SAFETY DATA SHEET
Zeranol Formulation

Version 3.3     Revision Date: 10.10.2020     SDS Number: 691070-00009     Date of last issue: 23.03.2020
Date of first issue: 19.05.2016

1. PRODUCT AND COMPANY IDENTIFICATION

Product name: Zeranol Formulation

Manufacturer or supplier’s details
Company: MSD
Address: Briahnager - Off Pune Nagar Road
         Wagholi - Pune - India  412 207
Telephone: +1-908-740-4000
Emergency telephone number: +1-908-423-6000
E-mail address: EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use
Recommended use: Veterinary product

2. HAZARDS IDENTIFICATION

Classification
Manufacture, Storage and Import of Hazardous Chemicals Rules 1989
Not classified as hazardous according to criteria laid down in Part I of Schedule-1.

GHS Classification
Carcinogenicity: Category 2
Reproductive toxicity: Category 1B
Specific target organ toxicity - repeated exposure: Category 1 (Endocrine system, Liver)

GHS label elements
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 (Endocrine system, Liver) through prolonged or repeated exposure.

Precautionary statements:
Prevention:
P203 Obtain, read and follow all safety 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:
P318 IF exposed or concerned, get medical advice.

Storage:
P405 Store locked up.

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

Other hazards which do not result in classification
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.

3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Mixture</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Components</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Chemical name</td>
<td>CAS-No.</td>
</tr>
<tr>
<td>zeranol</td>
<td>26538-44-3</td>
</tr>
<tr>
<td>Boric acid</td>
<td>10043-35-3</td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>557-04-0</td>
</tr>
</tbody>
</table>

4. 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.

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.

Most important symptoms and effects, both acute and delayed: 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.

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).

Notes to physician: Treat symptomatically and supportively.

5. FIREFIGHTING MEASURES

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

Unsuitable extinguishing media: High volume water jet

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

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.

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

6. ACCIDENTAL RELEASE MEASURES

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

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 spills cannot be contained.

Methods and materials for containment and 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.
7. HANDLING AND STORAGE

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.

Conditions for safe storage: Keep in properly labelled containers.
Store locked up.
Keep tightly closed.
Store in accordance with the particular national regulations.

Materials to avoid: Do not store with the following product types:
Strong oxidizing agents

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Permissible concentration</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></td>
<td></td>
<td>Wipe limit</td>
<td>20 µg/100 cm²</td>
<td>Internal</td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>557-04-0</td>
<td>TWA (Inhalable particulate matter)</td>
<td>10 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Respirable particulate matter)</td>
<td>3 mg/m³</td>
<td>ACGIH</td>
</tr>
</tbody>
</table>
9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : powder
### Colour
- yellow

### Odour
- odourless

### Odour Threshold
- No data available

### pH
- No data available

### Melting point/freezing point
- No data available

### Initial boiling point and boiling range
- No data available

### Flash point
- Not applicable

### Evaporation rate
- 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

### Vapour pressure
- No data available

### Relative vapour density
- No data available

### Relative density
- No data available

### Density
- No data available

### Solubility(ies)
- Water solubility
  - insoluble

### Partition coefficient: n-octanol/water
- No data available

### Auto-ignition temperature
- No data available

### Decomposition temperature
- No data available

### Viscosity
- Viscosity, kinematic
  - No data available

### Explosive properties
- Not explosive

### Oxidizing properties
- The substance or mixture is not classified as oxidizing.

### Molecular weight
- No data available
10. STABILITY AND REACTIVITY

Reactivity: Not classified as a reactivity hazard.

Chemical stability: Stable under normal conditions.

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

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

Incompatible materials: Oxidizing agents

Hazardous decomposition products: No hazardous decomposition products are known.

11. TOXICOLOGICAL INFORMATION

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

Acute toxicity:
Not classified based on available information.

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

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
Magnesium stearate:
Acute oral toxicity: LD50 (Rat): > 2,000 mg/kg
   Method: OECD Test Guideline 423
   Assessment: The substance or mixture has no acute oral toxicity
   Remarks: Based on data from similar materials

Acute dermal toxicity: LD50 (Rabbit): > 2,000 mg/kg
   Remarks: Based on data from similar materials

Skin corrosion/irritation
Not classified based on available information.

