SAFETY DATA SHEET

Zeranol Formulation

SECTION 1. IDENTIFICATION

Product name : Zeranol Formulation

Manufacturer or supplier’s details
Company name of supplier : Merck & Co., Inc
Address : 2000 Galloping Hill Road
            Kenilworth - New Jersey - U.S.A. 07033
Telephone : 908-740-4000
Telefax : 908-735-1496
Emergency telephone : 1-908-423-6000
E-mail address : EHSDATASETWARD@merck.com

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

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with 29 CFR 1910.1200
Combustible dust

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 : May form combustible dust concentrations in air.
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:
P201 Obtain special instructions before use.
P202 Do not handle until all safety precautions have been read and understood.
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.

Storage:
P405 Store locked up.

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

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

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Components</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Chemical name</td>
</tr>
<tr>
<td></td>
<td>zeranol</td>
</tr>
<tr>
<td></td>
<td>Boric acid</td>
</tr>
<tr>
<td></td>
<td>Magnesium stearate</td>
</tr>
</tbody>
</table>

Actual concentration is withheld as a trade secret

SECTION 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.

Protection of first-aiders: First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment.
SECTION 5. FIRE-FIGHTING MEASURES

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

Unsuitable extinguishing media: High volume water jet

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

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

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures: Use personal protective equipment.
 Follow safe handling advice and personal protective equipment recommendations.

Environmental precautions: Discharge into the environment must be avoided.
 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.
 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
SECTION 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. 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. Take care to prevent spills, waste and minimize release to the environment.

Conditions for safe storage: Keep in properly labeled 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 Organic peroxides Explosives Gases

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients 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>Boric acid</td>
<td>10043-35-3</td>
<td>TWA (Inhalable fraction)</td>
<td>2 mg/m³ (Borate)</td>
<td>ACGIH</td>
</tr>
<tr>
<td></td>
<td></td>
<td>STEL (Inhalable fraction)</td>
<td>6 mg/m³ (Borate)</td>
<td>ACGIH</td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>557-04-0</td>
<td>TWA (Inhalable fraction)</td>
<td>10 mg/m³ (Borate)</td>
<td>ACGIH</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Respirable fraction)</td>
<td>3 mg/m³</td>
<td>ACGIH</td>
</tr>
</tbody>
</table>
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

Respiratory protection: General and local exhaust ventilation is recommended to maintain vapor exposures below recommended limits. Where concentrations are above recommended limits or are unknown, appropriate respiratory protection should be worn. Follow OSHA respirator regulations (29 CFR 1910.134) and use NIOSH/MSHA approved respirators. Protection provided by air purifying respirators against exposure to any hazardous chemical is limited. Use a positive pressure air supplied respirator if there is any potential for uncontrolled release, exposure levels are unknown, or any other circumstance where air purifying respirators may not provide adequate protection.

Hand protection

Material: Chemical-resistant gloves

Remarks: Consider double gloving.

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.

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.

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.
Appearance : powder
Color : yellow
Odor : odorless
Odor 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
Vapor pressure : No data available
Relative vapor 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
Autoignition 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
Dust deflagration index (Kst) : 180 m.b./s  
Minimum ignition energy : 5 - 10 mJ  
Particle size : No data available

SECTION 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.

SECTION 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
SAFETY DATA SHEET
Zeranol Formulation

Version 5.2  Revision Date: 09/13/2019  SDS Number: 682073-00008  Date of last issue: 04/24/2019
Date of first issue: 05/19/2016

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
Safety Data Sheet

Zeranol Formulation

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<thead>
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</tr>
</tbody>
</table>

**Respiratory or skin sensitization**

**Skin sensitization**
Not classified based on available information.

**Respiratory sensitization**
Not classified based on available information.

**Components:**

- **Zeranol:**
  - Remarks: No data available

- **Boric acid:**
  - Test Type: Buehler Test
  - Routes of exposure: Skin contact
  - Species: Guinea pig
  - Method: OECD Test Guideline 406
  - Result: negative

- **Magnesium stearate:**
  - Test Type: Maximization Test
  - Routes of exposure: 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
SAFETY DATA SHEET

Zeranol Formulation

Version 5.2  Revision Date: 09/13/2019  SDS Number: 682073-00008  Date of last issue: 04/24/2019  Date of first issue: 05/19/2016

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
SAFETY DATA SHEET

Zeranol Formulation

IARC
No ingredient of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

OSHA
No component of this product present at levels greater than or equal to 0.1% is on OSHA’s list of regulated carcinogens.

