

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by
Commission Regulation (EU) 2020/878



Zeranol Formulation

Version
8.1

Revision Date:
14.04.2025

SDS Number:
691069-00021

Date of last issue: 03.12.2024
Date of first issue: 19.05.2016

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

1.1 Product identifier

Trade name : Zeranol Formulation

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

Use of the Substance/Mixture : Veterinary product

Recommended restrictions on use : Not applicable

1.3 Details of the supplier of the safety data sheet

Company : MSD
Drynam Road
K67 P263 Dublin, Ireland

Telephone : +1-908-740-4000

E-mail address of person responsible for the SDS : EHSDATASTEWARD@msd.com

1.4 Emergency telephone number

+1-908-423-6000

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008)

Carcinogenicity, Category 2	H351: Suspected of causing cancer.
Reproductive toxicity, Category 1B	H360FD: May damage fertility. May damage the unborn child.
Specific target organ toxicity - repeated exposure, Category 1	H372: Causes damage to organs through prolonged or repeated exposure.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

Hazard pictograms :



Signal word : Danger

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Hazard statements	:	H351 H360FD H372	Suspected of causing cancer. May damage fertility. May damage the unborn child. Causes damage to organs through prolonged or repeated exposure.
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Precautionary statements	:	Prevention: P201 P260 P264 P270 P280	Obtain special instructions before use. Do not breathe dust. Wash skin thoroughly after handling. Do not eat, drink or smoke when using this product. Wear protective gloves/ protective clothing/ eye protection/ face protection.
Response: P308 + P313 IF exposed or concerned: Get medical advice/ attention.			

Hazardous components which must be listed on the label:

zeranol
Boric acid

Additional Labelling

Restricted to professional users.

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.

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

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

Dust contact with the eyes can lead to mechanical irritation.
Contact with dust can cause mechanical irritation or drying of the skin.
May form combustible dust concentrations in air.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Components

Chemical name	CAS-No. EC-No. Index-No.	Classification	Concentration (% w/w)

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	Registration number		
zeranol	26538-44-3 247-769-0	Carc. 2; H351 Repr. 1B; H360FD STOT RE 1; H372 (Endocrine system, Liver)	>= 70 - < 90
Boric acid	10043-35-3 233-139-2 005-007-00-2 01-2119486683-25	Repr. 1B; H360FD	>= 10 - < 20

For explanation of abbreviations see section 16.

SECTION 4: First aid measures

4.1 Description of first aid measures

- General advice : In the case of accident or if you feel unwell, seek medical advice immediately.
When symptoms persist or in all cases of doubt seek medical advice.
- Protection of first-aiders : First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).
- If inhaled : If inhaled, remove to fresh air.
Get medical attention.
- In case of skin contact : In case of contact, immediately flush skin with soap and plenty of water.
Remove contaminated clothing and shoes.
Get medical attention.
Wash clothing before reuse.
Thoroughly clean shoes before reuse.
- In case of eye contact : If in eyes, rinse well with water.
Get medical attention if irritation develops and persists.
- If swallowed : If swallowed, DO NOT induce vomiting.
Get medical attention.
Rinse mouth thoroughly with water.

4.2 Most important symptoms and effects, both acute and delayed

- Risks : Contact with dust can cause mechanical irritation or drying of the skin.
Dust contact with the eyes can lead to mechanical irritation.

Suspected of causing cancer.
May damage fertility. May damage the unborn child.
Causes damage to organs through prolonged or repeated exposure.

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4.3 Indication of any immediate medical attention and special treatment needed

Treatment : Treat symptomatically and supportively.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media : Water spray
Alcohol-resistant foam
Carbon dioxide (CO₂)
Dry chemical

Unsuitable extinguishing media : High volume water jet

5.2 Special hazards arising from the substance or mixture

Specific hazards during fire-fighting : Avoid generating dust; fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard.
Do not use a solid water stream as it may scatter and spread fire.
Exposure to combustion products may be a hazard to health.

Hazardous combustion products : Carbon oxides
Boron oxides
Metal oxides

5.3 Advice for firefighters

Special protective equipment for firefighters : In the event of fire, wear self-contained breathing apparatus.
Use personal protective equipment.

