test Guideline 404
Result	: No skin irritation

Serious eye damage/eye irritation

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

Product:

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

manganese carbonate:

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

zinc oxide:

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

ethanediol:

Species	: Rabbit
Result	: No eye irritation

Humic acids, potassium salts:

Species	: Rabbit
Method	: Regulation (EC) No. 440/2008, Annex, B.5
Result	: No eye irritation

3-hydroxy-2'-methyl-2-naphthanilide:

Species	: Rabbit
Exposure time	: 24 h
Method	: Regulation (EC) No. 440/2008, Annex, B.5
Result	: No eye irritation
GLP	: yes

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

Species	:	Bovine cornea
Method	:	OECD Test Guideline 437
Result	:	No eye irritation
Species	:	Rabbit
Method	:	EPA OPP 81-4
Result	:	Irreversible effects on the eye

reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1):

Result	:	Irreversible effects on the eye
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mica:

Remarks	:	No data available
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titanium dioxide:

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

Respiratory or skin sensitisation

Skin sensitisation

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

Respiratory sensitisation

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

Product:

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

manganese carbonate:

Test Type	:	Local lymph node test
Species	:	Mouse
Method	:	OECD Test Guideline 429
Result	:	Does not cause skin sensitisation.
Remarks	:	Based on data from similar materials

zinc oxide:

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

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

ethanediol:

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

Humic acids, potassium salts:

Test Type	: Local lymph node assay (LLNA)
Species	: Mouse
Method	: Regulation (EC) No. 440/2008, Annex, B.42 (LLNA)
Result	: Not a skin sensitizer.

3-hydroxy-2'-methyl-2-naphthanilide:

Test Type	: Local lymph node assay (LLNA)
Exposure routes	: Dermal
Species	: Mouse
Method	: OECD Test Guideline 429
Result	: The product is a skin sensitiser, sub-category 1A.
GLP	: yes

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.

reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1):

Test Type	: Local lymph node assay (LLNA)
Species	: Mouse
Result	: The product is a skin sensitiser, sub-category 1A.

titanium dioxide:

Test Type	: Local lymph node assay (LLNA)
Species	: Mouse
Method	: OECD Test Guideline 429
Result	: Not a skin sensitizer.

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Germ cell mutagenicity

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

Components:

manganese carbonate:

- Genotoxicity in vitro : Test Type: reverse mutation assay
Method: OECD Test Guideline 471
Result: negative
Remarks: Based on data from similar materials
- Test Type: Chromosome aberration test in vitro
Method: OECD Test Guideline 473
Result: negative
Remarks: Based on data from similar materials
- Test Type: In vitro mammalian cell gene mutation test
Method: OECD Test Guideline 476
Result: negative
Remarks: Based on data from similar materials
- Genotoxicity in vivo : Test Type: Micronucleus test
Species: Mouse (female)
Application Route: Oral
Method: OECD Test Guideline 474
Result: negative
Remarks: Based on data from similar materials
- Germ cell mutagenicity- Assessment : Weight of evidence does not support classification as a germ cell mutagen.

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
Result: positive

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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

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

Humic acids, potassium salts:

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

Genotoxicity in vivo : Test Type: Micronucleus test
Species: Rat (male and female)
Application Route: Ingestion
Method: Regulation (EC) No. 440/2008, Annex, B.12

3-hydroxy-2'-methyl-2-naphthanilide:

Genotoxicity in vitro : Test Type: Ames test
Test system: Salmonella typhimurium
Concentration: 4 - 10000 µg/plate
Metabolic activation: with and without metabolic activation
Method: OECD Test Guideline 471
Result: negative
GLP: yes
Remarks: In vitro tests did not show mutagenic effects

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

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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.

titanium dioxide:

Genotoxicity in vitro

: 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

Method: OECD Test Guideline 474

Result: negative

Carcinogenicity

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

Components:

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

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Remarks : Based on data from similar materials

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

ethanediol:

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

mica:

Remarks : No data available

titanium dioxide:

Species : Mouse, male and female
Application Route : Oral
Exposure time : 103 weeks
Result : negative

Species : Rat, male and female
Application Route : Inhalation
Exposure time : 2 Years
Result : negative

Reproductive toxicity

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

Components:

manganese carbonate:

Effects on fertility : Test Type: Two-generation study
Species: Rat, male and female
Application Route: inhalation (dust/mist/fume)
Dose: 0, .005, .01, .02 mg/L
General Toxicity - Parent: NOEL: 0.02 mg/l
Method: OECD Test Guideline 416
Result: negative
Remarks: Based on data from similar materials

