

SAFETY DATA SHEETS

This SDS packet was issued with item:

078705139

N/A



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: 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

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 include 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.

MSDS NAME: Revalor XS

MSDS NUMBER: SP002133

Latest Revision Date: 16-May-2012

Page 2 of 7

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.

MSDS NAME: Revalor XS

MSDS NUMBER: SP002133

Latest Revision Date: 16-May-2012

Page 3 of 7

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.

OCCUPATIONAL EXPOSURE BAND (OEB):

OEB 5: <1 mcg/m³. 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.

OCCUPATIONAL EXPOSURE GUIDELINE (OEG):

Internal Occupational Exposure Limit of 0.05 mcg/m³ (8-hr TWA) for estradiol.

Internal Occupational Exposure Limit of 0.2 mcg/m³ (8-hr TWA) for Trenbolone acetate.

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 Occupational Exposure Guideline (OEG) 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

MSDS NAME: Revalor XS

MSDS NUMBER: SP002133

Latest Revision Date: 16-May-2012

Page 5 of 7

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 various organs also occurred. Ovarian dysfunction occurred 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 hypertrophy, pituitary hyperplasia, endometrial hypertrophy, testicular epithelia degeneration and testicular atrophy.

REPRODUCTIVE / DEVELOPMENTAL TOXICITY:

Female cattle dosed subcutaneously at either 48 weeks pre-mating 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 effects 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 mutagenicity 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 Latipes*, 96h)
EC50: 37 mg/L (Crustacea, *Daphnia magna*, 96h)
Estradiol Chronic Toxicity:
NOEC: 2.9 ng/L (Fish, *Oryzias Latipes*, reproduction)
NOEC: 10 ng/L (Crustacea, *Pennaescutentus*)

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/desorption coefficient (log Koc) in sludge of 5.11. The absorption/desorption coefficient (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.

MSDS NAME: Revalor XS

MSDS NUMBER: SP002133

Latest Revision Date: 16-May-2012

Page 6 of 7

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	CTR TK	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).

DEPARTMENT ISSUING MSDS:

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

MERCK MSDS HELPLINE:

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(908) 473-3371 (Worldwide)
Monday to Friday, 9am to 5pm (US Eastern Time)

MSDS CREATION DATE:

16-May-2012

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

New3 SDS
New regional format

MSDS NAME: Revalor XS

MSDS NUMBER: SP002133

Latest Revision Date: 16-May-2012

Page 7 of 7

Trenbolone / Estradiol Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 05/18/2017
4.2	06/01/2017	28298-00008	Date of first issue: 11/05/2014

SECTION 1. IDENTIFICATION

Product name : Trenbolone / Estradiol Formulation

Manufacturer or supplier's details

Company name of supplier : Merck & Co., Inc

Address : 2000 Galloping Hill Road
Kenilworth - New Jersey - USA 1685

Telephone : 908-740-4000

Telefax : 908-735-1496

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

SECTION 2. HAZARDS IDENTIFICATION**GHS classification in accordance with 29 CFR 1910.1200**

Combustible dust

Carcinogenicity : Category 1A

Reproductive toxicity : Category 1A

Specific target organ
systemic toxicity - repeated
exposure : Category 1 (Liver, Bone, Blood)

Specific target organ
systemic toxicity - repeated
exposure (Oral) : Category 1 (Endocrine system, Blood)

GHS label elements

Hazard pictograms :



Signal Word : Danger

Hazard Statements : If small particles are generated during further processing, handling or by other means, may form combustible dust concentrations in air.
H350 May cause cancer.

Trenbolone / Estradiol Formulation

Version Revision Date: SDS Number: Date of last issue: 05/18/2017
4.2 06/01/2017 28298-00008 Date of first issue: 11/05/2014

H360FD May damage fertility. May damage the unborn child.
H372 Causes damage to organs (Liver, Bone, Blood) through prolonged or repeated exposure.
H372 Causes damage to organs (Endocrine system, Blood) through prolonged or repeated exposure if swallowed.

