

SAFETY DATA SHEETS

This SDS packet was issued with item:

078056577

The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).

078352636 078423336 078569946 078923387

MATERIAL SAFETY DATA SHEET

SECTION I – PRODUCT INFORMATION

PRODUCT NAME: Regu-Mate Solution
OFFICIAL NAME: Regu-Mate Solution 0.22%
PRODUCT TYPE: Regu-Mate Solution is an oral progestin for horses and swine used to suppress estrus.
Intended for non-food animals only.
DIN: 00641987
DOSAGE FORM: Solution
ACTIVE INGREDIENT: Altrenogest - 2.2mg/mL

MANUFACTURER/SUPPLIER: Intervet, Inc.
405 State Street
P.O. Box 318
Millsboro, DE 19966

TELEPHONE: 1-800-268-4257
EMERGENCY #: 1-800-345-4735 (only to be used after hours between 4:30pm - 8:30am)
FAX: 1-888-498-4444

SECTION II – INGREDIENT INFORMATION

| INGREDIENT – COMPONENT | CAS# |
|--|------------|
| Altrenogest* (active ingredient) (17-alpha-allyl-17-beta hydroxyestra-4,9,11-trien-3-one) | 850-52-2 |
| Butylated Hydroxyanisole (BHA) | 25013-16-5 |
| Butylated Hydroxytoluene (BHT) | 128-37-0 |
| Neobee (Hydrogenated Vegetable Oil) | None |

*OSHA hazardous according to 29 CFR 1910.1200

SECTION III – PHYSICAL DATA

MELTING POINT: N/D
SOLUBILITY: Miscible
APPEARANCE AND ODOUR: Oil solution; no odour

SECTION IV – FIRE AND EXPLOSION DATA

FLAMMABLE PROPERTIES: Thermal decomposition may generate small amounts of CO and CO₂.
EXTINGUISHER MEDIA: Water, foam or CO₂ may be used to fight fires involving this product.
SPECIAL FIRE FIGHTING PROCEDURES: Wear full bunker gear, including SCBA, when responding to fires involving facilities where pharmaceutical products are stored.

SECTION V – HEALTH HAZARD DATA

EMERGENCY OVERVIEW: Pregnant women and others of child bearing age should exercise extreme caution when handling this product. Acute effects after a single exposure are possible, however, continued daily exposure has a greater potential for these effects: acute effects include disruption of the menstrual cycle, uterine or abdominal cramping, increased or decreased uterine bleeding and headaches. See list of people who should not handle this substance in Section XIV.

SECTION V – HEALTH HAZARD DATA (CONT.)

POTENTIAL HEALTH EFFECTS: See Emergency Overview

DELAYED/LONG TERM EFFECTS: N/D

CARCINOGENIC EFFECTS: This product is not considered a carcinogen and is not listed by OSHA, IARC, or NTP.

FIRST AID PROCEDURES:

Consult a doctor and/or nearest Poison Control Centre for all extreme exposures.

In case of contact with eyes, **IMMEDIATELY** flush with plenty of water for 15 minutes. Get medical attention.

In case of contact with skin, wash **IMMEDIATELY** with soap and water. Contact a physician.

Inhalation:

In case of ingestion, do not induce vomiting. Regu-Mate Solution 0.22% contains an oil which could be aspirated during vomiting.

Seek medical attention **IMMEDIATELY**. Bring MSDS sheet and or label.

NOTE TO PHYSICIAN: This product is not intended for human use. There has been no human use of this specific product. The information in this section is extrapolated from data available on other products of the same pharmaceutical class that have been used in humans. Effects anticipated are due to the progestational activity of altrenogest.

SECTION VI – REACTIVITY DATA

STABILITY: Stable:
Unstable:

HAZARDOUS POLYMERIZATION:

May Occur:

Will not occur:

Avoid contact with strong alkalis (NAOH, HOH)

SECTION VII – SPILL OR LEAK PROCEDURE

ACCIDENTAL RELEASE MEASURES:

STEPS TO BE TAKEN: Wear protective clothing and non-porous gloves. Spilled Regu-Mate Solution should be cleaned up and disposed of by incineration.

DISPOSAL METHODS: This substance should be disposed of by incineration in accordance with local, state, provincial, and federal regulations.

Please contact Intervet Canada Ltd. for disposal of pharmaceutical products 1-800 268-4257.

