SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Zeranol Formulation

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

1.3 Details of the supplier of the safety data sheet
   Company : MSD
   Kilshealan
   Clonmel Tipperary, IE
   Telephone : 353-51-601000
   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
   Hazard 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.
Precautionary statements:

**Prevention:**
P201 Obtain special instructions before use.
P260 Do not breathe dust.
P264 Wash skin thoroughly after handling.
P270 Do not eat, drink or smoke when using this product.
P280 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

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>EC-No.</th>
<th>Index-No.</th>
<th>Registration number</th>
<th>Classification</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>zeronol</td>
<td>26538-44-3</td>
<td>247-769-0</td>
<td></td>
<td></td>
<td>Carc. 2; H351 Repr. 1B; H360FD STOT RE 1; H372 (Endocrine system, Liver)</td>
<td>&gt;= 70 - &lt; 90</td>
</tr>
<tr>
<td>Boric acid</td>
<td>10043-35-3</td>
<td>233-139-2</td>
<td></td>
<td></td>
<td>Repr. 1B; H360FD</td>
<td>&gt;= 10 - &lt; 20</td>
</tr>
</tbody>
</table>
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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: Suspected of causing cancer. May damage fertility. May damage the unborn child. Causes damage to organs through prolonged or repeated exposure.

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

4.3 Indication of any immediate medical attention and special treatment needed

Treatment: Treat symptomatically and supportively.

For explanation of abbreviations see section 16.
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 firefighting:
- 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.
- 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. 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.
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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
  - 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

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Zeranol</td>
<td>26538-44-3</td>
<td>TWA</td>
<td>2 µg/m³ (OEB 4)</td>
<td>Internal</td>
</tr>
<tr>
<td>Boric acid</td>
<td>10043-35-3</td>
<td>OELV - 8 hrs (TWA)</td>
<td>2 mg/m³</td>
<td>IE OEL</td>
</tr>
<tr>
<td>Magnesium stea-</td>
<td>557-04-0</td>
<td>OELV - 8 hrs (TWA)</td>
<td>10 mg/m³</td>
<td>IE OEL</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Substance name</th>
<th>End Use</th>
<th>Exposure routes</th>
<th>Potential health effects</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Boric acid</td>
<td>Workers</td>
<td>Skin contact</td>
<td>Long-term systemic effects</td>
<td>392 mg/kg bw/day</td>
</tr>
<tr>
<td></td>
<td>Workers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>8.3 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Ingestion</td>
<td>Acute systemic effects</td>
<td>0.98 mg/kg bw/day</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Ingestion</td>
<td>Long-term systemic effects</td>
<td>0.98 mg/kg bw/day</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>4.15 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Skin contact</td>
<td>Long-term systemic effects</td>
<td>196 mg/kg bw/day</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Substance name</th>
<th>Environmental Compartment</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Boric acid</td>
<td>Fresh water</td>
<td>2.9 mg/l</td>
</tr>
<tr>
<td></td>
<td>Intermittent use/release</td>
<td>13.7 mg/l</td>
</tr>
</tbody>
</table>
8.2 Exposure controls

**Engineering measures**

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 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

- **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.
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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
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

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
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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

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
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SDS Number: 691069-00012
Date of last issue: 09.04.2021
Date of first issue: 19.05.2016

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

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

Carcinogenicity - Assessment: Limited evidence of carcinogenicity in animal studies

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:
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: Embryofetal 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: Embryofetal development
Species: Rabbit
Application Route: Oral
Developmental Toxicity: NOAEL: >= 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.

**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
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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
NOAEL : 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
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

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.
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
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
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**Boric acid:**

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

- **Bioconcentration factor (BCF):** <= 3.2

- **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 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.

- **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**

- Not regulated as a dangerous good
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14.2 UN proper shipping name
Not regulated as a dangerous good

14.3 Transport hazard class(es)
Not regulated as a dangerous good

14.4 Packing group
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, preparations and articles (Annex XVII): Conditions of restriction for the following entries should be considered: Boric acid (Number on list 30)

REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59). Regulation (EC) No 1005/2009 on substances that deplete the ozone layer: Not applicable

Regulation (EU) 2019/1021 on persistent organic pollutants (recast): Not applicable

Regulation (EC) 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


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
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Revision Date: 27.08.2021
SDS Number: 691069-00012
Date of last issue: 09.04.2021
Date of first issue: 19.05.2016

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 Occupational Exposure Limit Values - Schedule 1
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 - European 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.
Zeranol Formulation

Further information

Classification of the mixture:

<table>
<thead>
<tr>
<th>Classification</th>
<th>Code</th>
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</thead>
<tbody>
<tr>
<td>Carc. 2</td>
<td>H351</td>
</tr>
<tr>
<td>Repr. 1B</td>
<td>H360FD</td>
</tr>
<tr>
<td>STOT RE 1</td>
<td>H372</td>
</tr>
</tbody>
</table>

Classification procedure:
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 material 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.