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

Substance / Mixture : Mixture

Hazardous ingredients

Chemical name	CAS-No.	Concentration (% w/w)
17 β -hydroxyestra-4,9,11-trien-3-one 17-acetate	10161-34-9	≥ 50 - < 70
estradiol	50-28-2	≥ 10 - < 20

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

Trenbolone / Estradiol Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 05/18/2017
4.2	06/01/2017	28298-00008	Date of first issue: 11/05/2014

- 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 : Contact with dust can cause mechanical irritation or drying of the skin.
Dust contact with the eyes can lead to mechanical irritation.
May cause cancer.
May damage fertility. May damage the unborn child.
Causes damage to organs through prolonged or repeated exposure.
- 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.
- 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
- 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.

Trenbolone / Estradiol Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 05/18/2017
4.2	06/01/2017	28298-00008	Date of first issue: 11/05/2014

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 spillages 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 certain local or national requirements.

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 : 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.
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.

Trenbolone / Estradiol Formulation

Version 4.2 Revision Date: 06/01/2017 SDS Number: 28298-00008 Date of last issue: 05/18/2017
 Date of first issue: 11/05/2014

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

Ingredients	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
17 β -hydroxyestra-4,9,11-trien-3-one 17-acetate	10161-34-9	TWA	0.2 μ g/m ³ (OEB 5)	Merck
		Wipe limit	2 μ g/100 cm ²	Merck
estradiol	50-28-2	TWA	0.05 μ g/m ³	Merck
	Further information: Skin			
		Wipe limit	0.5 μ g/100 cm ²	Merck

Engineering measures : Minimize workplace exposure concentrations.
 Apply measures to prevent dust explosions.
 Ensure that dust-handling systems (such as exhaust ducts, dust collectors, vessels, and processing equipment) are designed in a manner to prevent the escape of dust into the work area (i.e., there is no leakage from the equipment).
 Use with local exhaust ventilation.
 Dust formation may be relevant in the processing of this product. In addition to substance-specific OELs, general limitations of concentrations of particulates in the air at workplaces have to be considered in workplace risk assessment. Relevant limits include: OSHA PEL for Particulates Not Otherwise Regulated of 15 mg/m³ - total dust, 5 mg/m³ - respirable fraction; and ACGIH TWA for Particles (insoluble or poorly soluble) Not Otherwise Specified of 3 mg/m³ - respirable particles, 10 mg/m³ - inhalable particles.

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

Trenbolone / Estradiol Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 05/18/2017
4.2	06/01/2017	28298-00008	Date of first issue: 11/05/2014

Material	:	Chemical-resistant gloves
Remarks	:	Choose gloves to protect hands against chemicals depending on the concentration specific to place of work. Breakthrough time is not determined for the product. Change gloves often! For special applications, we recommend clarifying the resistance to chemicals of the aforementioned protective gloves with the glove manufacturer. Wash hands before breaks and at the end of workday.
Eye protection	:	Wear the following personal protective equipment: Safety goggles
Skin and body protection	:	Select appropriate protective clothing based on chemical resistance data and an assessment of the local exposure potential. Skin contact must be avoided by using impervious protective clothing (gloves, aprons, boots, etc).
Hygiene measures	:	Ensure that eye flushing systems and safety showers are located close to the working place. When using do not eat, drink or smoke. Wash contaminated clothing before re-use.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	:	powder
Color	:	yellow
Odor	:	No information available.
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 explosive dust-air mixture during processing, handling or other means.
Flammability (liquids)	:	No data available
Upper explosion limit / Upper	:	No data available

Trenbolone / Estradiol Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 05/18/2017
4.2	06/01/2017	28298-00008	Date of first issue: 11/05/2014

flammability limit

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

Solubility(ies)
Water solubility : No data availablePartition 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 reac-
tions : Dust can form an explosive mixture in air.
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

Trenbolone / Estradiol Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 05/18/2017
4.2	06/01/2017	28298-00008	Date of first issue: 11/05/2014

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

Ingredients:**17 β -hydroxyestra-4,9,11-trien-3-one 17-acetate:**

Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg
LD50 (Mouse): 2,700 mg/kg

estradiol:

Acute oral toxicity : LD50 (Rat): > 2,000 mg/kg

Acute toxicity (other routes of administration) : LC50 (Rat): > 300 mg/kg

Skin corrosion/irritation

Not classified based on available information.

Serious eye damage/eye irritation

Not classified based on available information.

Ingredients:**estradiol:**

Result: No eye irritation

Respiratory or skin sensitization**Skin sensitization**

Not classified based on available information.

Respiratory sensitization

Not classified based on available information.