SECTION VIII - SPECIAL PROTECTION INFORMATION

PROTECTIVE EQUIPMENT: Skin contact must be avoided as Regu-Mate Solution is easily absorbed through unbroken skin.

PROTECTIVE GLOVES: Protective gloves must be worn by all persons handling this material. Regu-Mate Solution should not penetrate intact rubber or impervious gloves. See list of people who should not handle this substance in Section XIV.

INHALATION: Exposure limit: 0.8 micrograms per cubic meter of air (8 hr twa) for altrenogest.

SECTION IX - STORAGE AND HANDLING PRECAUTIONS

STORAGE AND HANDLING: Keep this and all drugs out of the reach of children. Store at room temperature (below 25°C) in well-closed containers. Protect from freezing. Pregnant women and others of child bearing age should exercise extreme caution when handling this product. Handle in a manner that will not generate aerosols. Skin contact must be avoided. See list of people who should not handle this substance in Section XIV.

SECTION X – TOXICOLOGICAL INFORMATION

ORAL LD50: (Rats) >2,000mg/kg

This product is contraindicated in pregnant mares. The safety of the drug in pregnant mares has not been established. Various synthetic progestins, including altrenogest, when administered to rats during the embryogenic stage of pregnancy at doses many fold greater than the recommended equine dose caused fetal anomalies, specifically of the female genitalia.

Altrenogest is non-mutagenic when studied in the Ames test, mammalian point mutation assays, in vitro and in vivo chromosome aberration assays and DNA damage assays.

Do not use in horses intended for use in food.

SECTION XI – ECOLOGICAL INFORMATION

ECOTOXICITY: Regu-Mate Solution administered to horses presents negligible impact on the environment.

SECTION XII- TRANSPORTATION

TDG/DOT CLASSIFICATION: Not regulated by DOT.

ICAO/IATA CLASSIFICATION: N/D

SECTION XIII – REGULATORY INFORMATION

PROVINCIAL REGULATIONS: complies

FEDERAL REGULATIONS: This product is a prescription Drug. Federal law restricts this drug to use by or on the order of licensed veterinarian.

SECTION XIV – ADDITIONAL INFORMATION

Other Information: Warning: Regu-Mate Solution is readily absorbed by the skin. Skin contact must be avoided; protective gloves must be worn when handling this product.

People who should not handle this product: Women who are pregnant or suspect they are pregnant; anyone with thrombophlebitis or thromboembolic disorders or with a history of these events; people with cerebral-vascular or coronary-artery disease; women with known or suspected carcinoma of the breast; people with known or suspected estrogen-dependent neoplasia; women with undiagnosed vaginal bleeding; people with a benign or malignant tumor which developed during the use of oral contraceptives or other estrogen containing products; anyone with liver dysfunction or disease.

Disclaimer: The information contained herein is offered only as a guide to the handling of this special material. Since such information does not relate to the use of the material with any other material or in any process, any person using this information must determine for themselves its suitability for any particular application. The buyer and user assume all risk and liability of use, storage and/or handling of this product not in accordance with the terms of the product label.

FOR ANIMAL USE ONLY

**The information contained herein is true and accurate to the best of the knowledge of Intervet Canada Ltd.
However, all data, instructions and/or recommendations are made without guarantee.**

SIGNED: _____

DATE ISSUED: January 2, 2008



Merck Animal Health
One Merck Dr.
Whitehouse Station, NJ 08889

MATERIAL SAFETY DATA SHEET

Merck Animal Health urges each user or recipient of this MSDS to read the entire data sheet to become aware of the hazards associated with this material.

SECTION 1. IDENTIFICATION OF SUBSTANCE AND CONTACT INFORMATION

MSDS NAME: Regu-Mate Solution 0.22%

SYNONYM(S): Regu-Mate Solution 0.22%
Regu-Mate Solution 0.22% for Equine and Swine
REGUMATE Equine

MSDS NUMBER: SP002244

EMERGENCY NUMBER(S): (908) 423-6000 (24/7/365) English Only
Emergencies - CHEMTREC:
(800) 424-9300 (Inside Continental USA)
(703) 527-3887 (Outside Continental USA)

INFORMATION: Animal Health Technical Services:
For Small Animals and Horses: (800) 224-5318
For Livestock: (800) 211-3573
For Poultry: (800) 219-9286

MERCK MSDS HELPLINE: (800) 770-8878 (US and Canada)
(908) 473-3371 (Worldwide)
Monday to Friday, 9am to 5pm (US Eastern Time)

SECTION 2. HAZARDS IDENTIFICATION

EMERGENCY OVERVIEW

Liquid
Color not reported
Odorless
May be harmful if absorbed through skin.
May be harmful by inhalation.
May cause effects to:
endocrine system
central nervous system
gastrointestinal tract
reproductive system
fetus
May cause impaired fertility.

