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SAFETY DATA SHEET

This SDS was created in accordance with Regulation EC 1907/2006 and all amendments. Merck urges each user or recipient of this SDS to read the entire data sheet to become aware of the hazards associated with this material.

SECTION 1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

PRODUCT IDENTIFIER

SDS NAME: SUSTANON-250 A1

SYNONYM(S): AMPUL MET TESTOSTERON DECANOAT, TESTOSTERON FENYLPROP., TESTOSTERON ISOCAPRONAAT, TESTOSTERON PROPIONAAT, BENZYL ALCOHOL (KG) EN ARACHISOLIE GEZUIVERD (KG)

CHEMICAL NAME: AMPUL WITH TESTOSTERONE DECANOATE (10%), TESTOSTERONE PHENYL PROPIONATE (6%), TESTOSTERONE ISOCAPROATE (6%) AND TESTOSTERONE PROPIONATE (3%) IN BENZYL ALCOHOL (<25%) AND PEANUT OIL

SDS Number: SP483550

REACH REGISTRATION NUMBER Not available

RELEVANT IDENTIFIED USES OF THE SUBSTANCE OR MIXTURE AND USES ADVISED AGAINST

IDENTIFIED USE(S): Pharmaceutical production and analysis

USE(S) ADVISED AGAINST: None known.

DETAILS OF THE SUPPLIER OF THE SAFETY DATA SHEET

MERCK SDS HELPLINE: +1 (908) 473-3371 (Worldwide)
Monday to Friday, 9am to 5pm (US Eastern Time)

SDS EMAIL: mercksds@merck.com

EMERGENCY TELEPHONE NUMBER

EMERGENCY NUMBER(S): +1 (908) 423-6000 (24/7/365) English Only

SECTION 2. HAZARDS IDENTIFICATION

CLASSIFICATION OF THE SUBSTANCE OR MIXTURE

Classification according to EC Directive 1272/2008:
Carc. 2 (H351), Repr. 1B (H360Df), Acute Tox. 4 (H332)

Classification according to EC Directives 67/548/EEC (substances) or 1999/45/EC (mixtures):
Repr.Cat.2;R61 Repr.Cat.3;R62 Carc.Cat.3;R40 Xn;R20

COLOR: Color not reported
FORM: Viscous liquid
ODOR: Odor unknown

LABEL ELEMENTS

SIGNAL WORD:

DANGER



HAZARD STATEMENT(S):

Suspected of causing cancer
May damage the unborn child. Suspected of damaging fertility
Harmful if inhaled

PRECAUTIONARY STATEMENT(S):

Do not breathe dust/fume/gas/mist/vapor/spray. Do not handle until all safety precautions have been read and understood. Wash hands thoroughly after handling. Obtain special instructions before use. IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing. IF exposed or concerned: Get medical attention/advice.

OTHER HAZARDS

Health-Related Hazards:

Causes effects to:
endocrine system
May cause developmental effects.
May cause impaired fertility.
fetus
reproductive system
gastrointestinal tract

LISTED CARCINOGENS

INGREDIENT	CAS NUMBER	IARC	EU
Testosterone Propionate	57-85-2	2A	

2A (IARC): IARC Group 2A - Probably Carcinogenic to Humans

Environmental-Related Hazards:

Assessment is not required for PBT or vPVB.

Other Hazards:

No other information known.

SECTION 3. COMPOSITION AND INFORMATION ON INGREDIENTS

SUBSTANCE

CHEMICAL NAME:

AMPUL WITH TESTOSTERONE DECANOATE (10%), TESTOSTERONE PHENYL PROPIONATE (6%), TESTOSTERONE ISOCAPROATE (6%) AND TESTOSTERONE PROPIONATE (3%) IN BENZYL ALCOHOL (<25%) AND PEANUT OIL

