



SDS COMPLETED 10TH FEBRUARY 2015
SUPERSEDES SDS: 9TH FEBRUARY 2011

VERSION: 02
REVISION NUMBER: 01

SAFETY DATA SHEET

1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1 Product Identifier:

BULLET Maxwell T.E. Complete

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

Use as a horticultural/amenity fertiliser

1.3 Details of the supplier of the safety data sheet:

Maxwell Amenity Ltd

Allscott Park, Allscott, Telford, TF6 5DY
Tel: 01952 897910
Fax: 01952 247369
Web: www.maxwellamenity.co.uk

Contact: The Safety Officer

1.4 Emergency phone number

Phone number: + 44 (0) 1743 860924

2. Hazards Identification

2.1 Classification of the substance or mixture

CLASSIFICATION according to Directive EC 1272/2008 Classification, Labelling and Packaging

Eye Dam. 1; H318 Causes serious eye damage.

Aquatic Chr. 2; H411 Toxic to aquatic life with long lasting effects

CLASSIFICATION according to Directive 1999/45/EC and statutory instrument No.716 2009 Chemicals (Hazard Information and Packaging) regulation)

Xi; R36 Irritant; Irritating to eyes.

N; R51/53 Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

Primary Hazard

Causes serious eye damage.

2.2 Label Elements

Maxwell T.E. Complete

(contains: Manganese sulphate E.C. 232-089-9)



Signal word: Danger

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Hazard Statements:

- H318 Causes serious eye damage.
- H411 Toxic to aquatic life with long lasting effects.

Precautionary Statements

- P280 Wear protective gloves/eye protection.
- P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove Contact lenses, if present and easy to do. Continue rinsing.
- P310 Immediately call a POISON Center or doctor/physician.
- P391 Collect spillage
- P501 Dispose of contents/container in accordance with local/national regulations.








2.3 Other Hazards











Mixture not classified as PBT or vPvB

3. COMPOSITION/INFORMATION ON INGREDIENTS

Product Code: HFL032A/B/D/E/F

3.2 Mixtures

Chemical Name	CAS-No./ EINECS-No.	Annex Index or REACH number	Symbol(s)	Phrase(s)	Concentrations [%]
Manganese sulphate	10034-96-5/ 232-089-9	Index no.: 025-003-00-4 REACH registration no.: 01-2119456624-35	According to 1272/2008: GHS05  GHS08  GHS09  According to 67/548/EEC:  Xn – HARMFUL  N – DANGEROUS FOR THE ENVIRONMENT	According to 1272/2008: Eye Damage 1, H318 STOT Rep. 2, H373 Aqu. Tox. chron. 2, H411 According to 67/548/EEC: R41 R48/20/22 R51/53	2.5 – 7.5
Disodium octaborate tetrahydrate	12280-03-4/ 234-541-0	REACH No: 01-2119490860-33	According to 1272/2008: GHS08  According to 67/548/EEC:  T – TOXIC	According to 1272/2008: Repr. 1B H360 According to 67/548/EEC: Repr. Cat. 2; R60 Repr. Cat. 2; R61	< 3.0

Zinc sulphate monohydrate	7446-20-0/ 231-793-3	Index number: 030-006-00-9 REACH registration number: 01-2119474684-27	<p>According to 1272/2008: GHS05 </p> <p>GHS07 </p> <p>GHS09 </p> <p>According to 67/548/EEC: </p> <p>Xn - HARMFUL</p> <p></p> <p>Xi - IRRITANT</p> <p></p> <p>N – DANGEROUS FOR THE ENVIRONMENT</p>	<p>According to 1272/2008: Acute Tox. 4 - H302 Eye Dam. 1 – H318 Aquatic acute 1 - H400 Aquatic chronic 1 - H410</p> <p>According to 67/548/EEC: R22, R41, R50/53</p>	< 2.0
Copper sulphate pentahydrate	7758-99-8/ 231-847-6	Index no.: 029-004-00-0 REACH Registration number: 01-2119520566-40	<p>According to 1272/2008: GHS07 </p> <p>GHS09 </p> <p>According to 67/548/EEC: </p> <p>Xn – HARMFUL</p> <p></p> <p>Xi - IRRITANT</p>	<p>According to 1272/2008: Acute Tox. 4 - H302 Skin Irrit. 2 -H315 Eye Irrit. 2 -H319 Environmental Aquatic Acute 1 – H400 Aquatic Chronic 1 - H410 M-factor: 10</p> <p>According to 67/548/EEC: R22, R36/38, R50/53</p>	<2.0

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			 N – DANGEROUS FOR THE ENVIRONMENT		
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The full hazard information for individual components if not displayed in section 2 or 3 is displayed in Section 16.