POTENTIAL HEALTH EFFECTS:

The toxicological properties of the mixture(s) have not been fully characterized in humans or animals. Therefore, laboratory or process control systems and appropriate work practices should be in place to minimize the potential for inhalation exposure, skin contact, eye contact, or ingestion when working with this material.

Although some ingredients used in the manufacture of this product are considered hazardous on an individual basis, the final formulation of this product is considered non-hazardous when used according to manufacturer's directions.

Altrenogest is a progestogen and is harmful by inhalation and in contact with skin. Symptoms of exposure may include headache, dizziness, gastrointestinal complaints, nausea, vomiting, water retention and sodium retention. Effects of overexposure are those as for progestogens in general: changes in libido, impaired glucose tolerance, reversible gynecomastia in males, amenorrhea in females, and effects on fertility. Exposure to Altrenogest may cause harm to the unborn child, and may pose a possible risk of impaired fertility. There is limited evidence of a carcinogenic effect.

LISTED CARCINOGENS

Progestogens, as a group, have been classified as IARC Group 2B (Possibly Carcinogenic to Humans). This evaluation applies to the group of compounds as a whole and not necessarily to individual compounds within the group.

SECTION 3. COMPOSITION AND INFORMATION ON INGREDIENTS

CHEMICAL FAMILY: Progestogens
PRODUCT USE: Veterinary product
CHEMICAL FORMULA: Mixture.

The formulation for this product is proprietary information. Only hazardous ingredients in concentrations of 1% or greater and/or carcinogenic ingredients in concentrations of 0.1% or greater are listed in the Chemical Composition table. Active ingredients in any concentration are listed. For additional information about carcinogenic ingredients see Section 2.

CHEMICAL COMPOSITION

| INGREDIENT | CAS NUMBER | PERCENT |
|----------------|------------|---------|
| Altrenogest | 850-52-2 | 0.22 |
| Benzyl Alcohol | 100-51-6 | <10 |

ADDITIONAL INFORMATION: This MSDS is written to provide health and safety information for individuals who will be handling the final product formulation during research, manufacturing, and distribution. For health and safety information for individual ingredients used during manufacturing, refer to the appropriate MSDS for each ingredient. Refer to the package insert or product label for handling guidance for the consumer.

SECTION 4. FIRST AID MEASURES

INHALATION: Remove to fresh air. If any trouble breathing, get immediate medical attention. Administer artificial respiration if breathing has ceased. If irritation or symptoms occur or persist, consult a physician.

SKIN CONTACT: In case of skin contact, IMMEDIATELY flush exposed skin thoroughly with plenty of water. While wearing protective gloves, remove any contaminated clothing, including shoes and continue to wash skin thoroughly with soap and water for at least 15 minutes. Get IMMEDIATE medical attention.

EYE CONTACT: In case of eye contact, immediately rinse eyes thoroughly with plenty of water. If wearing contact lenses, remove only after initial rinse, and continue rinsing eyes for at least 15 minutes. If irritation occurs or persists, consult a physician.

INGESTION: Rinse mouth and drink a glass of water. Do not induce vomiting unless under the direction of a qualified medical professional or Poison Control Center. If symptoms persist, consult a physician.

SECTION 5. FIRE FIGHTING MEASURES

FLAMMABILITY DATA:

Flash Point: Not determined (liquids) or not applicable (solids).

SPECIAL FIRE HAZARDS:

May form thick soot or smoke by incomplete combustion in flames.

SPECIAL FIRE FIGHTING PROCEDURES:

Wear full protective clothing and self-contained breathing apparatus (SCBA).

SUITABLE EXTINGUISHING MEDIA:

Carbon dioxide (CO₂), extinguishing powder or water spray.

See Section 9 for Physical and Chemical Properties.

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SECTION 6. ACCIDENTAL RELEASE MEASURES

PERSONAL PRECAUTIONS:

Wear appropriate personal protective equipment as specified in Section 8. Keep personnel away from the clean-up area.