Specific extinguishing methods : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Use water spray to cool unopened containers.
Remove undamaged containers from fire area if it is safe to do so.
Evacuate area.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions : Use personal protective equipment.
Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

6.2 Environmental precautions

Environmental precautions : Avoid release to the environment.
Prevent further leakage or spillage if safe to do so.

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Retain and dispose of contaminated wash water.
Local authorities should be advised if significant spillages cannot be contained.

6.3 Methods and material for containment and cleaning up

- Methods for cleaning up : Sweep up or vacuum up spillage and collect in suitable container for disposal.
Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air).
Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration.
Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable.
Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

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

- Technical measures : Static electricity may accumulate and ignite suspended dust causing an explosion.
Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.
- Local/Total ventilation : If sufficient ventilation is unavailable, use with local exhaust ventilation.
- Advice on safe handling : Do not get on skin or clothing.
Do not breathe dust.
Do not swallow.
Avoid contact with eyes.
Wash skin thoroughly after handling.
Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment
Keep container tightly closed.
Minimize dust generation and accumulation.
Keep container closed when not in use.
Keep away from heat and sources of ignition.
Take precautionary measures against static discharges.
Do not eat, drink or smoke when using this product.
Take care to prevent spills, waste and minimize release to the environment.
- Hygiene measures : If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. Wash contaminated clothing before re-use.

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The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

7.2 Conditions for safe storage, including any incompatibilities

- | | |
|---|--|
| Requirements for storage areas and containers | : Keep in properly labelled containers. Store locked up. Keep tightly closed. Store in accordance with the particular national regulations. |
| Advice on common storage | : Do not store with the following product types:
Strong oxidizing agents
Self-reactive substances and mixtures
Organic peroxides
Explosives
Gases |

7.3 Specific end use(s)

- | | |
|-----------------|---------------------|
| Specific use(s) | : No data available |
|-----------------|---------------------|

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational Exposure Limits

dusts non-specific	4 mg/m ³	Value type (Form of exposure): OELV - 8 hrs (TWA) (Respirable dust)
		Basis: IE OEL

10 mg/m ³	Value type (Form of exposure): OELV - 8 hrs (TWA) (inhalable dust)
	Basis: IE OEL

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
zeranol	26538-44-3	TWA	2 µg/m ³ (OEB 4)	Internal
		Wipe limit	20 µg/100 cm ²	Internal
Boric acid	10043-35-3	OELV - 8 hrs (TWA)	2 mg/m ³	IE OEL
	Further information: Repr 1B - Substances which are presumed human reproductive toxicants			
Magnesium stearate	557-04-0	OELV - 8 hrs (TWA)	10 mg/m ³	IE OEL

Derived No Effect Level (DNEL) according to Regulation (EC) No. 1907/2006

Substance name	End Use	Exposure routes	Potential health effects	Value

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Boric acid	Workers	Skin contact	Long-term systemic effects	392 mg/kg bw/day
	Workers	Inhalation	Long-term systemic effects	8.3 mg/m3
	Consumers	Ingestion	Acute systemic effects	0.98 mg/kg bw/day
	Consumers	Ingestion	Long-term systemic effects	0.98 mg/kg bw/day
	Consumers	Inhalation	Long-term systemic effects	4.15 mg/m3
	Consumers	Skin contact	Long-term systemic effects	196 mg/kg bw/day

Predicted No Effect Concentration (PNEC) according to Regulation (EC) No. 1907/2006

Substance name	Environmental Compartment	Value
Boric acid	Fresh water	2.9 mg/l
	Intermittent use/release	13.7 mg/l
	Marine water	2.9 mg/l
	Sewage treatment plant	10 mg/l
	Soil	5.7 mg/kg dry weight (d.w.)

8.2 Exposure controls

Engineering measures

The information below is intended for larger pilot/commercial-scale operations and manufacturing. For smaller scale, clinical, or pharmacy settings, site-specific internal risk assessment practices should be conducted to determine appropriate exposure control measures. The health hazard risks of handling this material are dependent on multiple factors, including but not limited to physical form and quantity handled. If applicable, use process enclosures, local exhaust ventilation (e.g., Biosafety Cabinet, Ventilated Balance Enclosures), or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels as low as reasonably achievable.

Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of the compound to uncontrolled areas (e.g., vacuum conveying from a closed system, packout head with inflatable seal from stationary container, ventilated enclosure, etc.).

