#059423
Revalor 200
Implants 052517

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: **Revalor XS**

SYNONYM(S):
Revalor XS
Revalor
Revalor LA (Duplo)
Revalor G
Revalor H
Revalor 200
Revalor-S
Revalor-IS
Revalor-IH
Trenbolone acetate

MSDS NUMBER: SP002133

EMERGENCY NUMBER(S): (908) 423-6000 (24/7/365) English Only

Transportation Emergencies - CHEMTREC:
(800) 424-9300 (Inside Continental USA)
(703) 527-3887 (Outside Continental USA)

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

INFORMATION:
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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

Pellets
Yellow
Odor unknown
May cause cancer.
May cause impaired fertility.
May cause harm to the unborn child.
Prolonged exposure may cause serious health effects.
Causes effects to:
endocrine system
May cause effects to:
gastrointestinal tract
central nervous system
cardiovascular system
male reproductive system
female reproductive system
breast
fetus
Harmful to aquatic life with long lasting effects.

POTENTIAL HEALTH EFFECTS:

The toxicological properties of the mixture(s) have not been fully characterized in humans or animals. However, there are data to describe the toxicological properties of the individual ingredients. The following summary is based upon available information about the individual ingredients of the mixture(s), or of the expected properties of the mixture(s).

Trenbolone acetate, an androgenic (anabolic) steroid, is harmful with prolonged or repeated exposure by inhalation, in contact with skin, or if swallowed. Symptoms of exposure may inlcude headache, gastrointestinal complaints, dizziness, tremor, sweating, vomiting, nausea, water retention and sodium retention. Effects of overexposure may include effects as for androgens in general: androgenic and anabolic activity, changes in libido, reversible gynecomastia in male, effects on fertility and effects on menstruation.

Estradiol, an estrogen/oestrogen, is harmful with repeated or prolonged exposure by inhalation, skin absorption, or if swallowed. Symptoms of exposure may include headache, gastrointestinal complaints, nausea, dizziness, vomiting, diarrhea, water retention and sodium retention. Effects of overexposure may include effects as for estrogens in general: effects on menstruation in female, edema, reversible gynecomastia in male; may cause tenderness of breasts, changes in libido. Exposure to Estradiol may pose a possible risk of harm to the unborn child and may impair fertility. There is evidence of a carcinogenic effect.

Estradiol is an estrogen hormone normally produced by the ovary and is a metabolite of testosterone. Adverse effects observed during clinical therapy with estradiol include central nervous system effects (e.g. headaches, dizziness, nervousness, mood disturbances, or irritability), changes in body weight, leg cramps, water retention, visual disturbances, gastrointestinal effects, cardiovascular effects (e.g. chest pain, increases in blood pressure, blood clots, heart attacks, or stroke), skin reactions (e.g. contact dermatitis, pruritus, or rash), or effects to breasts (e.g. tenderness, enlargement, or pain). Estrogens have also been shown to cause increased incidences in ovarian, breast, or endometrial cancer. Estrogen administration has been shown to decrease the quantity and quality of breast milk. Estrogens have also been shown to be present in breast milk.

LISTED CARCINOGENS

INGREDIENT	CAS NUMBER	OSHA	IARC	NTP	ACGIH
Estradiol	50-28-2		1		

1 (IARC): IARC Group 1 - Carcinogenic to Humans

SECTION 3. COMPOSITION AND INFORMATION ON INGREDIENTS

CHEMICAL FAMILY: Bovine Pharmaceuticals, Androgenic (anabolic) steroids.

PRODUCT USE: Veterinary product

CHEMICAL FORMULA: Mixture.

The formulations for these products are proprietary information. These formulations have the same hazardous profile; however, the presence of hazardous ingredients may vary by formulation. 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
Trenbolone Acetate	10161-34-9	58.65 - 74.0
Estradiol	50-28-2	7.4 - 12.5
Magnesium Stearate	557-04-0	<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. Administer artificial respiration if breathing has ceased. IMMEDIATELY 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. Treat symptomatically.

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: Do not induce vomiting unless under the direction of a qualified medical professional or Poison Control Center. IMMEDIATELY consult a physician. Do not attempt to give anything by mouth to a seizing, drowsy or unconscious person. If alert, rinse mouth and drink a glass of water.