Ingredients:**estradiol:**

Routes of exposure: Skin contact
Species: Guinea pig
Assessment: Does not cause skin sensitization.
Result: negative

Germ cell mutagenicity

Not classified based on available information.

Trenbolone / Estradiol Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 05/18/2017
4.2	06/01/2017	28298-00008	Date of first issue: 11/05/2014

Ingredients:**17 β -hydroxyestra-4,9,11-trien-3-one 17-acetate:**

Genotoxicity in vitro	:	Test Type: Bacterial reverse mutation assay (AMES) Species: Salmonella typhimurium Result: negative
	:	Test Type: Micronucleus test Species: Chinese hamster fibroblasts Result: negative
Genotoxicity in vivo	:	Test Type: Micronucleus test Species: Mouse Result: negative
	:	Test Type: Micronucleus test Species: Rat Result: negative
Germ cell mutagenicity - Assessment	:	Weight of evidence does not support classification as a germ cell mutagen.

estradiol:

Genotoxicity in vitro	:	Test Type: DNA damage and repair, unscheduled DNA synthesis in mammalian cells (in vitro) Species: mammalian cells Result: positive
	:	Test Type: Chromosome aberration test in vitro Species: mammalian cells Result: positive
	:	Test Type: Chromosomal aberration Species: mammalian cells Result: positive
Genotoxicity in vivo	:	Test Type: Chromosomal aberration Species: Rat Cell type: Bone marrow Result: negative
	:	Test Type: Chromosomal aberration Species: Mouse Cell type: Bone marrow Result: negative

Carcinogenicity

May cause cancer.

Ingredients:**17 β -hydroxyestra-4,9,11-trien-3-one 17-acetate:**Species: Mouse, (male and female)
Application Route: Oral

Trenbolone / Estradiol Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 05/18/2017
4.2	06/01/2017	28298-00008	Date of first issue: 11/05/2014

Result: positive
Target Organs: Liver

Species: Rat, (male and female)
Application Route: Oral
Result: positive
Target Organs: Pancreas

Carcinogenicity - Assessment : Limited evidence of carcinogenicity in animal studies

estradiol:

Species: Mouse
Application Route: Ingestion
Exposure time: 24 Months
100 µg/kg
Result: positive
Target Organs: female reproductive organs

Species: Rat
Application Route: Subcutaneous
Exposure time: 13 weeks
20 mg/kg body weight
Result: positive
Target Organs: Endocrine system

Carcinogenicity - Assessment : Positive evidence from human epidemiological studies

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

Known to be human carcinogen

estradiol

50-28-2

Reproductive toxicity

May damage fertility. May damage the unborn child.

Ingredients:**17β-hydroxyestra-4,9,11-trien-3-one 17-acetate:**

Effects on fertility : Test Type: Two-generation study
Species: Rat
Application Route: Oral
Fertility: LOAEL: 0.18 mg/kg body weight
Result: Postimplantation loss.

Effects on fetal development : Test Type: Embryo-fetal development
Species: Rat

Trenbolone / Estradiol Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 05/18/2017
4.2	06/01/2017	28298-00008	Date of first issue: 11/05/2014

- Application Route: oral (feed)
 Developmental Toxicity: LOAEL: 20 mg/kg body weight
 Result: Malformations were observed.
- Reproductive toxicity - Assessment : Some evidence of adverse effects on sexual function and fertility, based on animal experiments., Some evidence of adverse effects on development, based on animal experiments.
- estradiol:**
- Effects on fertility : Test Type: One-generation reproduction toxicity study
 Species: Rat
 Application Route: Ingestion
 Fertility: LOAEL: 0.5 mg/kg body weight
 Result: Effects on fertility.
- Test Type: One-generation reproduction toxicity study
 Species: Rat
 Duration of Single Treatment: 90 d
 Fertility: LOAEL: 0.69 mg/kg body weight
 Result: Effects on fertility.
- Test Type: Two-generation study
 Species: Mouse
 Application Route: Oral
 Fertility: LOAEL: 0.1 mg/kg body weight
 Result: Effects on fertility.
- Effects on fetal development : Test Type: Embryo-fetal development
 Species: Mouse, female
 Application Route: Subcutaneous
 Teratogenicity: LOAEL: 4 mg/kg body weight
 Symptoms: Malformations were observed.
 Result: positive, Teratogenic effects.
- Test Type: One-generation reproduction toxicity study
 Species: Rat
 Application Route: Subcutaneous
 Teratogenicity: LOAEL: 0.002 mg/kg body weight
 Symptoms: Reduced body weight
 Result: positive, Embryotoxic effects and adverse effects on the offspring were detected.
- Test Type: Embryo-fetal development
 Species: Rat
 Application Route: Subcutaneous
 Developmental Toxicity: LOAEL: \geq 0.2 mg/kg body weight
 Symptoms: Early Resorptions / resorption rate., Reduced number of viable fetuses., Reduced body weight
 Result: Embryotoxic effects and adverse effects on the offspring were detected only at high maternally toxic doses
- Reproductive toxicity - Assessment : Positive evidence of adverse effects on sexual function and fertility from human epidemiological studies., Clear evidence