4. FIRST AID MEASURES

4.1 Description of first aid measures

4.1.1 Inhalation

If symptoms arise remove from source of exposure to fresh air; seek medical attention if symptoms persist or develop

4.1.2 Skin & Eye exposure

Skin: Drench immediately with water. Remove any contaminated clothing and launder before re-use. Obtain medical attention if symptoms persist or develop.

Eyes: Immediately rinse with clean water for 15 minutes. Obtain medical attention IMMEDIATELY

4.1.3 Ingestion

Do not induce vomiting. Wash out mouth with water and give water to drink. Obtain medical attention IMMEDIATELY.

4.2 Most important symptoms and effects, both acute and delayed

Causes serious eye damage.

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

Information not available

5. FIRE-FIGHTING MEASURES

5.1 Extinguishing media

Use foam, carbon dioxide, dry powder, sand. The mixture is not classified as flammable as such extinguishing media should also be chosen as appropriate for surrounding materials.

5.2 Special Hazards arising from the substance or mixture

Possible irritant fumes arising from combustion

5.3 Advice for fire-fighters

Cool down containers/equipment exposed to heat with a water spray. Contain spread of extinguishing fluids (these fluids may be hazardous for the environment). Wear complete protective clothing and self-contained breathing apparatus

6. ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

The following precautions are considered to be good practice when using any chemicals irrespective of their classification unless otherwise specified.

Ensure adequate ventilation

Use personal protective equipment,

- Gloves
- Eye protection
- Suitable respirator if dust is generated during handling

6.2 Environmental Precautions

Do not allow to enter storm drains or water courses. If this product enters a water course or a sewer (including via contaminated soil & vegetation) in large quantities contact local water authority and inform the Environment Agency

6.3 Methods and material for containment and cleaning up

Use soil, sand or other absorbent material. Contact specialist waste disposal contractor.

6.4 Reference to other sections

See also section 8

7. HANDLING AND STORAGE

7.1 Precaution for safe handling

Avoid contact with skin and eyes. Wash Hands thoroughly after handling
Do not eat, drink or smoke when using this product

7.2 Conditions for safe storage, including any incompatibilities

Store in a cool dry atmosphere, in original labelled containers. Refer to manufacturer for maximum safe stacking height.
Keep away from heat sources, combustible materials and strong oxidising agents.

7.3 Specific end use(s)

No Information available

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control Parameters

Workplace exposure Limits as defined by UK HSE in document EH40/2005 where available:

Substance	CAS number	Workplace Exposure Limit				Comments
		Long-term exposure limit (8-hr TWA reference period)		Short-term exposure limit (15 minute reference period)		
		ppm	mg.m ⁻³	ppm	mg.m ⁻³	
Manganese and its inorganic compounds (as Mn)	-	-	0.5	-	-	The Carc, Sen and Sk notations are not exhaustive. Notations have been applied to the substances identified in IOELV Directives*

*IOELV – Indicative Occupational Exposure Limit Values (IOELV).

Sk Can be absorbed through the skin. The assigned substances are those for which there are concerns that dermal absorption will lead to systemic toxicity.

Zinc sulphate:

DNEL

Industry	Inhalation	Long Term	Systemic Effects	1 mg/m ³
Industry	Dermal	Long Term	Systemic Effects	8.3 mg/Kg/day
Consumer	Oral	Long Term	Systemic Effects	0.83 mg/Kg/day
Professional	Inhalation	Long Term	Systemic Effects	1.3 mg/m ³
Consumer	Dermal	Long Term	Systemic Effects	8.3 mg/Kg/day

The units are expressed in 'mg/µg' of: Zinc.

PNEC

Freshwater	0.0206 mg/l
Marine water	0.0061 mg/l
Sediment (freshwater)	235.6* mg/Kg
Sediment (Marine water)	113* mg/Kg
Soil	106.8** mg/Kg
STP	0.0052*** mg/l

The units are expressed in 'mg/µg' of: Zinc. These PNECs are added value PNECs- they are to be added to the natural background levels of: Zinc. - in the appropriate compartments (e.g. soils, sediments).

(*) A generic bioavailability factor of 0.5 is applied by default, according to the EU risk assessment (ECB 2008).