All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.

Essentially no open handling permitted.

Use closed processing systems or containment technologies.

Personal protective equipment

Eye/face protection : Wear safety glasses with side shields or goggles. If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles. Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.

Hand protection

Material : Chemical-resistant gloves

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Remarks	:	Consider double gloving.
Skin and body protection	:	Work uniform or laboratory coat. Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces. Use appropriate degowning techniques to remove potentially contaminated clothing.
Respiratory protection	:	If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection. Equipment should conform to I.S. EN 143
Filter type	:	Particulates type (P)

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Physical state	:	powder
Colour	:	yellow
Odour	:	odourless
Odour Threshold	:	No data available
Melting point/freezing point	:	No data available
Initial boiling point and boiling range	:	No data available
Flammability (solid, gas)	:	May form combustible dust concentrations in air.
Flammability (liquids)	:	No data available
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Flash point	:	Not applicable
Auto-ignition temperature	:	No data available
Decomposition temperature	:	No data available
pH	:	No data available
Viscosity		
Viscosity, kinematic	:	No data available

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Solubility(ies)	
Water solubility	: insoluble
Partition coefficient: n-octanol/water	: No data available
Vapour pressure	: No data available
Relative density	: No data available
Density	: No data available
Relative vapour density	: No data available
Particle characteristics	
Particle size	: No data available

9.2 Other information

Explosives	: Not explosive
Oxidizing properties	: The substance or mixture is not classified as oxidizing.
Dust deflagration index (Kst)	: 180 m.b./s
Evaporation rate	: No data available
Minimum ignition energy	: 5 - 10 mJ
Molecular weight	: No data available

SECTION 10: Stability and reactivity

10.1 Reactivity

Not classified as a reactivity hazard.

10.2 Chemical stability

Stable under normal conditions.

10.3 Possibility of hazardous reactions

Hazardous reactions : May form combustible dust concentrations in air.
Can react with strong oxidizing agents.

10.4 Conditions to avoid

Conditions to avoid : Heat, flames and sparks.
Avoid dust formation.

10.5 Incompatible materials

Materials to avoid : Oxidizing agents

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10.6 Hazardous decomposition products

No hazardous decomposition products are known.

SECTION 11: Toxicological information

11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

Information on likely routes of exposure : Inhalation
Skin contact
Ingestion
Eye contact

Acute toxicity

Not classified based on available information.

Components:

zeranol:

Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg
Acute inhalation toxicity : Remarks: No data available
Acute dermal toxicity : Remarks: No data available

Boric acid:

Acute oral toxicity : LD50 (Rat): 3,450 mg/kg
Acute inhalation toxicity : LC50 (Rat): > 2.03 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
Acute dermal toxicity : LD50 (Rabbit): > 2,000 mg/kg
Assessment: The substance or mixture has no acute dermal toxicity

Skin corrosion/irritation

Not classified based on available information.

Components:

zeranol:

Remarks : No data available

Boric acid:

Species : Rabbit
Result : No skin irritation

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Serious eye damage/eye irritation

Not classified based on available information.

Components:

zeranol:

Remarks : No data available

Boric acid:

Species : Rabbit
Result : No eye irritation

Respiratory or skin sensitisation

Skin sensitisation

Not classified based on available information.

Respiratory sensitisation

Not classified based on available information.

Components:

zeranol:

Remarks : No data available

Boric acid:

Test Type : Buehler Test
Exposure routes : Skin contact
Species : Guinea pig
Method : OECD Test Guideline 406
Result : negative

Germ cell mutagenicity

Not classified based on available information.

Components:

zeranol:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)
Result: negative

Test Type: DNA damage and repair, unscheduled DNA synthesis in mammalian cells (in vitro)
Test system: rat hepatocytes
Result: negative

Genotoxicity in vivo : Test Type: Cytogenetic assay
Species: Mouse
Cell type: Bone marrow
Result: negative

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Boric acid:

Genotoxicity in vitro	: Test Type: Bacterial reverse mutation assay (AMES) Result: negative
	Test Type: In vitro mammalian cell gene mutation test Result: equivocal
	Test Type: Chromosome aberration test in vitro Result: negative
Genotoxicity in vivo	: Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay) Species: Mouse Application Route: Ingestion Result: negative

Carcinogenicity

Suspected of causing cancer.