SECTION 5. FIRE FIGHTING MEASURES

FLAMMABILITY DATA:

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

EXPLOSION HAZARDS:
Under normal conditions of use, this material does not present a significant fire or explosion hazard. However, like most organic compounds, this material may present a dust deflagration hazard if sufficient quantities are suspended in air. This hazard may exist where sufficient quantities of finely divided material are (or may become) suspended in air during typical process operations. An assessment of each operation should be conducted and suitable deflagration prevention and protection techniques employed. The sensitivity of this material to ignition by electrostatic discharges has not been determined. In the absence of testing data, all conductive plant items and operations personnel handling this material should be suitably grounded.

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.

ENVIRONMENTAL PRECAUTIONS:
This product is harmful to aquatic organisms. Do not allow product to reach ground water, water course, sewage or drainage systems.

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.

STORAGE:
Store in a cool, dry, well ventilated area.

SPECIAL PRECAUTIONS:
Keep out of the reach of children.

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):
OEB 5: <1 mcg/m^3. Materials in an OEB 5 category are considered extreme health hazards. The OEB is a 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):
Estradiol: This material has a notation of "S" for its ability to cause systemic toxicity through skin absorption.

INTERNAL OCCUPATIONAL EXPOSURE LIMIT (8-hr TWA):
0.2 mcg/m^3 for Trenbolone Acetate
0.05 mcg/m^3 for Estradiol

Wipe Limit:
2 mcg/100 cm2 for Trenbolone Acetate
0.5 mcg/100 cm2 for Estradiol

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

INGREDIENT	CAS NUMBER	ACGIH TLV (TWA)	OSHA PEL (TWA)
Magnesium Stearate	557-04-0	10 mg/m^3	

See Internal Occupational Exposure Limit listed above.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

FORM: Pellets
COLOR: Yellow
ODOR: Odor unknown
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:
None known.

HAZARDOUS POLYMERIZATION PRODUCTS / REACTIONS:
Does not occur.

HAZARDOUS DECOMPOSITION PRODUCTS / REACTIONS:
No dangerous decomposition is expected if used according to manufacturer's specifications.

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:
Trenbolone Acetate: Oral LD50: >5000 mg/kg (Rat) Trenbolone Acetate: Oral LD50: 2700 mg/kg (Mouse)

Estradiol: Oral LD50: >2000 mg/kg (Rat)

DERMAL AND RESPIRATORY SENSITIZATION:
No data available.

REPEAT DOSE TOXICITY DATA

SUBCHRONIC / CHRONIC TOXICITY:
Estradiol had an oral TDLo (1 day pre-mating) as low as 4.195 ug/kg in rats by showing maternal effects in a developmental study. [Oral TDLo (1 day pre-mating): 4.195 ug/kg (rats)].

Estradiol had an oral TDLo (3 day pre-mating) as low as 0.667 ug/kg in mice by showing maternal effects in a developmental study. [Oral TDLo (3 day pre-mating): 0.667 ug/kg (rats)].

A repeat oral subchronic toxicity study in rats resulted in a dose-dependent increase in feed intake and body weight at doses from 0.17 to 4.1 mg/kg per day. At 0.69 to 4.1 mg/kg per day there were effects including slight anemia, lymphopenia, and decreased serum cholesterol. Changes in weights of varous organs also occured. Ovarian dysfunction occured at doses from 0.17 to 4.1 mg/kg per day. Effects in both sexes occurred from 0.69 to 4.1 mg/kg per day and included liver hypertrophia, pituitary hyperplasia, endometrial hypertrophia, testicular epithelia degeneration and testicular atrophy.

REPRODUCTIVE / DEVELOPMENTAL TOXICITY:
Female cattle dosed subcutaneously at either 48 weeks premating days or 1 to 28 after conception with 4 mg/kg Trenbolone Acetate showed maternal effect including changes in the uterus, cervix or vagina as well as efffects on menstruation.