(**) by default this value was multiplied by '3' to take into account "lab-to-field" differences in toxicity. (STP) The PNEC for STP was derived by applying an assessment factor to the lowest relevant toxicity value (5.2mg Zn/L). (Dutka et al., 1983)

Copper sulphate:

DNEL

Oral	Long Term	Systemic Effects	0.041 mg/kg/day
Oral	Short Term	Systemic Effects	0.082 mg/kg/day
Inhalation.	Long Term	Local Effects	(*)= 1 mg/m ³
Inhalation.	Long Term	Local Effects	(**)= 0.01 mg/m ³
Dermal	Long Term	Local Effects	(***)136.67 mg/kg/day

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Dermal	Long Term	Local Effects	(****)13.67 mg/kg/day
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(*)Dust. (**)Fume. (***)Powder. (****)Liquid.

Disodium octaborate tetrahydrate

DNEL – Workers:

Worker- DNELlong-term, inhalation, systemic = 6.92 mg/m³ or 1.45 mg B/m³

Worker- DNELlong-term, dermal, systemic = 22901 mg/day or 4800 mg B/day.

DNEL - General population:

DNELlong-term, oral, systemic = 0.81 mg/kg or 0.17 mg B/kg body weight/day.

DNELlong-term, inhalation, systemic = 3.48 mg/m³ or 0.73 mg B/m³.

DNELlong-term, dermal, systemic = 164 mg/kg body weight /day or 34.3 mg B/kg body weight /day.

DNELlong-term, oral, local = 12 mg/m³ or 2.52mg B/m³

PNEC:

PNECadd, water = 1.35 mg B/L (freshwater and marine water) and 9.1 mg B/L (water with intermittent releases).

PNECadd, sediment = 1.8 mg B/kg (dry sediment of freshwater and marine sediment).

PNECsoil = 5.4 mg B/kg soil body weight

PNEC STP(sewage treatment plant) = 1.75 mg B/L

8.2 Exposure controls

The following precautions are considered to be good practice when using any chemicals irrespective of their classification unless otherwise specified.

Primary Hazard considered as handling of concentrate.

Gloves: to BS EN374 of gauntlet type in Natural Rubber or PVC (not Nitrile) recommended for acid resistance. Clothing:

Coveralls/apron to BS EN465/466/467

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance; Red / Brown liquid

Odour; No Information available

Odour threshold; No Information available

pH; 5.0 – 7.0

Melting point/freezing; No Information available

Initial boiling point and boiling range; No Information available

Flash point; No Information available

Evaporation rate; No Information available

Flammability (solid, gas); Mixture is not classed as flammable

Upper /lower flammability or explosive limits; Mixture is not classed as explosive

Vapour Pressure; No Information available

Vapour density; No Information available

Specific Gravity; 1.20 – 1.25

Solubility (ies); No Information available

Partition coefficient: n-octanol/water; No Information available

Auto ignition temperature; No Information available

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Decomposition temperature: No Information available

9.2 Other Information

No other relevant information available

10. STABILITY AND REACTIVITY

10.1 Reactivity

Unknown

10.2 Chemical Stability

Stable under normal conditions

10.3 Possibility of hazardous reactions

Possibility of corrosive reaction with metals

10.4 Conditions to avoid

Extremes of temperature

10.5 Incompatible materials

Metals

10.6 Hazardous decomposition products

Possible Irritant fumes

11. TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

The mixture has not been assessed for toxicological effects, the mixture classification is given in section 2 based on individual component contents. Individual component hazards are given in section 3

Toxicological information on hazardous ingredients:

Manganese sulphate:

Acute toxicity:

- Oral: LD50 > 2000mg/kg

- Dermal: MnSO4 is unlikely to be absorbed through the skin.

- Inhalation: LC50 > 4.98 mg/L

Skin corrosion/irritation: Not irritating

Serious eye damage/irritation: Irreversible ocular damage (base on one rabbit only)

Respiratory or skin sensitisation : not sensitising

Germ cell mutagenicity: non - mutagenic

Carcinogenicity: insufficient evidence for classification

Reproductive toxicity: no effects

STOT-single exposure : insufficient evidence for classification

STOT-repeated exposure: STOT Rep 2 by inhalation exposure

Aspiration hazard: insufficient evidence for classification

Disodium octaborate tetrahydrate:

Oral acute toxicity:

Low acute oral toxicity;

Value used for CSA:

LD50 (male rat): 2000 mg/kg body weight (Test material: Diboron trioxide, OECD Guideline 401 (Acute Oral Toxicity))

LD50 (male albino rat): 3450 mg Boric acid/kg, equivalent to 604 mg B/kg body weight (Test material: Boric Acid).

LD50 (female albino rat): 4080 mg Boric acid/kg, equivalent to 714 mg B/kg body weight (Test material: Boric Acid).