Components:

zeranol:

Species	:	Mouse
Application Route	:	Oral
Exposure time	:	2 Years
Result	:	positive
Target Organs	:	female reproductive organs, Pituitary gland

Species	:	Rat
Application Route	:	Oral
Exposure time	:	2 Years
Result	:	negative

Species	:	Dog
Application Route	:	Oral
Exposure time	:	2 Years
Result	:	negative

Carcinogenicity - Assessment	:	Limited evidence of carcinogenicity in animal studies
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Boric acid:

Species	:	Mouse
Application Route	:	Ingestion
Exposure time	:	103 weeks
Result	:	negative

Reproductive toxicity

May damage fertility. May damage the unborn child.

Components:

zeranol:

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Effects on fertility : Test Type: Three-generation reproduction toxicity study
Species: Rat
Application Route: Oral
Result: No significant adverse effects were reported

Test Type: Two-generation reproduction toxicity study
Species: Rat
Application Route: Oral
General Toxicity F1: LOAEL: 3 mg/kg body weight
Symptoms: Reduced body weight
Result: Effects on reproduction parameters

Test Type: Fertility
Species: Rat, males
Application Route: Oral
Fertility: LOAEL: 1.25 mg/kg body weight
Symptoms: Reduced fertility

Effects on foetal development : Test Type: Embryo-foetal development
Species: Rat
Application Route: Oral
Developmental Toxicity: LOAEL: 2 mg/kg body weight
Symptoms: Reduced number of viable fetuses
Result: Embryolethal effects, No teratogenic effects

Test Type: Embryo-foetal development
Species: Rabbit
Application Route: Oral
Developmental Toxicity: NOAEL: \geq 5 mg/kg body weight
Result: No significant adverse effects were reported

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

Boric acid:

Effects on fertility : Test Type: Three-generation reproduction toxicity study
Species: Rat
Application Route: Ingestion
Result: positive

Effects on foetal development : Test Type: Embryo-foetal development
Species: Rabbit
Application Route: Ingestion
Result: positive

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

STOT - single exposure

Not classified based on available information.

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STOT - repeated exposure

Causes damage to organs through prolonged or repeated exposure.

Components:

zeranol:

Target Organs : Endocrine system, Liver
Assessment : Causes damage to organs through prolonged or repeated exposure.

Repeated dose toxicity

Components:

zeranol:

Species	:	Rat
NOAEL	:	0.175 mg/kg
LOAEL	:	1.225 mg/kg
Application Route	:	Oral
Exposure time	:	13 Weeks
Target Organs	:	Liver

Species	:	Dog
NOAEL	:	0.25 mg/kg
LOAEL	:	1.25 mg/kg
Application Route	:	Oral
Exposure time	:	14 Weeks
Target Organs	:	male reproductive organs

Species	:	Rat
NOAEL	:	0.1 mg/kg
LOAEL	:	0.8 mg/kg
Application Route	:	Oral
Exposure time	:	26 Weeks
Symptoms	:	Liver disorders

Species	:	Dog
NOAEL	:	0.025 mg/kg
LOAEL	:	2.5 mg/kg
Application Route	:	Oral
Exposure time	:	29 Weeks
Target Organs	:	Reproductive organs, Bone marrow, Bladder
Symptoms	:	hair loss

Species	:	Dog, female
LOAEL	:	15 mg/kg
Application Route	:	Oral
Exposure time	:	7 yr
Target Organs	:	female reproductive organs
Symptoms	:	Changes in the blood count

Species	:	Monkey, female
Application Route	:	Oral

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Exposure time : 10 yr
Target Organs : female reproductive organs

Boric acid:

Species : Rat
NOAEL : 100 mg/kg
LOAEL : 334 mg/kg
Application Route : Ingestion
Exposure time : 2 yr

Aspiration toxicity

Not classified based on available information.

11.2 Information on other hazards

Endocrine disrupting properties

Not classified based on available information.

Product:

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

Experience with human exposure

Components:

zeranol:

Ingestion : Remarks: May cause adverse reproductive effects.