SPILL RESPONSE / CLEANUP:

All spills should be handled according to site requirements and based on precautions cited in the MSDS. In the case of liquids, use proper absorbent materials. For laboratories and small-scale operations, incidental spills within a hood or enclosure should be cleaned by using a HEPA filtered vacuum or wet cleaning methods as appropriate. For large dry or liquid spills or those spills outside enclosure or hood, appropriate emergency response personnel should be notified. In manufacturing and large-scale operations, HEPA vacuuming prior to wet mopping or cleaning is required.

See Sections 9 and 10 for additional physical, chemical, and hazard information.

SECTION 7. HANDLING AND STORAGE

HANDLING:

Keep containers adequately sealed during material transfer, transport, or when not in use. Wash face, hands, and any exposed skin after handling. Do not eat, drink, or smoke when using this substance or mixture.

Appropriate handling of this material is dependent on many factors, including physical form, duration and frequency of process or task, and effectiveness of engineering controls. Site-specific risk assessments should be conducted to determine the feasibility and the appropriateness of all exposure control measures. See Section 8 (Exposure Controls) for additional guidance.

Avoid skin contact. Avoid aerosol generation. Avoid exposure to women especially during pregnancy and lactation.

STORAGE:

Keep in closed tight containers. Store at or below 25°C (77° F). Do not freeze.

See Section 8 for exposure controls and additional safe handling information.

SECTION 8. EXPOSURE CONTROLS AND PERSONAL PROTECTION

EXPOSURE CONTROLS

The health hazard risks of handling this material are dependent on many factors, including physical form, duration and frequency of process or task, and effectiveness of engineering controls. Site-specific risk assessments should be conducted to determine the feasibility and the appropriateness of all exposure control measures. Exposure controls for normal operating or routine procedures follow a tiered strategy. Engineering controls are the preferred means of long-term or permanent exposure control. If engineering controls are not feasible, appropriate use of personal protective equipment (PPE) may be considered as alternative control measures. Exposure controls for non-routine operations must be evaluated and addressed as part of the site-specific risk assessment.

RECOMMENDED PERSONAL PROTECTIVE EQUIPMENT (PPE):

| | |
|-------------------------|--|
| Respiratory Protection: | Respiratory protective equipment (RPE) may be required for certain laboratory and large-scale manufacturing tasks if potential airborne breathing zone concentrations of substances exceed the relevant exposure limit(s). Workplace risk assessment should be completed before specifying and implementing RPE usage. Potential exposure points and pathways, task duration and frequency, potential employee contact with the substance, and the ability of the substance to be rendered airborne during specific tasks should be evaluated. Initial and ongoing strategies of quantitative exposure measurement should be obtained as required by the workplace risk assessment. All RPE must conform to local and regional specifications for efficacy and performance. Consult your site or corporate health and safety professional for additional guidance. |
| Skin Protection: | Gloves that provide an appropriate barrier to the skin are recommended if there is potential for contact with this material. Consult your site safety staff for guidance. |
| Eye Protection: | Safety glasses with side shields. Use of goggles or full face protection may be required based on hazard, potential for contact, or level of exposure. Consult your site safety staff for guidance. |
| Body Protection: | <p>In small-scale or laboratory operations, lab coats or equivalent protection is required. Disposable Tyvek or other dust impermeable suit should be considered based on procedure or level of exposure. Use of additional PPE such as shoe coverings, gauntlets, hood, or head covering may be necessary. Consult your site safety staff for guidance.</p> <p>In large-scale or manufacturing operations, disposable Tyvek or other dust impermeable suit is recommended and based on level of exposure. Use of additional PPE such as shoe coverings, gauntlets, hood, or head covering may be necessary. Consult your site safety staff for guidance.</p> |

EXPOSURE LIMIT VALUES

No exposure limits are available for the active ingredient(s) or any other hazardous ingredient in this formulation.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

FORM: Liquid
COLOR: Color not reported
ODOR: Odorless
SOLUBILITY:
Water: Not determined

See Section 5 for flammability/explosivity information.

SECTION 10. STABILITY AND REACTIVITY

STABILITY/ REACTIVITY:
Stable under normal conditions.

INCOMPATIBLE MATERIALS / CONDITIONS TO AVOID:
Strong Oxidizers.

HAZARDOUS DECOMPOSITION PRODUCTS / REACTIONS:
Possible Acrolein formation. Carbon monoxide (CO). Carbon dioxide (CO₂).