Inhalation: Low acute inhalation toxicity.

LD50 (4h) (male/female rat), > 2.01 mg/L air (Test material: Disodium octaborate tetrahydrate, OECD Guideline 403 (Acute Inhalation Toxicity))

LC50 (5h) in rats ((male/female): > 2030 mg/m³ air (Test material: Boric acid).

Dermal:

LD50 (24h) (rabbit male/female): > 2000 mg/kg of body weight (Test material: Boric acid, according to FIFRA 40 CFR 163 and OECD Guideline 402 (Acute Dermal Toxicity)). No acute dermal toxicity and no clinical or pathological findings were observed. Disodium octaborate tetrahydrate is poorly absorbed through intact skin.

Skin/corrosion/irritation

In the acute dermal irritation studies on the rabbits, no irritancy was observed. (Test material: Disodium octaborate tetrahydrate, according to FIFRA (40 CFR 158, 162, 163) and Toxic Substances Control Act (40 CFR 798).

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Based on available data, the classification criteria as skin corrosion/irritant are not met.

Serious eye damage/irritation

The primary eye irritation of Disodium octaborate tetrahydrate was evaluated. The test material produced iris and conjunctival irritation, when applied with rinsing at 24h to the eyes of New Zealand white rabbits. Irritation scores in individual animals ranged from 0 to 19 (from a max of 110). No evidence of corrosion was noted. Guideline FIFRA (40 CFR, 162) and TSCA (40 CFR 798).

Years of occupational exposure to Disodium octaborate tetrahydrate indicates no adverse effects on human eye. Therefore is not considered to be a human eye irritant in normal industrial use.

Based on available data, the classification criteria as eye irritant are not met

Respiratory or skin sensitization

Disodium octaborate tetrahydrate was determined to be not sensitizing in guinea pigs according to OECD Guideline 406 (Skin Sensitization).

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

Germ cell mutagenicity:

The study on bacterial reverse mutation assay (e.g. Ames test) was made on *S. typhimurium* TA 1535, TA 1537, TA 98 and TA 100. No mutagenic activity was observed. (Test material: Boric Acid).

Based on available data, the classification criteria as mutagen are not met

Carcinogenicity:

The study according OECD Guideline 451 on B6C3F1 mice treated in diet for 103 weeks with 0, 2500 or 5000 ppm Boric acid showed no evidence of carcinogenicity.

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

Reproductive/toxicity:

Animal feeding studies in rat, mouse and dog at high doses, have demonstrated adverse haematological effects and the main target organ of boron toxicity is the testis. Studies in rat, mouse and rabbit, at high doses, demonstrate developmental effects on the fetus, including fetal weight loss and minor skeletal variations. The doses administered were many times higher than those to which humans would normally be exposed to.

A three generation study on rat Sprague-Dawley showed no adverse effects on reproduction and no gross abnormalities in the organs at exposures of 50 and 155 mg/kg body weight borax (corresponding to a level of 5.9 and 17.5 mg B/kg body weight).

Was reported no adverse effects on fertility, lactation, litter size, progeny weight or appearance in rats exposed to either 5.9 or 17.5 mg B/kg body weight.

NOAEL (No Observed Adverse Effect Level) for fertility (rat males) of 17.5 mg B/kg/day).

Rats exposed to the high dose of 518 mg/kg body weight of borax (corresponding to a level of 58.5 mg B/kg body weight) were sterile. Microscopic examination of the atrophied testes of all males in this group showed no viable sperm. It was also reported evidence of decreased ovulation in the majority of ovaries examined from the females exposed to 58.5 mg B/kg body weight and no litters were obtained from these high dose females when mated with control male animals.

LOAEL (Lowest Observed Adverse Effect Level) for fertility (rat female/male) of 58.5 mg B/kg body weight/day.

The high dose group (58.5 mg B/kg body weight) males and females showed clinical signs of toxicity with rough fur, scaly tails, respiratory distress and inflamed eyelids.

Based on these study data, was concluded that exposure of rats at levels up to 17.5 mg B/kg body weight in the diet in a 3 generation reproduction study was without adverse effect.

There is no evidence of developmental effects in humans attributable to boron in studies of populations with high exposures to boron.

Disodium octaborate tetrahydrate is self classified as Toxic for reproduction, Repro 1B, H360FD according to the new classification system from EC Regulation 1272/2008 (CLP)

Repeated Dose toxicity:

2-year dietary feeding study in Sprague Dawley rats (male/female), exposed at different values of Boric acid (0, 33 (5.9), 100 (17.5), 334 (58.5) mg Boric acid (B)/kg body weight per day), showed effects as: coarse hair coats, hunched position, swollen pads and inflamed bleeding eyes, testicular atrophy and seminiferous tubule degeneration were observed in animals receiving the highest dose of Boric acid.

