



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): Rocky Mountain Poison Center (For Human Exposure):
(303) 595-4869

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

(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:

SECTION 2. HAZARDS IDENTIFICATION

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, while wearing protective gloves, carefully remove any contaminated clothing, including shoes, and wash skin thoroughly with soap and water. If irritation or symptoms occur or persist, consult a physician.

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).

SECTION 5. FIRE FIGHTING MEASURES

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.

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

The following guidance applies to the handling of the active ingredient(s) in this formulation. The end-user should perform an appropriate risk assessment when handling other forms or formulations of this active ingredient.

OCCUPATIONAL EXPOSURE BAND (OEB):

Altrenogest: OEB 4: $\geq 1 < 10$ mcg/m³. Materials in an OEB 4 category are considered high health hazards. The OEB is range of airborne concentrations expressed as an 8-hour Time Weighted Average (8-hr. TWA) and is intended to be used with Industrial Hygiene Risk Assessment to assist with industrial hygiene sampling and selection of proper controls for worker protection. Consult your site safety and industrial hygiene staff for guidance on handling and control strategies.

OEB/OEL NOTATION(S):

Altrenogest: This material has a notation of "S" for its ability to cause systemic toxicity through skin absorption.

INTERNAL OCCUPATIONAL EXPOSURE LIMIT (8-hr TWA):

Altrenogest: 1 mcg/m³

Wipe Limit:

Altrenogest: 10 mcg/100cm²

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: 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.
- 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.

EXPOSURE LIMIT VALUES

See Internal Occupational Exposure Limit listed above.

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

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	CTRTRK	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

SECTIONS CHANGED (US SUBFORMAT):
SIGNIFICANT CHANGES (US SUBFORMAT):

1, 4, 8
Phone Number(s), OEL, OEB, Wipe Limit