SECTION 11. TOXICOLOGICAL INFORMATION

The toxicological properties of the mixture(s) have not been fully characterized in humans or animals. The information presented below pertains to the following individual ingredients, and not to the mixture(s).

ACUTE TOXICITY DATA

INHALATION:
No data available.

SKIN:
No data available.

EYE:
No data available.

ORAL:
Altrenogest: Oral LD50: > 2000 mg/kg (rat).

DERMAL AND RESPIRATORY SENSITIZATION:
No data available.

REPEAT DOSE TOXICITY DATA

SUBCHRONIC / CHRONIC TOXICITY:
No data available.

REPRODUCTIVE / DEVELOPMENTAL TOXICITY:
Altrenogest is an experimental teratogen and caused reproductive effects in experimental animals.
Oral TDLo (10 days pre-mating): 2.5 mg/kg (female pig).
Oral TDLo (18 days pre-mating): 3 mg/kg (female pig).

MUTAGENICITY / GENOTOXICITY:
No data available.

CARCINOGENICITY:
Altrenogest shows sufficient evidence of carcinogenicity in experimental animal.

SECTION 12. ECOLOGICAL INFORMATION

ECOTOXICITY DATA

MSDS NAME: Regu-Mate Solution 0.22%

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There are no ecotoxicity data available for this product or its components.

ENVIRONMENTAL DATA

There are no environmental data available for this product or its components.

SECTION 13. DISPOSAL CONSIDERATIONS

MATERIAL WASTE:

Disposal must be in accordance with applicable federal, state/provincial, and/or local regulations. Incineration is the preferred method of disposal, when appropriate. Operations that involve the crushing or shredding of waste materials or returned goods must be handled to meet the recommended exposure limit(s).

PACKAGING AND CONTAINERS:

Disposal must be in accordance with applicable federal, state/provincial, and/or local regulations.

SECTION 14. TRANSPORT INFORMATION

This material is not subject to the transportation regulations of DOT, IATA, IMO, and the ADR.

SECTION 15. REGULATORY INFORMATION

TSCA LISTING

| INGREDIENT | TSCA |
|----------------|------|
| Benzyl Alcohol | X |

This material or product is not subject to TSCA requirements.

U.S. STATE REGULATIONS

| INGREDIENT | California Proposition 65 | CARTK | NJRTK | CTRTK | MARTK |
|----------------|---------------------------|-------|-------|-------|-------|
| Benzyl Alcohol | | | | | X |

| INGREDIENT | PARTK | MNRTK | MIRTK | RIRTK |
|----------------|-------|-------|-------|-------|
| Benzyl Alcohol | X | X | | |

Check state requirements for ingredient listing.

SECTION 16. OTHER INFORMATION

Although reasonable care has been taken in the preparation of this document, we extend no warranties and make no representations as to the accuracy or completeness of the information contained therein, and assume no responsibility regarding the suitability of this information for the user's intended purposes or for the consequence of its use. Each individual should make a determination as to the suitability of the information for their particular purpose(s).

DEPARTMENT ISSUING MSDS:

Global Safety & the Environment
Merck & Co., Inc.
One Merck Drive
Whitehouse Station, NJ 08889

MERCK MSDS HELPLINE:

(800) 770-8878 (US and Canada)
(908) 473-3371 (Worldwide)
Monday to Friday, 9am to 5pm (US Eastern Time)

MSDS CREATION DATE:

01-Feb-2012

SIGNIFICANT CHANGES (US SUBFORMAT):

Conversion

MSDS NAME: Regu-Mate Solution 0.22%

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Altrenogest (0.22%) Formulation

Version Revision Date: SDS Number: Date of last issue: 04/09/2022
2.5 10/01/2022 5842513-00007 Date of first issue: 05/08/2020

SECTION 1. IDENTIFICATION

Product name : Altrenogest (0.22%) Formulation

Manufacturer or supplier's details

Company name of supplier : Merck & Co., Inc
Address : 126 E. Lincoln Avenue
 : Rahway, New Jersey U.S.A. 07065
Telephone : 908-740-4000
Emergency telephone : 1-908-423-6000
E-mail address : EHSDATASTEWARD@merck.com

Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product

Restrictions on use : Not applicable

SECTION 2. HAZARDS IDENTIFICATION**GHS classification in accordance with the OSHA Hazard Communication Standard (29 CFR 1910.1200)**

Reproductive toxicity : Category 1B

GHS label elements

Hazard pictograms :



Signal Word : Danger

Hazard Statements : H360 May damage fertility or the unborn child.