Trenbolone / Estradiol Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 05/18/2017
4.2	06/01/2017	28298-00008	Date of first issue: 11/05/2014

of adverse effects on development, based on animal experiments.

STOT-single exposure

Not classified based on available information.

STOT-repeated exposure

Causes damage to organs (Liver, Bone, Blood) through prolonged or repeated exposure.

Causes damage to organs (Endocrine system, Blood) through prolonged or repeated exposure if swallowed.

Ingredients:**17 β -hydroxyestra-4,9,11-trien-3-one 17-acetate:**

Routes of exposure: Ingestion

Target Organs: Endocrine system, Blood

Assessment: Causes damage to organs through prolonged or repeated exposure.

estradiol:

Target Organs: Liver, Bone, Blood

Assessment: Causes damage to organs through prolonged or repeated exposure.

Repeated dose toxicity**Ingredients:****17 β -hydroxyestra-4,9,11-trien-3-one 17-acetate:**

Species: Pig

NOAEL: 0.004 mg/kg

LOAEL: 0.08 mg/kg

Exposure time: 14 Weeks

Target Organs: Testes, Ovary, Liver, Uterus (including cervix)

Species: Rat

NOAEL: 0.04 mg/kg

LOAEL: 3.6 mg/kg

Application Route: Oral

Exposure time: 23 Weeks

Target Organs: Blood

Species: Monkey, female

NOAEL: 0.01 mg/kg

LOAEL: 0.04 mg/kg

Application Route: Oral

Exposure time: 122 Days

Target Organs: female reproductive organs

Species: Monkey, males

NOAEL: 0.002 mg/kg

LOAEL: 0.04 mg/kg

Application Route: Oral

Exposure time: 30 Days

Target Organs: male reproductive organs

Trenbolone / Estradiol Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 05/18/2017
4.2	06/01/2017	28298-00008	Date of first issue: 11/05/2014

Species: Rat
NOAEL: 0.05 mg/kg
LOAEL: 0.1 mg/kg
Application Route: Oral
Exposure time: 3 Months
Target Organs: male reproductive organs, Ovary, Uterus (including cervix)

estradiol:

Species: Rat
LOAEL: ≥ 0.17 mg/kg
Application Route: Ingestion
Exposure time: 90 d
Target Organs: Mammary gland, Ovary, Uterus (including cervix), Liver, Bone, Endocrine system, Blood, Testes

Aspiration toxicity

Not classified based on available information.

Experience with human exposure**Ingredients:****17 β -hydroxyestra-4,9,11-trien-3-one 17-acetate:**

Ingestion : Symptoms: male reproductive effects, gynecomastia, changes in libido

estradiol:

Inhalation : Symptoms: tingling, Nose bleeding

Skin contact : Symptoms: Skin irritation, Redness, pruritis

Ingestion : Symptoms: Headache, Gastrointestinal disturbance, Dizziness, Vomiting, Diarrhea, water retention, liver function change, changes in libido, breast tenderness

SECTION 12. ECOLOGICAL INFORMATION**Ecotoxicity****Ingredients:****17 β -hydroxyestra-4,9,11-trien-3-one 17-acetate:**

Toxicity to fish (Chronic toxicity) : NOEC (Pimephales promelas (fathead minnow)): 0.000035 mg/l
Exposure time: 21 d
Method: OECD Test Guideline 229
Remarks: Based on data from similar materials

M-Factor (Chronic aquatic toxicity) : 1,000

estradiol:

Trenbolone / Estradiol Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 05/18/2017
4.2	06/01/2017	28298-00008	Date of first issue: 11/05/2014