NOAEL 17.5 mg Boron/kg body weight/day

LOAEL 58.5 mg Boron/kg body weight/day

No treatment related effects were observed in the mid and low dose groups.

Zinc sulphate:

Acute toxicity:

Acute Toxicity (Oral LD50)

> 574 mg/kg Rat

Very soluble zinc sulphate (monohydrate, hexahydrate and heptahydrate) has LD50 oral values ranging from 574 to 2, 949 mg/kg bw, 862

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to 4, 429 mg/kg bw and 920 to 4, 725 mg/kg bw, respectively for the three forms of zinc sulphate. Tests conducted to standard protocols Litton (Bionetics, 1974, Courtois et al., 1978.)

Acute Toxicity (Dermal LD50) > 2000 mg/kg Rat

Test method(s): OECD 402. (Van Huygevoort 1999)

Acute Toxicity (Inhalation LC50)

Rat 4 hours

Effects of inhalation exposure to zinc sulphate were limited to pulmonary effects only.

Skin Corrosion/Irritation:

Dose Rabbit

Primary dermal irritation index (PDI) 0

Erythema/eschar score

No erythema (0).

Oedema score

No oedema (0).

Not classified. Test method(s): OECD 404. (Van Huygevoort 1999)

Not irritating.

Serious eye damage/irritation:

Irritating. Test method(s): OECD 405. (Van Huygevoort 1999)

Respiratory or skin sensitisation:

Skin sensitisation

Patch Test: Mouse

(Van Huygevoort, 1999 i, Ikarashi et al, 1992)

Not Sensitising.

Germ cell mutagenicity:

Genotoxicity - In Vitro

Gene Mutation:

In vitro genotoxicity studies indicate that zinc compounds do not have genotoxic activity [Zinc CSR(s), 2010]. This conclusion is in line with those achieved by other regulatory reviews of the genotoxicity of zinc compounds (WHO, 2001; EU RAR, 2004, MAK, 2009).

Negative.

Genotoxicity - In Vivo

Chromosome aberration:

In vivo genotoxicity studies indicate that zinc compounds do not have genotoxic activity [Zinc CSR(s), 2010]. This conclusion is in line with those achieved by other regulatory reviews of the genotoxicity of zinc compounds (WHO, 2001; EU RAR, 2004, MAK, 2009).

Negative.

Carcinogenicity:

Carcinogenicity

No experimental or epidemiological evidence exists to justify classification of zinc compounds for carcinogenic activity (based on cross-reading between Zn compounds; no classification for carcinogenicity required) (Chemical Safety report (CSR) zinc oxide. 2010).

Reproductive Toxicity:

Reproductive Toxicity - Fertility -

No experimental or epidemiological evidence exists to justify classification of zinc compounds for reproductive or developmental toxicity (based on cross-reading between Zn compounds; no classification for reproductive toxicity required) (Chemical Safety Report (CSR) for zinc compounds. 2010)

Specific target organ toxicity - single exposure:

STOT - Single exposure -

No experimental or epidemiological sufficient evidence for specific target organ toxicity (single exposure) (based on cross-reading from ZnO; no classification for target organ toxicity (single exposure: STOT-SE) required) (Heydon and Kagan, 1990; Gordon et al., 1992; Mueller and Seger, 1985 [Cited in Chemical Safety report (CSR) zinc sulphate. 2010]).

Specific target organ toxicity - repeated exposure:

STOT - Repeated exposure -

No experimental or epidemiological sufficient evidence for specific target organ toxicity (repeated exposure) (no classification for specific target organ toxicity (repeated exposure: STOT-RE) required) (Lam et al, 1985, 1988; Conner et al. , 1988 [Cited in Chemical Safety Report (CSR) for zinc(s). 2010]).

Aspiration hazard:

Viscosity

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No data available.

Health Warnings

INHALATION. Prolonged inhalation of high concentrations may damage respiratory system. SKIN CONTACT. Acts as a defatting agent on skin. May cause cracking of skin, and eczema. Prolonged or repeated exposure may cause severe irritation. EYE CONTACT. May cause severe irritation to eyes. INGESTION. The product causes irritation of mucous membranes and may cause abdominal discomfort if swallowed.