Precautionary Statements :
Prevention:
P201 Obtain special instructions before use.
P202 Do not handle until all safety precautions have been read and understood.
P280 Wear protective gloves, protective clothing, eye protection and face protection.
Response:
P308 + P313 IF exposed or concerned: Get medical attention.
Storage:
P405 Store locked up.
Disposal:
P501 Dispose of contents and container to an approved waste disposal plant.

Altrenogest (0.22%) Formulation

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Other hazards

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

| Chemical name | CAS-No. | Concentration (% w/w) |
|----------------|----------|-----------------------|
| Benzyl alcohol | 100-51-6 | >= 1 - < 5 |
| Altrenogest | 850-52-2 | >= 0.1 - < 1 |

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 : Flush eyes with water as a precaution.
 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 : May damage fertility or the unborn child.
- 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.

SECTION 5. FIRE-FIGHTING MEASURES

- Suitable extinguishing media : Water spray
 Alcohol-resistant foam
 Carbon dioxide (CO₂)
 Dry chemical
- Unsuitable extinguishing media : None known.
- Specific hazards during fire fighting : Exposure to combustion products may be a hazard to health.
- Hazardous combustion products : Carbon oxides

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| | | | |
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- 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 (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.
Prevent spreading over a wide area (e.g., by containment or oil barriers).
Retain and dispose of contaminated wash water.
Local authorities should be advised if significant spillages cannot be contained.
- Methods and materials for containment and cleaning up : Soak up with inert absorbent material.
For large spills, provide diking or other appropriate containment to keep material from spreading. If diked material can be pumped, store recovered material in appropriate container.
Clean up remaining materials from spill with suitable absorbent.
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.
-

SECTION 7. HANDLING AND STORAGE

- Technical measures : See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.
- 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 vapors or spray mist.
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.
Take care to prevent spills, waste and minimize release to the environment.
- Conditions for safe storage : Keep in properly labeled containers.
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Materials to avoid : Keep tightly closed.
 Store in accordance with the particular national regulations.
 : Do not store with the following product types:
 Strong oxidizing agents
 Self-reactive substances and mixtures
 Organic peroxides
 Explosives
 Gases

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

| Components | CAS-No. | Value type (Form of exposure) | Control parameters / Permissible concentration | Basis |
|---------------------------|----------|----------------------------------|--|----------|
| Benzyl alcohol | 100-51-6 | TWA | 10 ppm | US WEEL |
| Altrenogest | 850-52-2 | TWA | 1 µg/m ³ (OEB 4) | Internal |
| Further information: Skin | | | | |
| | | Wipe limit | 10 µg/100 cm ² | Internal |

Engineering measures : 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. If handled in a laboratory, use a properly designed biosafety cabinet, fume hood, or other containment device if the potential exists for aerosolization. If this potential does not exist, handle over lined trays or benchtops.

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

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| | | |
|--------------------------|---|--|
| Skin and body protection | : | <p>aerosols.</p> <p>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.</p> |
| Hygiene measures | : | <p>If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place.</p> <p>When using do not eat, drink or smoke. Wash contaminated clothing before re-use.</p> <p>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.</p> |

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

| | | |
|--|---|-------------------|
| Appearance | : | liquid |
| Color | : | No data available |
| 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 | : | No data available |
| Evaporation rate | : | No data available |
| Flammability (solid, gas) | : | Not applicable |
| 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 |

Altrenogest (0.22%) Formulation

| | | | |
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| | | |
|--|---|--|
| Density | : | No data available |
| Solubility(ies) | : | |
| Water solubility | : | No data available |
| 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 |
| 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 | : | Can react with strong oxidizing agents. |
| Conditions to avoid | : | None known. |
| 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 |
| Acute inhalation toxicity | : | Acute toxicity estimate: > 200 mg/l Exposure time: 4 h Test atmosphere: dust/mist Method: Calculation method |

Altrenogest (0.22%) Formulation

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Components:**Benzyl alcohol:**

| | | |
|---------------------------|---|---|
| Acute oral toxicity | : | LD50 (Rat): 1,620 mg/kg |
| Acute inhalation toxicity | : | LC50 (Rat): > 4.178 mg/l Exposure time: 4 h Test atmosphere: dust/mist Method: OECD Test Guideline 403 |

Altrenogest:

| | | |
|---------------------|---|--|
| Acute oral toxicity | : | LD50 (Rat): 177 mg/kg LD50 (Dog): 400 mg/kg |
|---------------------|---|--|

Skin corrosion/irritation

Not classified based on available information.