NTP
No ingredient of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

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

OSHA
No component of this product present at levels greater than or equal to 0.1% is on OSHA’s list of regulated carcinogens.

NTP
No ingredient of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

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

OSHA
No component of this product present at levels greater than or equal to 0.1% is on OSHA’s list of regulated carcinogens.

NTP
No ingredient of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

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

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NTP
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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

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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

OSHA
No component of this product present at levels greater than or equal to 0.1% is on OSHA’s list of regulated carcinogens.

NTP
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Reproductive toxicity
May damage fertility. May damage the unborn child.

Components:
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</tr>
</tbody>
</table>

- **Species**: Rat  
- **Application Route**: Ingestion  
- **Result**: positive

**Effects on fetal development**:  
- **Test Type**: Embryo-fetal 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.

**Magnesium stearate**:

**Effects on fertility**:  
- **Test Type**: Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test  
- **Species**: Rat  
- **Application Route**: Ingestion  
- **Method**: OECD Test Guideline 422  
- **Result**: negative  
- **Remarks**: Based on data from similar materials

**Effects on fetal development**:  
- **Test Type**: Embryo-fetal development  
- **Species**: Rat  
- **Application Route**: Ingestion  
- **Result**: negative  
- **Remarks**: Based on data from similar materials

**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**  
- **Assessment**: Endocrine system, Liver  
- **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
## SAFETY DATA SHEET

### Zeranol Formulation

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</tr>
</tbody>
</table>

- **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
  - **Target Organs**: 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 y
  - **Target Organs**: female reproductive organs
  - **Symptoms**: Changes in the blood count

- **Species**: Monkey, female
  - **Application Route**: Oral
  - **Exposure time**: 10 y
  - **Target Organs**: female reproductive organs

### Boric acid:
- **Species**: Rat
  - **NOAEL**: 100 mg/kg
  - **LOAEL**: 334 mg/kg
  - **Application Route**: Ingestion
  - **Exposure time**: 2 y

### 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.

### SECTION 12. ECOLOGICAL INFORMATION

**Ecotoxicity**

**Components:**

**Boric acid:**

<table>
<thead>
<tr>
<th>Toxicity to fish</th>
<th>LC50 (Pimephales promelas (fathead minnow)): 74 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Exposure time: 96 h</td>
</tr>
<tr>
<td>Toxicity to daphnia and other aquatic invertebrates</td>
<td>EC50 (Ceriodaphnia dubia (water flea)): 102 mg/l</td>
</tr>
<tr>
<td></td>
<td>Exposure time: 48 h</td>
</tr>
<tr>
<td>Toxicity to algae/aquatic plants</td>
<td>EC50 (Pseudokirchneriella subcapitata (green algae)): 52.4 mg/l</td>
</tr>
<tr>
<td></td>
<td>Exposure time: 72 h</td>
</tr>
<tr>
<td></td>
<td>Method: OECD Test Guideline 201</td>
</tr>
<tr>
<td></td>
<td>NOEC (Pseudokirchneriella subcapitata (green algae)): 17.5 mg/l</td>
</tr>
<tr>
<td></td>
<td>Exposure time: 72 h</td>
</tr>
<tr>
<td></td>
<td>Method: OECD Test Guideline 201</td>
</tr>
<tr>
<td>Toxicity to fish (Chronic toxicity)</td>
<td>NOEC (Danio rerio (zebra fish)): 6.4 mg/l</td>
</tr>
<tr>
<td></td>
<td>Exposure time: 34 d</td>
</tr>
<tr>
<td></td>
<td>Method: OECD Test Guideline 210</td>
</tr>
<tr>
<td>Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)</td>
<td>NOEC (Daphnia magna (Water flea)): 10.8 mg/l</td>
</tr>
<tr>
<td></td>
<td>Exposure time: 21 d</td>
</tr>
<tr>
<td>Toxicity to microorganisms</td>
<td>EC10: 35.4 mg/l</td>
</tr>
<tr>
<td></td>
<td>Exposure time: 3 h</td>
</tr>
<tr>
<td></td>
<td>Method: OECD Test Guideline 209</td>
</tr>
</tbody>
</table>