Effects on foetal development : Species: Rat
Application Route: inhalation (dust/mist/fume)
Duration of Single Treatment: 15 d
General Toxicity Maternal: NOAEL: 0.025 mg/L
Developmental Toxicity: LOAEL: 0.025 mg/L
Embryo-foetal toxicity: NOAEL: 0.025 mg/L
Method: OECD Test Guideline 414
Result: negative
Remarks: Based on data from similar materials

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

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

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

Effects on foetal development : Species: Rat
Application Route: inhalation (dust/mist/fume)
Dose: .0003, 0.002, 0.008 milligram per liter
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

Humic acids, potassium salts:

Effects on fertility : Test Type: reproductive and developmental toxicity study
Species: Rat, male and female
Application Route: Ingestion
Method: OECD Test Guideline 421
Result: negative

Effects on foetal development : Test Type: Pre-natal
Species: Rat
Application Route: Ingestion
Method: Regulation (EC) No. 440/2008, Annex, B.31
Result: negative

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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

titanium dioxide:

Effects on foetal development : Test Type: Embryo-foetal development
Species: Rat
Application Route: Oral
Method: OECD Test Guideline 414
Result: negative

STOT - single exposure

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

Components:

manganese carbonate:

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

STOT - repeated exposure

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

Components:

ethanediol:

Exposure routes : Oral
Target Organs : Kidney
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.

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Repeated dose toxicity

Components:

manganese carbonate:

Species	: Rabbit, male
LOAEC	: 0.0039 mg/l
Application Route	: Inhalation
Test atmosphere	: dust/mist
Exposure time	: 4 - 6 weeks
Dose	: 0, .001, .0039 mg/L
Remarks	: Based on data from similar materials

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
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

ethanediol:

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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

Humic acids, potassium salts:

Species	: Rat, male and female
NOAEL	: 500 mg/kg
Application Route	: Oral - gavage
Method	: Regulation (EC) No. 440/2008, Annex, B.7

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

reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1):

Species	: Dog
NOAEL	: 22 mg/kg
Application Route	: Oral

Species	: Rat
NOAEL	: 16.3 - 24.7 mg/kg
Application Route	: Skin contact

Species	: Rat
NOAEL	: 2.36 mg/m ³
Application Route	: Inhalation

titanium dioxide:

Species	: Rat
NOAEL	: 1,000 mg/kg
Application Route	: Ingestion

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Method : OECD Test Guideline 408

Species : Mouse, female
LOAEC : 0.0108 mg/l
Application Route : inhalation (dust/mist/fume)
Exposure time : 13 weeks

Aspiration toxicity

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

Experience with human exposure

Components:

zinc oxide:

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

Ingestion : Symptoms: Gastrointestinal discomfort

Further information

Product:

Remarks : No data available

SECTION 12: Ecological information

12.1 Toxicity

Components:

manganese carbonate:

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): 3.17 mg/l
Exposure time: 96 h
Test Type: flow-through test
Remarks: Based on data from similar materials

Toxicity to daphnia and other : EC50 (Daphnia magna (Water flea)): > 3.6 mg/l
aquatic invertebrates
Exposure time: 48 h
Method: OECD Test Guideline 202

Toxicity to algae/aquatic : EC50 (Pseudokirchneriella subcapitata (green algae)): > 2.2
plants
mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

NOEC (Pseudokirchneriella subcapitata (green algae)): 0.69
mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

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Toxicity to microorganisms : NOEC (activated sludge): 1,000 mg/l
Exposure time: 3 h
Method: OECD Test Guideline 209
Remarks: Based on data from similar materials

EC50 (activated sludge): > 1,000 mg/l
Exposure time: 3 h
Method: OECD Test Guideline 209
Remarks: Based on data from similar materials

Toxicity to fish (Chronic toxicity) : NOEC: 0.55 mg/l
Exposure time: 65 d
Species: *Salvelinus fontinalis* (Brook trout)
Test Type: flow-through test
Remarks: Based on data from similar materials

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC: 1.3 mg/l
Exposure time: 8 d
Species: *Ceriodaphnia dubia* (water flea)
Test Type: static test
Remarks: Based on data from similar materials

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

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Species: *Jordanella floridae* (flagfish)
Method: OECD Test Guideline 210
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) : 1

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

ethanediol:

Toxicity to fish : LC50 (*Pimephales promelas* (fathead minnow)): > 72,860 mg/l
Exposure time: 96 h

Toxicity to daphnia and other : EC50 (*Daphnia magna* (Water flea)): > 100 mg/l

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aquatic invertebrates	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)

sodium acrylate:

Ecotoxicology Assessment

Acute aquatic toxicity	: Very toxic to aquatic life. Remarks: Based on estimation
Chronic aquatic toxicity	: Toxic to aquatic life with long lasting effects. Remarks: Based on estimation