Rats were given subcutaneous injections of 0.8 to 0.35 mg/day estradiol on gestation days 12 to 21. Reductions of litter size and increases in post-partum mortality were observed. Abnormalities of the reproductive tract and absence of corpora lutea were observed in female offspring, and well developed nipples, undescended testes and impairment of Wolffian-derived tissue was observed in male offspring. In mice, abnormal estrous cycles and abnormalities of the cervicovaginal epithelium were observed in the female offspring of mice given 0.5 mg on day 15 of gestation. Cleft palate was observed in the offspring of mice injected subcutaneously with 0.1 to 0.2 mg/day of estradiol 3-benzoate on days 11 to 16 of gestation.

Estradiol is an experimental teratogen. It has been shown to cause reproductive effects in humans and experimental animals.

Oral TDLo (31 week(s) pre-mating): 4400 ug/kg (Human Female)
Oral TDLo (1 day pre-mating): 50 ug/kg (rabbit); Study showed effects on fertility.

Subcutaneous developmental studies in rats dosed from 50 to 250 ug during pregnancy resulted in effects such as resorptions of embryos, decreased number of fetuses or litter size, and fetal mortality.

Estradiol caused malformations experimentally. Disturbances also occurred in humans. The lowest Estradiol concentration which caused effects in a one-generation rat reproductive study was 0.0025 mg/kg . This effect at 0.0025 mg/kg was decreased pupweight.

MUTAGENICITY / GENOTOXICITY:
Estradiol was negative in an in vivo bone-marrow chromosomal aberration study in mice. In treated hamsters, unusual nucleotides were found in kidney DNA. It was positive for inducing micronuclei, chromosomal aberrations, and sister chromatid exchanges in human cells in vitro. In rodent cells in vitro, it induced aneuploidy and unscheduled DNA synthesis; however, it did not induce DNA strand breaks or sister chromatid exchanges. It was negative in bacterial mutagenicty assays.

CARCINOGENICITY:
Trenbolone Acetate showed limited evidence of a carcinogenic effect.

Chronic oral and subcutaneous studies with estradiol and its esters have been conducted in mice, rats, hamsters, and guinea-pigs. Increased incidences of mammary, pituitary, uterine, cervical, vaginal, testicular, lymphoid, bone, or kidney tumors were observed.

SECTION 12. ECOLOGICAL INFORMATION

There are no data for the final product or its formulation(s). The information presented below pertains to the following ingredient(s).

ECOTOXICITY DATA

INGREDIENT ECOTOXICITY

Estradiol: Acute Toxicity:
LC50: 3.9 mg/L (Fish, Oryzias Lapites, 96h)
EC50: 37 mg/L (Crustacea, Daphnia magna, 96h)
Estradiol Chronic Toxicity:
NOEC: 2.9 ng/L (Fish, Oryzias Lapites, reproduction)
NOEC: 10 ng/L (Crustacea, Penaens esculentus)

ENVIRONMENTAL DATA

Partition Coefficient (log Pow) Results: 4.01 (Estradiol)

ENVIRONMENTAL FATE AND EFFECTS:
Estradiol is not readily biodegradable based on studies showing a half life of 4 to 8 days in water.
has an absorption/desoprtion coefficeint (log Koc) in sludge of 5.11. The absorption/desoprtion coefficent (log Koc) in soil is 3.14 to 5.38.

Estradiol: Fish bioconcentration factor (BCF): 800; Mollusk bioconcentration factor (BCF): 840 Estradiol: Results of PBT assessment: negative. Results of vPvB assessment: negative.

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
Magnesium Stearate	X

Substances not included in the table above are TSCA exempt or not regulated under TSCA.

U.S. STATE REGULATIONS

INGREDIENT	California Proposition 65	CARTK	NJRTK	CTRTK	MARTK
Estradiol	C	X			X

INGREDIENT	PARTK	MNRTK	MIRTK	RIRTK
Estradiol	X	X		X
Magnesium Stearate		X		

Fields in the above tables that do not contain data indicate that those materials have not been listed by local regulations. "WARNING: This product contains a chemical known to the State of California to cause cancer."

X: Listed on applicable state hazardous substance or right-to-know lists.
C: Carcinogen

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).

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SECTIONS CHANGED (US SUBFORMAT):
New3 SDS
SIGNIFICANT CHANGES (US SUBFORMAT):
New regional format