**Magnesium stearate:**

<table>
<thead>
<tr>
<th>Toxicity to fish</th>
<th>LC50 (Leuciscus idus (Golden orfe)): &gt; 100 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Exposure time: 48 h</td>
</tr>
<tr>
<td></td>
<td>Method: DIN 38412</td>
</tr>
<tr>
<td></td>
<td>Remarks: Based on data from similar materials</td>
</tr>
<tr>
<td>Toxicity to daphnia and other aquatic invertebrates</td>
<td>EL50 (Daphnia magna (Water flea)): &gt; 1 mg/l</td>
</tr>
<tr>
<td></td>
<td>Exposure time: 47 h</td>
</tr>
<tr>
<td></td>
<td>Test substance: Water Accommodated Fraction</td>
</tr>
<tr>
<td></td>
<td>Remarks: Based on data from similar materials</td>
</tr>
<tr>
<td></td>
<td>No toxicity at the limit of solubility.</td>
</tr>
</tbody>
</table>
**Toxicity to algae/aquatic plants**

<table>
<thead>
<tr>
<th>Test substance</th>
<th>Concentration</th>
<th>Exposure time</th>
<th>Method</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Water Accommodated Fraction</td>
<td>&gt; 1 mg/l</td>
<td>72 h</td>
<td>OECD Test Guideline 201</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

**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**

<table>
<thead>
<tr>
<th>Test substance</th>
<th>Concentration</th>
<th>Exposure time</th>
<th>Method</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Water Accommodated Fraction</td>
<td>&gt; 100 mg/l</td>
<td>16 h</td>
<td>OECD Test Guideline 201</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

**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

SECTION 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.

SECTION 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 Annex II of MARPOL 73/78 and the IBC Code
Not applicable for product as supplied.

Domestic regulation

49 CFR
Not regulated as a dangerous good

SECTION 15. REGULATORY INFORMATION

EPCRA - Emergency Planning and Community Right-to-Know

CERCLA Reportable Quantity
This material does not contain any components with a CERCLA RQ.

SARA 304 Extremely Hazardous Substances Reportable Quantity
This material does not contain any components with a section 304 EHS RQ.

SARA 302 Extremely Hazardous Substances Threshold Planning Quantity
This material does not contain any components with a section 302 EHS TPQ.

SARA 311/312 Hazards : Combustible dust
Carcinogenicity
Reproductive toxicity
Specific target organ toxicity (single or repeated exposure)
SAFETY DATA SHEET

Zeranol Formulation

Version 5.2  Revision Date: 09/13/2019  SDS Number: 682073-00008  Date of last issue: 04/24/2019  Date of first issue: 05/19/2016

SARA 313
This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

US State Regulations

Pennsylvania Right To Know
zeranol 26538-44-3
D-Glucose, 4-O-beta-D-galactopyranosyl-, monohydrate 64044-51-5
Magnesium stearate 557-04-0
Boric acid 10043-35-3

California Permissible Exposure Limits for Chemical Contaminants
Magnesium stearate 557-04-0

The ingredients of this product are reported in the following inventories:
AICS: not determined
DSL: not determined
IECSC: not determined

SECTION 16. OTHER INFORMATION

Further information

NFPA 704:

<table>
<thead>
<tr>
<th>Flammability</th>
<th>Health</th>
<th>Instability</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>0</td>
<td>2</td>
</tr>
</tbody>
</table>

HMIS® IV:

- HEALTH: *
- FLAMMABILITY: 2
- PHYSICAL HAZARD: 0

HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "*" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.

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

AICS - Australian Inventory of Chemical Substances; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the
German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; 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; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; HMIS - Hazardous Materials Identification System; 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; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NTP - National Toxicology Program; 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; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative


Revision Date: 09/13/2019

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.

US / Z8