Target Organs

Skin Eyes Respiratory system, lungs

Copper sulphate pentahydrate

Toxicological information

Copper is an essential element and therefore, its concentration in the body is strictly and efficiently regulated by homeostatic mechanisms.

Inhalation: The “respirable” fraction is assumed to be 100% absorbed. Absorption of the “inhalable” fraction depends on particle size. The Multiple Path Model of Particle Deposition (MPPD) can quantify the particle dependent absorption.

Oral: An oral absorption of 25% has been adopted, based on studies in the rat.

Dermal: A dermal absorption of 0.3% has been adopted for soluble and insoluble copper substances in solution or suspension, based on in- vitro percutaneous tests with human skin. For dry exposure, a dermal absorption value of 0.03% applies.

Acute toxicity:

Acute Toxicity (Oral LD50) ~ 480 mg/kg Rat

Test method(s): OECD 401.

Harmful if swallowed.

Acute Toxicity (Dermal LD50) > 2000 mg/kg Rat

Not classified. Test method(s): OECD 402.

Based on available data the classification criteria are not met.

Acute Toxicity (Inhalation LC50)

Not determined.

Inhalation is not considered to be a likely route of exposure based on the physical properties of the substance.

Based on available data the classification criteria are not met.

Skin Corrosion/Irritation:

Dose: 0.5 g 4 hr Rabbit

Erythema\eschar score average < (1)

Oedema score: No oedema (0).

Test method(s): OECD 404. This OECD study concluded that there should be no classification - this result is less severe than the harmonized classification as a Category II skin irritant set out in Annex VI of Regulation 1272/2008.

Not irritating.

Serious eye damage/irritation:

A test carried out in 3 male rabbits resulted in severe ocular irritation that was not reversible within the duration of the test.

Test guideline OECD 405.

Copper sulphate pentahydrate meets the criteria for causing serious eye damage. This is more severe than the harmonized classification as an eye irritant set out in Annex VI of Regulation EC 1272/2008.

Respiratory or skin sensitisation:

Skin sensitisation

Guinea pig maximization test (GPMT): Test method(s): OECD 406.

Not Sensitising.

Germ cell mutagenicity:

Genotoxicity - In Vitro

Gene Mutation: Test method(s): OECD 471.

Negative.

Genotoxicity - In Vivo

DNA damage and/or repair:

Test method(s): OECD 486. A mouse micronucleus test (EC method B.12) also gave negative results.

Negative.

Carcinogenicity:

Carcinogenicity - Based on a weight of evidence approach, it was concluded that copper compounds do not have carcinogenic potential. Test method(s):

Journal of the American Pharmaceutical Association, 43(12): 722-737,

Br. J. Cancer Sep; 23(3): 591-596,

Fd Cosmet. Toxicol. 11: 827-840.

Not Classified

Reproductive Toxicity:

Reproductive Toxicity - Fertility

Two-generation study: LOAEL 23.5 mg/kg Oral Rat F2a

The units are expressed in 'mg/µg' of: Copper. Not classified. Test method(s): OECD 416.

Reproductive Toxicity - Development

Teratogenicity: LOAEL 9 mg/kg Oral Rabbit

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Not classified. Test method(s): OECD 414.

Specific target organ toxicity - single exposure:

STOT - Single exposure

Scientifically unjustified.

Already classified for Acute Oral Toxicity.

Specific target organ toxicity - repeated exposure:

STOT - Repeated exposure –

A 90-day oral repeat dose study conducted with copper sulphate pentahydrate in rats and mice (test method equivalent to EU B.26) gave the following results:

For stomach lesions:

NOAEL in the rat: 16.7 mg Cu/kg bw/day

NOAEL in male mice 97 mg Cu/kg bw/day

NOAEL in female mice: 126 mg Cu/kg bw/day

Liver and kidney damage:

NOAEL in the rat: 16.7 mg Cu/kg bw/day

This study was used to calculate of an oral and systemic DNEL of 0.041 mg Cu/kg bw/day (including a Safety factor of 100 and an oral absorption of 25%).

[This product does not meet the criteria for classification.]

Not classified.

Aspiration hazard:

Viscosity

No data available.

Inhalation

Prolonged inhalation of high concentrations may damage respiratory system.

Ingestion

May irritate and cause stomach pain, vomiting and diarrhoea.

Skin contact

Acts as a defatting agent on skin. May cause cracking of skin, and eczema. Prolonged or repeated exposure may cause severe irritation.

Eye contact

Causes serious eye damage.

Health Warnings

The product causes irritation of mucous membranes and may cause abdominal discomfort if swallowed.

Target Organs: Skin Eyes Respiratory system, lungs.