Components:**Benzyl alcohol:**

| | | |
|---------|---|-------------------------|
| Species | : | Rabbit |
| Method | : | OECD Test Guideline 404 |
| Result | : | No skin irritation |

Serious eye damage/eye irritation

Not classified based on available information.

Components:**Benzyl alcohol:**

| | | |
|---------|---|--|
| Species | : | Rabbit |
| Result | : | Irritation to eyes, reversing within 21 days |
| Method | : | OECD Test Guideline 405 |

Respiratory or skin sensitization**Skin sensitization**

Not classified based on available information.

Respiratory sensitization

Not classified based on available information.

Components:**Benzyl alcohol:**

| | | |
|--------------------|---|-------------------------|
| Test Type | : | Maximization Test |
| Routes of exposure | : | Skin contact |
| Species | : | Guinea pig |
| Method | : | OECD Test Guideline 406 |
| Result | : | negative |

Altrenogest (0.22%) Formulation

| | | | |
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Species: Rat
 Application Route: Ingestion
 Result: negative
 Remarks: Based on data from similar materials

Effects on fetal development : Test Type: Embryo-fetal development
 Species: Mouse
 Application Route: Ingestion
 Result: negative

Altrenogest:

Effects on fertility : Test Type: Two-generation reproduction toxicity study
 Species: Rat
 Application Route: Oral
 Fertility: NOAEL: 0.016 mg/kg body weight
 Result: Effects on fertility., No effects on mating performance.

Test Type: Fertility/early embryonic development
 Species: Monkey, female
 Application Route: Oral
 Fertility: NOAEL: 0.004 mg/kg body weight

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

STOT-single exposure

Not classified based on available information.

STOT-repeated exposure

Not classified based on available information.

Components:

Altrenogest:

Routes of exposure : Oral
 Target Organs : Immune system, Adrenal gland
 Assessment : May cause damage to organs through prolonged or repeated exposure.

Routes of exposure : Oral
 Target Organs : Pituitary gland

Repeated dose toxicity

Components:

Benzyl alcohol:

Species : Rat
 NOAEL : 1.072 mg/l
 Application Route : inhalation (dust/mist/fume)
 Exposure time : 28 Days
 Method : OECD Test Guideline 412

Altrenogest (0.22%) Formulation

| | | | |
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Altrenogest:

| | | |
|-------------------|---|--|
| Species | : | Rat |
| NOAEL | : | 0.06 mg/kg |
| Application Route | : | Oral |
| Exposure time | : | 13 Weeks |
| Target Organs | : | Immune system, male reproductive organs, female reproductive organs, Adrenal gland |
| Remarks | : | Effects on fertility. |

| | | |
|-------------------|---|--|
| Species | : | Pig |
| NOAEL | : | 0.004 mg/kg |
| Application Route | : | Oral |
| Exposure time | : | 13 Weeks |
| Target Organs | : | male reproductive organs, female reproductive organs |
| Remarks | : | Effects on fertility. |

| | | |
|-------------------|---|---|
| Species | : | Pig |
| NOAEL | : | 0.002 mg/kg |
| Application Route | : | Oral |
| Exposure time | : | 1 y |
| Target Organs | : | male reproductive organs, Pituitary gland |
| Remarks | : | Effects on fertility. |

| | | |
|-------------------|---|--|
| Species | : | Horse |
| LOAEL | : | 220 mg/kg |
| Application Route | : | Oral |
| Exposure time | : | 86 Days |
| Remarks | : | No significant adverse effects were reported |

Aspiration toxicity

Not classified based on available information.