Humic acids, potassium salts:

Toxicity to fish	: LC50 (Poecilia reticulata (guppy)): 128 mg/l Exposure time: 96 h Method: Regulation (EC) No. 440/2008, Annex, C.1
Toxicity to daphnia and other aquatic invertebrates	: EC50 (Daphnia magna (Water flea)): > 116 mg/l Exposure time: 48 h Method: Regulation (EC) No. 440/2008, Annex, C.2
Toxicity to algae/aquatic plants	: EC50 (Desmodesmus subspicatus (green algae)): 100 mg/l Exposure time: 72 h Method: Regulation (EC) No. 440/2008, Annex, C.3
Toxicity to microorganisms	: EC50 (activated sludge): > 1,000 mg/l Exposure time: 3 h Method: EU Method C11
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	: Species: Daphnia magna (Water flea) Method: OECD Test Guideline 211

3-hydroxy-2'-methyl-2-naphthanilide:

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- Toxicity to fish : LC50 (Danio rerio (zebra fish)): 1.33 - 3.25 mg/l
End point: mortality
Exposure time: 96 h
Test Type: semi-static test
Method: OECD Test Guideline 203
GLP: yes
Remarks: No toxicity at the limit of solubility
- Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): > 0.108 mg/l
End point: Immobilization
Exposure time: 48 h
Test Type: static test
Analytical monitoring: yes
GLP: yes
Remarks: No toxicity at the limit of solubility
- Toxicity to algae/aquatic plants : ErC50 (Desmodesmus subspicatus (green algae)): > 0.711 mg/l
End point: Growth rate
Exposure time: 72 h
Test Type: static test
Analytical monitoring: yes
Method: OECD Test Guideline 201
GLP: yes
Remarks: No toxicity at the limit of solubility
- Toxicity to microorganisms : EC50 (activated sludge): > 1,000 mg/l
Exposure time: 3 h
Analytical monitoring: no
Method: OECD Test Guideline 209
GLP: yes
- Toxicity to fish (Chronic toxicity) : Remarks: No data available
- Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : Remarks: No data available

Ecotoxicology Assessment

Chronic aquatic toxicity : Toxic to aquatic life with long lasting effects.

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) : 1

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

M-Factor (Chronic aquatic toxicity) : 1

reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1):

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): 0.19 mg/l
Exposure time: 96 h
GLP: yes

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 0.16 mg/l
Exposure time: 48 h

NOEC (Daphnia magna (Water flea)): 0.1 mg/l
Exposure time: 21 d

EC50 (Daphnia magna (Water flea)): 0.18 mg/l
Exposure time: 21 d

Toxicity to algae/aquatic plants : NOEC (Skeletonema costatum (marine diatom)): 0.00049 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 201

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NOEC (Skeletonema costatum (marine diatom)): 0.019 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

EC50 (Skeletonema costatum (marine diatom)): 0.037 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 201

M-Factor (Acute aquatic toxicity) : 100

Toxicity to microorganisms : NOEC (activated sludge): 0.91 mg/l
Exposure time: 3 h
Method: OECD Test Guideline 209
GLP: yes

EC50 (activated sludge): 4.5 mg/l
Exposure time: 3 h
Method: OECD Test Guideline 209
GLP: yes

Toxicity to fish (Chronic toxicity) : NOEC: 0.02 mg/l
Exposure time: 35 d
Species: Danio rerio (zebra fish)
Method: OECD Test Guideline 210
GLP: yes

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC: 0.1 mg/l
Exposure time: 21 d
Species: Daphnia magna (Water flea)

Chronic Toxicity Value: 0.18 mg/l
Exposure time: 21 d
Species: Daphnia magna (Water flea)

M-Factor (Chronic aquatic toxicity) : 100

titanium dioxide:

Toxicity to fish : LC50 (Carassius auratus (goldfish)): > 100 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 (Lemna minor (duckweed)): > 100 mg/l
Exposure time: 7 d

Toxicity to microorganisms : EC50 : >= 1,000 mg/l
Exposure time: 3 h

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Test Type: Respiration inhibition

12.2 Persistence and degradability

Components:

ethanediol:

Biodegradability : Result: Readily biodegradable.
Biodegradation: 90 - 100 %
Exposure time: 10 d
Method: OECD Test Guideline 301A

Humic acids, potassium salts:

Biodegradability : Result: Not biodegradable
Biodegradation: 1.6 %
Exposure time: 28 d
Method: Closed Bottle test

3-hydroxy-2'-methyl-2-naphthanilide:

Biodegradability : Test Type: aerobic
Inoculum: activated sludge
Concentration: 32.3 mg/l
Result: Not readily biodegradable.
Biodegradation: 12 %
Exposure time: 28 d
Method: OECD Test Guideline 301B
GLP: yes