12. ECOLOGICAL INFORMATION

12.1 Toxicity

Mixture Classified as Toxic to aquatic life with long lasting effects to the environment in accordance with the Dangerous Preparations Directive 1999/45/EC

Toxicity of ingredients where available:

Manganese sulphate:

Fish short-term toxicity (Oncorhynchus mykiss): LC50 (96h):14.5 mg/l Mn (Freshwater)

Fish long-term toxicity (Oncorhynchus mykiss): NOEC(4month): 0.6 mg/L Mn (Freshwater)

Aquatic invertebrates short-term toxicity (Daphnia): LC50 (48h): 9.8 mg/L as Mn²⁺

Aquatic invertebrates long-term toxicity (Daphnia): LC50 (3weeks): 5700µg/L as Mn²⁺

Copper sulphate:

Acute toxicity of copper ions was assessed using 451 L(E)C50 values from studies on soluble copper compounds. The lowest

species-specific geometric mean reference value of 25.0 µg Cu/L was an L(E)C50 obtained for Daphnia magna at pH 5.5 - 6.5.

CHRONIC FRESHWATER TOXICITY- test results and PNEC derivation:

Chronic toxicity of copper ions from soluble copper compounds was assessed using 139 NOEC/EC10 values from 27 species representing different trophic levels (fish, invertebrates and algae). Species-specific NOECs were normalised using Biotic Ligand Models and used to derive Species Sensitivity Distributions (SSD) and a lowest HC5 (the median fifth percentile of the SSD) of 7.8 µg dissolved Cu/L. This value is considered to be protective of 90% of EU surface waters and represents a reasonable worst case. Applying an assessment factor of 1, a default chronic freshwater PNEC of 7.8 µg dissolved Cu/L is assigned to assess local risks.

CHRONIC MARINE WATERS TOXICITY- test results and PNEC derivation:

Chronic toxicity of copper ions from soluble copper compounds was assessed using 51 NOEC/EC10 values from 24 species representing different trophic levels (fish, invertebrates and algae). Species-specific NOECs were calculated after normalizing to dissolved organic carbon (DOC) and were used to derive SSDs and HC5 values. Normalisation at a typical DOC for coastal waters of 2 mg/l resulted in an HC5 of 5.2 µg dissolved Cu/L. Applying an assessment factor of 1, a default chronic marine PNEC of 5.2 µg dissolved Cu/L is assigned to assess local risks.

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CHRONIC FRESHWATER SEDIMENT TOXICITY- test results and PNEC derivation:

Toxicity of copper ions from soluble copper compounds was assessed using 62 NOEC values from 6 benthic species. The NOECs were related to DOC and Acid Volatile Sulphide (AVS) and were used to derive SSDs and HC5 values. An HC5 of 1741 mg Cu/kg OC, corresponding to 87 mg Cu/kg dry weight, was calculated for a low AVS sediment with a default OC of 5%. Applying an assessment factor of 1, a default chronic freshwater sediment PNEC of 87 mg Cu/kg dry weight is assigned to assess local risks.

CHRONIC TERRESTRIAL TOXICITY- test results and PNEC derivation:

Toxicity of copper ions from soluble copper compounds was assessed using 252 NOEC/EC10 values from 28 different species representing different trophic levels (decomposers, primary producers, primary consumers). NOEC values were adjusted to account for differences between lab-spiked soils and field-contaminated soils by the addition of a leaching ageing factor of 2. The adjusted values were then normalized to a range of EU soils using regression bioavailability models and used to derive SSDs and a lowest HC5 value of 65.5 mg Cu/kg dry weight. Applying an assessment factor of 1, a default chronic soil PNEC of 65.5 mg Cu/kg dry weight is assigned.

TOXICITY TO SEWAGE TREATMENT PLANT (STP) MICRO-ORGANISMS

The toxicity of copper ions from soluble copper compounds was assessed using NOEC and EC50 values from high quality studies with STP bacteria and protozoa. The statistically-derived NOEC was 0.23 mg Cu/L in the STP. Applying an assessment factor of 1, a PNEC of 0.23 mg Cu/L is assigned for Sewage Treatment Plant.