Experience with human exposure

Components:

Altrenogest:

| | | |
|--------------|---|--|
| Inhalation | : | Symptoms: respiratory tract irritation |
| Skin contact | : | Symptoms: Skin irritation |
| Eye contact | : | Symptoms: Eye irritation |

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Benzyl alcohol:

| | | |
|------------------|---|--|
| Toxicity to fish | : | LC50 (Pimephales promelas (fathead minnow)): 460 mg/l Exposure time: 96 h |
|------------------|---|--|

| | | |
|---|---|---|
| Toxicity to daphnia and other aquatic invertebrates | : | EC50 (Daphnia magna (Water flea)): 230 mg/l Exposure time: 48 h Method: OECD Test Guideline 202 |
|---|---|---|

Altrenogest (0.22%) Formulation

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Toxicity to algae/aquatic plants : EC50 (Pseudokirchneriella subcapitata (green algae)): 770 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

NOEC (Pseudokirchneriella subcapitata (green algae)): 310 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (Daphnia magna (Water flea)): 51 mg/l
Exposure time: 21 d
Method: OECD Test Guideline 211

Altrenogest:

Toxicity to fish (Chronic toxicity) : NOEC (Danio rerio (zebra fish)): 0.0004 µg/l
Exposure time: 32 d
Method: OECD Test Guideline 210

Persistence and degradability

Components:

Benzyl alcohol:

Biodegradability : Result: Readily biodegradable.
Biodegradation: 92 - 96 %
Exposure time: 14 d

Bioaccumulative potential

Components:

Benzyl alcohol:

Partition coefficient: n-octanol/water : log Pow: 1.05

Altrenogest:

Partition coefficient: n-octanol/water : log Pow: 3.78

Mobility in soil

Components:

Altrenogest:

Distribution among environmental compartments : log Koc: 3.3

Other adverse effects

No data available

Altrenogest (0.22%) Formulation

| | | | |
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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

UN number : UN 3082
 Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (altrenogest)
 Class : 9
 Packing group : III
 Labels : 9

IATA-DGR

UN/ID No. : UN 3082
 Proper shipping name : Environmentally hazardous substance, liquid, n.o.s. (Altrenogest)
 Class : 9
 Packing group : III
 Labels : Miscellaneous
 Packing instruction (cargo aircraft) : 964
 Packing instruction (passenger aircraft) : 964
 Environmentally hazardous : yes

IMDG-Code

UN number : UN 3082
 Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Altrenogest)
 Class : 9
 Packing group : III
 Labels : 9
 EmS Code : F-A, S-F
 Marine pollutant : yes

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

UN/ID/NA number : UN 3082
 Proper shipping name : Environmentally hazardous substance, liquid, n.o.s. (Altrenogest)
 Class : 9
 Packing group : III

Altrenogest (0.22%) Formulation

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| | | |
|------------------|---|---|
| Labels | : | CLASS 9 |
| ERG Code | : | 171 |
| Marine pollutant | : | yes(Altrenogest) |
| Remarks | : | Above applies only to containers over 119 gallons or 450 liters. Shipment by ground under DOT is non-regulated; however it may be shipped per the applicable hazard classification to facilitate multi-modal transport involving ICAO (IATA) or IMO. |

Special precautions for user

The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

SECTION 15. REGULATORY INFORMATION

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 : Reproductive toxicity

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

| | |
|---|------------|
| Glycerides, mixed decanoyl and octanoyl | 73398-61-5 |
| Benzyl alcohol | 100-51-6 |

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

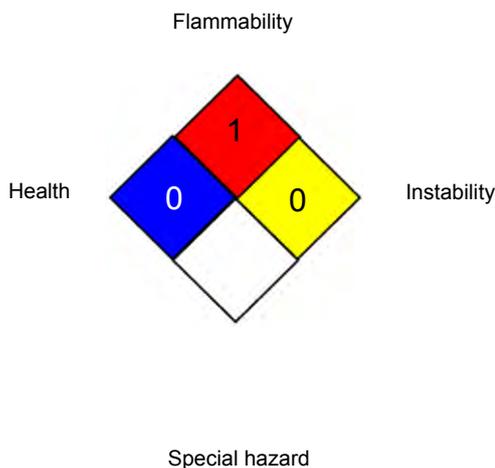
SAFETY DATA SHEET



Altrenogest (0.22%) Formulation

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Date of first issue: 05/08/2020

NFPA 704:



HMIS® IV:

| | | |
|-----------------|---|---|
| HEALTH | * | 0 |
| FLAMMABILITY | | 1 |
| 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

US WEEL : USA. Workplace Environmental Exposure Levels (WEEL)
US WEEL / TWA : 8-hr TWA

AIIC - Australian Inventory of Industrial Chemicals; 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; TECL - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act

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(United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

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

Revision Date : 10/01/2022

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.

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