SECTION 12: Ecological information

12.1 Toxicity

Components:

Boric acid:

Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): 74 mg/l
Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates : EC50 (Ceriodaphnia dubia (water flea)): 102 mg/l
Exposure time: 48 h

Toxicity to algae/aquatic plants : EC50 (Pseudokirchneriella subcapitata (green algae)): 52.4 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

NOEC (Pseudokirchneriella subcapitata (green algae)): 17.5 mg/l

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Exposure time: 72 h
Method: OECD Test Guideline 201

Toxicity to microorganisms : EC10 : 35.4 mg/l
Exposure time: 3 h
Method: OECD Test Guideline 209

Toxicity to fish (Chronic toxicity) : NOEC: 6.4 mg/l
Exposure time: 34 d
Species: Danio rerio (zebra fish)
Method: OECD Test Guideline 210

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC: 10.8 mg/l
Exposure time: 21 d
Species: Daphnia magna (Water flea)

12.2 Persistence and degradability

Components:

zeranol:

Biodegradability : Result: Not readily biodegradable.
Biodegradation: 50 %
Exposure time: 91 d

12.3 Bioaccumulative potential

Components:

zeranol:

Partition coefficient: n-octanol/water : log Pow: 3.13

Boric acid:

Bioaccumulation : Species: Cyprinus carpio (Carp)
Bioconcentration factor (BCF): <= 3.2
Method: OECD Test Guideline 305

Partition coefficient: n-octanol/water : log Pow: -1.09

12.4 Mobility in soil

Components:

zeranol:

Distribution among environmental compartments : log Koc: 2.95

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

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very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

12.6 Endocrine disrupting properties

Product:

Assessment

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

12.7 Other adverse effects

No data available

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product

: Dispose of in accordance with local regulations. According to the European Waste Catalogue, Waste Codes are not product specific, but application specific. Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities. Do not dispose of waste into sewer.

Contaminated packaging

: Empty containers should be taken to an approved waste handling site for recycling or disposal. If not otherwise specified: Dispose of as unused product.

SECTION 14: Transport information

14.1 UN number or ID number

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

14.2 UN proper shipping name

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

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14.3 Transport hazard class(es)

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

14.4 Packing group

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

14.5 Environmental hazards

Not regulated as a dangerous good

14.6 Special precautions for user

Not applicable

14.7 Maritime transport in bulk according to IMO instruments

Remarks : Not applicable for product as supplied.

SECTION 15: Regulatory information

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

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII)

: Conditions of restriction for the following entries should be considered:
Number on list 30: Boric acid

Number on list 75: If you intend to use this product as tattoo ink, please contact your vendor.

Substance(s) or mixture(s) are listed here according to their appearance in the regulation, irrespective of their use/purpose or the conditions of the restriction. Please refer to the conditions in corresponding Regulation to determine whether an entry is appli-

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REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59).	cable to the placing on the market or not.
Regulation (EU) No 2024/590 on substances that deplete the ozone layer	: Boric acid
Regulation (EU) 2019/1021 on persistent organic pollutants (recast)	: Not applicable
Regulation (EU) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals	: Not applicable
REACH - List of substances subject to authorisation (Annex XIV)	: Not applicable
Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances.	: Not applicable

Other regulations:

Take note of Directive 92/85/EEC regarding maternity protection or stricter national regulations, where applicable.

Take note of Directive 94/33/EC on the protection of young people at work or stricter national regulations, where applicable.

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

AICS : not determined

DSL : not determined

IECSC : not determined

15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

Other information : Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

Full text of H-Statements

H351 : Suspected of causing cancer.
H360FD : May damage fertility. May damage the unborn child.
H372 : Causes damage to organs through prolonged or repeated exposure.

Full text of other abbreviations

Carc. : Carcinogenicity
Repr. : Reproductive toxicity
STOT RE : Specific target organ toxicity - repeated exposure
IE OEL : Ireland. List of Chemical Agents and Carcinogens with Occupational Exposure Limit Values - Code of Practice, Schedule 1

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and 2

IE OEL / OELV - 8 hrs (TWA) : Occupational exposure limit value (8-hour reference period)

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

Further information

Sources of key data used to compile the Safety Data Sheet : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, <http://echa.europa.eu/>

Classification of the mixture:

Carc. 2	H351
Repr. 1B	H360FD
STOT RE 1	H372

Classification procedure:

Calculation method
Calculation method
Calculation method

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS mate-

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rial is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.

IE / EN