Zinc sulphate:

The reference values for acute aquatic toxicity, based on the lowest observed EC50 values of the corresponding databases at different pH and expressed as Zn⁺⁺ ion concentration are:

- for pH <7: 0.413 mg Zn⁺⁺/l (48 hr - Ceriodaphnia dubia test according to US EPA 821-R-02-012 standard test protocol; reference: Hyne et al 2005)
- for pH >7-8.5: 0.136 mg Zn⁺⁺/l (72 hr - Selenastrum capricornutum (=Pseudokirchneriella subcapitata) test according to OECD 201 standard protocol; reference: Van Ginneken, 1994)

After applying the molecular weight correction (transformation/dissolution testing is not relevant since this zinc compound is readily soluble), the specific reference values for acute aquatic toxicity of the different zinc sulphates are:

For zinc monohydrate (a ZnSO₄.H₂O/Zn molecular weight ratio of 2.74):

- for pH <7: 1.13 mg Zn/l (based on 48 hr Ceriodaphnia dubia test cfr above)
- for pH >7-8.5: 3.73 mg Zn/l (based on 72 hr Selenastrum capricornutum test cfr above)

For zinc hexahydrate (a ZnSO₄.6H₂O/Zn molecular weight ratio of 4.12):

- for pH <7: 1.70 mg Zn/l (based on 48 hr Ceriodaphnia dubia test cfr above)
- for pH >7-8.5: 0.56 mg Zn/l (based on 72 hr Selenastrum capricornutum test cfr above)

For zinc heptahydrate (a ZnSO₄.7H₂O/Zn molecular weight ratio of 4.4):

- for pH <7: 1.82 mg Zn/l (based on 48 hr Ceriodaphnia dubia test cfr above)
- for pH >7-8.5: 0.60 mg Zn/l (based on 72 hr Selenastrum capricornutum test cfr above)

M-factor: 1

CHRONIC AQUATIC TOXICITY:

The chronic freshwater aquatic toxicity database on zinc contains high quality chronic NOEC/EC10 values on 23 species (8 taxonomic groups) obtained under a variety of conditions.

The chronic marine-water aquatic toxicity database on zinc contains high quality chronic NOEC/EC10 values on 39 species (9 taxonomic groups) obtained under a variety of conditions.

These data, outlined in the CSR, were compiled in a species sensitivity distribution, from which the PNECs for freshwater and marine-water were derived (expressed as Zn⁺²ion concentration).

12.2 Persistence and degradability

Information not available

12.3 Bioaccumulative potential

Information not available

12.4 Mobility in soil

Information not available

12.5 Results of PBT and vPvB

Not classified

12.6 Other adverse effects

Information not available

13.1 Waste Treatment Methods

Use only licensed waste disposal companies for unwanted chemical. Do not re-use empty containers for any purpose.

14. TRANSPORT INFORMATION

14.1 UN number: UN3077

14.2 UN proper shipping name: Environmentally hazardous substance, liquid N.O.S. (contains: Manganese sulphate E.C. 232-089-9)

14.3 Transport hazard: 9

14.4 Packing group: III

14.5 Environmental hazards: Product is classified as toxic to aquatic life with long lasting effects.

14.6 Special precautions for user: Not specified

14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC code

Applicable for Maritime bulk transport only. Check with carrier.

15. REGULATORY INFORMATION

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

This substance is classified and labelled in accordance with regulation 1999/45/EC, 1272/2008, the statutory instrument No.716 2009 Chemicals (Hazard Information and Packaging) regulations and the EC Fertiliser Regulations 2003, Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC, including amendments. Regulation (EC)

15.2 Chemical Safety Assessment

CSA not undertaken for this substance

16. OTHER INFORMATION

Hazard Information assigned to individual ingredients, but not carried to final classification:

R22:	Harmful if swallowed.
R36/38:	Irritating to eyes and skin
R41:	Risk of serious damage to eyes.
R48/20/22:	Harmful: danger of serious damage to health by prolonged exposure through inhalation and if swallowed
R50/53:	Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
R60:	May impair fertility
R61:	May cause harm to the unborn child
H302:	Harmful if swallowed.
H315:	Causes skin irritation.
H319:	Causes serious eye irritation.
H360FD:	May damage fertility. May damage the unborn child.
H373:	May cause damage to organs through prolonged or repeated exposure.
H400:	Toxic to aquatic life.
H410:	Very toxic to aquatic life with long lasting effects.

SDS information:

This Safety data sheet is compiled using data submitted for raw materials and practical experience. This product is intended for professional users only.

This Safety Data Sheet is prepared in compliance with Directive 1999/45/EC, regulation 1272/2008 and Annex I of the REACH regulation 453/2010.

THE INFORMATION GIVEN HEREIN IS, TO THE BEST OF OUR KNOWLEDGE, CORRECT AND IS PRESENTED IN GOOD FAITH BUT NO WARRANTY, EXPRESSED OR IMPLIED IS GIVEN.

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