Components:
zeranol:
   Remarks: No data available

Boric acid:
   Species: Rabbit
   Result: No skin irritation

Magnesium stearate:
   Species: Rabbit
   Result: No skin irritation
   Remarks: Based on data from similar materials

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

Magnesium stearate:
   Species: Rabbit
   Result: No eye irritation
   Remarks: Based on data from similar materials

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

Magnesium stearate:
Test Type: Maximisation Test
Exposure routes: Skin contact
Species: Guinea pig
Method: OECD Test Guideline 406
Result: negative
Remarks: Based on data from similar materials

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

**Magnesium stearate:**  
Genotoxicity in vitro:  
Test Type: In vitro mammalian cell gene mutation test  
Result: negative  
Remarks: Based on data from similar materials

Test Type: Chromosome aberration test in vitro  
Method: OECD Test Guideline 473  
Result: negative  
Remarks: Based on data from similar materials

Test Type: Bacterial reverse mutation assay (AMES)  
Result: negative  
Remarks: Based on data from similar materials

**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

**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:
Effect 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

Effect 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: >= 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.

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

Effect 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.

Magnesium stearate:


STOT - single exposure
Not classified based on available information.

STOT - repeated exposure
Causes damage to organs (Endocrine system, Liver) 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: 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
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

**Magnesium stearate:**
Species: Rat
NOAEL: > 100 mg/kg
Application Route: Ingestion
Exposure time: 90 Days
Remarks: Based on data from similar materials

**Aspiration toxicity**
Not classified based on available information.

**Experience with human exposure**

**Components:**

**zeranol:**
Ingestion: Remarks: May cause adverse reproductive effects.

12. ECOLOGICAL INFORMATION

**Ecotoxicity**

**Components:**

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

Toxicity to daphnia and other: EC50 (Ceriodaphnia dubia (water flea)): 102 mg/l
<table>
<thead>
<tr>
<th>Aquatic Invertebrates</th>
<th>Exposure time: 48 h</th>
</tr>
</thead>
</table>
| **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) |

**Magnesium stearate:**

| Toxicity to fish | LC50 (Leuciscus idus (Golden orfe)): > 100 mg/l  
Exposure time: 48 h  
Method: DIN 38412  
Remarks: Based on data from similar materials |
| Toxicity to daphnia and other aquatic invertebrates | EL50 (Daphnia magna (Water flea)): > 1 mg/l  
Exposure time: 47 h  
Test substance: Water Accommodated Fraction  
Remarks: Based on data from similar materials  
No toxicity at the limit of solubility |
| Toxicity to algae/aquatic plants | EL50 (Pseudokirchneriella subcapitata (green algae)): > 1 mg/l  
Exposure time: 72 h  
Test substance: Water Accommodated Fraction  
Method: OECD Test Guideline 201  
Remarks: Based on data from similar materials  
No toxicity at the limit of solubility  
NOELR (Pseudokirchneriella subcapitata (green algae)): > 1 mg/l  
Exposure time: 72 h  
Test substance: Water Accommodated Fraction  
Method: OECD Test Guideline 201  
Remarks: Based on data from similar materials |
| Toxicity to microorganisms | EC10 (Pseudomonas putida): > 100 mg/l |
Persistence and degradability

Components:

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

Magnesium stearate:
Biodegradability: Result: Not biodegradable
Remarks: Based on data from similar materials

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

Magnesium stearate:
Partition coefficient: n-octanol/water: log Pow: > 4

Mobility in soil

Components:

zeranol:
Distribution among environmental compartments: log Koc: 2.95

Other adverse effects
No data available
13. DISPOSAL CONSIDERATIONS

Disposal methods
Waste from residues: Dispose of in accordance with local regulations.
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.

14. TRANSPORT INFORMATION

International Regulations

UNRTDG
Not regulated as a dangerous good

IATA-DGR
Not regulated as a dangerous good

IMDG-Code
Not regulated as a dangerous good

Transport in bulk according to IMO instruments
Not applicable for product as supplied.

15. REGULATORY INFORMATION

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

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

AICS: not determined
DSL: not determined
IECSC: not determined

16. OTHER INFORMATION

Further information

Date format: dd.mm.yyyy

Full text of other abbreviations
ACGIH: USA. ACGIH Threshold Limit Values (TLV)
ACGIH / TWA: 8-hour, time-weighted average
ACGIH / STEL: Short-term exposure limit
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.

IN / EN