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

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

reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1):

Biodegradability : Result: Readily biodegradable.

titanium dioxide:

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

12.3 Bioaccumulative potential

Components:

zinc oxide:

Bioaccumulation : Species: Oncorhynchus mykiss (rainbow trout)
Exposure time: 14 d

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Bioconcentration factor (BCF): 2,060

ethanediol:

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

Humic acids, potassium salts:

Partition coefficient: n-octanol/water : log Pow: -2.16 (20 °C)

3-hydroxy-2'-methyl-2-naphthanilide:

Partition coefficient: n-octanol/water : log Pow: 2.55 (23 °C)
pH: 7
Method: OECD Test Guideline 107

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: Substance is not persistent, bioaccumulative, and toxic (PBT).

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

log Pow: 0.99 (20 °C)
pH: 5

reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1):

Bioaccumulation : Exposure time: 28 d
Bioconcentration factor (BCF): < 54
Method: OECD Test Guideline 305

Partition coefficient: n-octanol/water : Pow: 0.75

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

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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.

12.6 Other adverse effects

Product:

Endocrine disrupting potential : This substance/mixture does not contain components considered to have endocrine disrupting properties for environment according to UK REACH Article 57(f).

Additional ecological information : An environmental hazard cannot be excluded in the event of unprofessional handling or disposal.
Toxic to aquatic life.
Very 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 : UN 3082
ADR : UN 3082
RID : UN 3082
IMDG : UN 3082
IATA : UN 3082

14.2 UN proper shipping name

ADN : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,

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	N.O.S. (Zinc oxide)
ADR	: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Zinc oxide)
RID	: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Zinc oxide)
IMDG	: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Zinc oxide)
IATA	: Environmentally hazardous substance, liquid, n.o.s. (Zinc oxide)

14.3 Transport hazard class(es)

	Class	Subsidiary risks
ADN	: 9	
ADR	: 9	
RID	: 9	
IMDG	: 9	
IATA	: 9	

14.4 Packing group

ADN	
Packing group	: III
Classification Code	: M6
Hazard Identification Number	: 90
Labels	: 9
ADR	
Packing group	: III
Classification Code	: M6
Hazard Identification Number	: 90
Labels	: 9
Tunnel restriction code	: (-)
RID	
Packing group	: III
Classification Code	: M6
Hazard Identification Number	: 90
Labels	: 9
IMDG	
Packing group	: III
Labels	: 9
EmS Code	: F-A, S-F
IATA (Cargo)	

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Packing instruction (cargo aircraft) : 964
Packing instruction (LQ) : Y964
Packing group : III
Labels : Miscellaneous

IATA (Passenger)

Packing instruction (passenger aircraft) : 964
Packing instruction (LQ) : Y964
Packing group : III
Labels : Miscellaneous

14.5 Environmental hazards

ADN

Environmentally hazardous : yes

ADR

Environmentally hazardous : yes

RID

Environmentally hazardous : yes

IMDG

Marine pollutant : yes

IATA (Passenger)

Environmentally hazardous : yes

IATA (Cargo)

Environmentally hazardous : yes

14.6 Special precautions for user

The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

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) (Poly(oxy-1,2-ethanediyl), alpha-sulfo-omega-[2,4,6-tris(1-
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phenylethyl)phenoxy]-, ammonium
salt (Number on list 3)
acetone (Number on list 3)
Alcohols, C9-11-iso-, C10-rich, eth-
oxylated (Number on list 3)
reaction mass of 5-chloro-2-methyl-
2H-isothiazol-3-one and 2-methyl-
2H-isothiazol-3-one (3:1) (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) on substances that deplete the ozone layer : Not applicable

UK REACH List of substances subject to authorisation (Annex XIV) : Not applicable

Control of Major Accident Hazards Regulations 2015 (COMAH) E1 ENVIRONMENTAL HAZARDS
E2
E1

Other regulations:

Take note of The Management of Health and Safety at Work Regulations 1999 (requirements relating to new and expectant mothers at work contained in Regulation 16 to 18) and of the Pregnant Workers Directive 92/85/EEC.

Take note of The Management of Health and Safety at Work Regulations 1999 (requirements relating to protection of young people at work contained in Regulation 19) and of Directive 94/33/EC on the protection of young people at work.

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
ENCS	: Not in compliance with the inventory
ISHL	: Not in compliance with the inventory

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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

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.
H330	: Fatal if inhaled.
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.
H412	: Harmful 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 Corr.	: Skin corrosion
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)

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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; TECI - 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

Further information

Classification of the mixture:

Aquatic Chronic 2 H411

Classification procedure:

Calculation method

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