Toxicity to fish	:	LC50 (Oryzias latipes (Japanese medaka)): 3.9 mg/l Exposure time: 96 h
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia magna (Water flea)): 2.7 mg/l Exposure time: 48 h
Toxicity to algae	:	NOEC (Pseudokirchneriella subcapitata (green algae)): 1.7 mg/l Exposure time: 72 h Method: OECD Test Guideline 201 EC50 (Pseudokirchneriella subcapitata (green algae)): > 1.7 mg/l Exposure time: 72 h Method: OECD Test Guideline 201
Toxicity to fish (Chronic toxicity)	:	NOEC (Oryzias latipes (Orange-red killifish)): 0.000003 mg/l Exposure time: 160 d Method: OECD Test Guideline 210
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	:	NOEC (Daphnia magna (Water flea)): 0.2 mg/l Exposure time: 21 d
M-Factor (Chronic aquatic toxicity)	:	10,000
Toxicity to microorganisms	:	EC50: > 100 mg/l Exposure time: 3 h Test Type: Respiration inhibition Method: OECD Test Guideline 209 NOEC: 100 mg/l Exposure time: 3 h Test Type: Respiration inhibition Method: OECD Test Guideline 209

Persistence and degradability

No data available

Bioaccumulative potential**Ingredients:****17 β -hydroxyestra-4,9,11-trien-3-one 17-acetate:**

Partition coefficient: n-octanol/water : log Pow: 3.77

estradiol:

Partition coefficient: n-octanol/water : log Pow: 4.01

Trenbolone / Estradiol Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 05/18/2017
4.2	06/01/2017	28298-00008	Date of first issue: 11/05/2014

Mobility in soil**Ingredients:****estradiol:**

Distribution among environmental compartments : log Koc: 3.81

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**

UN number : UN 3077

Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.
(estradiol, 17 β -hydroxyestra-4,9,11-trien-3-one 17-acetate)

Class : 9

Packing group : III

Labels : 9

IATA-DGR

UN/ID No. : UN 3077

Proper shipping name : Environmentally hazardous substance, solid, n.o.s.
(estradiol, 17 β -hydroxyestra-4,9,11-trien-3-one 17-acetate)

Class : 9

Packing group : III

Labels : Miscellaneous

Packing instruction (cargo aircraft) : 956

Packing instruction (passenger aircraft) : 956

IMDG-Code

UN number : UN 3077

Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.
(estradiol, 17 β -hydroxyestra-4,9,11-trien-3-one 17-acetate)

Class : 9

Packing group : III

Labels : 9

EmS Code : F-A, S-F

Trenbolone / Estradiol Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 05/18/2017
4.2	06/01/2017	28298-00008	Date of first issue: 11/05/2014

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 3077
Proper shipping name	: Environmentally hazardous substance, solid, n.o.s. (estradiol, 17 β -hydroxyestra-4,9,11-trien-3-one 17-acetate)
Class	: 9
Packing group	: III
Labels	: CLASS 9
ERG Code	: 171
Marine pollutant	: yes(estradiol, 17 β -hydroxyestra-4,9,11-trien-3-one 17-acetate)
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.

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 : Fire Hazard
Chronic Health Hazard

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**

17 β -hydroxyestra-4,9,11-trien-3-one 17-acetate	10161-34-9
Cholesterol	57-88-5
estradiol	50-28-2
Polyglactin	26780-50-7

California Prop. 65

WARNING! This product contains a chemical known in the State of California to cause cancer.
estradiol 50-28-2

Trenbolone / Estradiol Formulation

Version 4.2 Revision Date: 06/01/2017 SDS Number: 28298-00008 Date of last issue: 05/18/2017
 Date of first issue: 11/05/2014

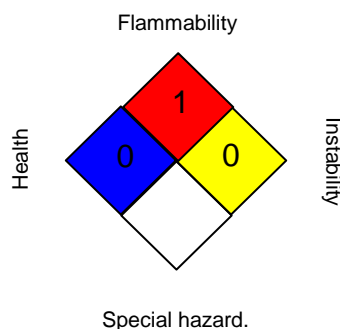
California List of Hazardous Substances

estradiol

50-28-2

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:****HMIS® IV:**

HEALTH	*	3
FLAMMABILITY		3
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

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)

Trenbolone / Estradiol Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 05/18/2017
4.2	06/01/2017	28298-00008	Date of first issue: 11/05/2014

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

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 : 06/01/2017

Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

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