CHEMICAL COMPOSITION

INGREDIENT	CAS NUMBER	EC NUMBER	REACH REGISTRATION NUMBER	EU CLASSIFICATION	GHS CLASSIFICATION	PERCENT	REASON FOR LISTING
Testosterone Isocaproate	15262-86-9	239-307-1	Not available	Repr.Cat.2;R61 Repr.Cat.3;R62 Carc.Cat.3;R40 Xn;R20	Carc. 2 (H351) Repr. 1B (H360Df) Acute Tox. 4 (H332)	6	Active Pharmaceutical Ingredient Classified
Testosterone Propionate	57-85-2	200-351-1	Not available	Repr.Cat.2;R61 Repr.Cat.3;R62 Carc.Cat.3;R40 Xn;R20	Carc. 2 (H351) Repr. 1B (H360Df) Acute Tox. 4 (H332)	3	Active Pharmaceutical Ingredient Classified
Testosterone Phenyl Propionate	1255-49-8	215-014-4	Not available	Repr.Cat.2;R61 Repr.Cat.3;R62 Carc.Cat.3;R40 Xn;R20	Carc. 2 (H351) Repr. 1B (H360Df) Acute Tox. 4 (H332)	6	Active Pharmaceutical Ingredient Classified
Testosterone Decanoate	5721-91-5	227-226-4	Not available	Repr.Cat.2;R61 Repr.Cat.3;R62 Carc.Cat.3;R40 Xn;R20	Carc. 2 (H351) Repr. 1B (H360Df) Acute Tox. 4 (H332)	10	Active Pharmaceutical Ingredient Classified
Benzyl Alcohol	100-51-6	202-859-9	Not available	Xn;R20/22	Acute Tox. 4 (H332) Acute Tox. 4 (H302)	<25	Classified Community workplace exposure limit

See section 16 for definitions of risk phrases and GHS classifications.

SECTION 4. FIRST AID MEASURES

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.
FIRST AID RESPONDER PROTECTION:	Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves with appropriate personal protective equipment. Induce artificial respiration with the aid of a pocket mask equipped with a one-way valve or other proper respiratory medical device. DO NOT use mouth-to-mouth method if victim ingested or inhaled the substance.

MOST IMPORTANT SYMPTOMS AND EFFECTS, BOTH ACUTE AND DELAYED

The toxicological properties of this material have not been fully characterized in humans and 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.

Testosterone, and its salt forms, are androgenic (anabolic) steroids. They are harmful 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, effects on menstruation.

INDICATION OF ANY IMMEDIATE MEDICAL ATTENTION AND SPECIAL TREATMENT NEEDED

NOTE TO PHYSICIAN: In cases of overexposure treat supportively and symptomatically.

SECTION 5. FIRE FIGHTING MEASURES

EXTINGUISHING MEDIA

SUITABLE EXTINGUISHING MEDIA:

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

UNSUITABLE EXTINGUISHING MEDIA:

None known.

SPECIAL HAZARDS ARISING FROM THE SUBSTANCE OR MIXTURE

SPECIAL FIRE HAZARDS:

None known.

THERMAL DECOMPOSITION PRODUCTS:

Carbon monoxide (CO). Carbon dioxide (CO₂).

ADVICE FOR FIREFIGHTERS

SPECIAL FIRE FIGHTING PROCEDURES:

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

See Section 9 for Physical and Chemical Properties.

SECTION 6. ACCIDENTAL RELEASE MEASURES

PERSONAL PRECAUTIONS, PROTECTIVE EQUIPMENT AND EMERGENCY PROCEDURES

PERSONAL PRECAUTIONS:

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

METHODS AND MATERIAL FOR CONTAINMENT AND CLEANING UP

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

PRECAUTIONS FOR SAFE HANDLING

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.

CONDITIONS FOR SAFE STORAGE, INCLUDING ANY INCOMPATIBILITIES

STORAGE:

Store at 15-25 deg C. Store in adequately sealed container. Protect from light.

SPECIFIC END USE(S)

Refer to Section 1 for identified use(s).

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

SECTION 8. EXPOSURE CONTROLS AND PERSONAL PROTECTION

CONTROL PARAMETERS

OCCUPATIONAL EXPOSURE BAND (OEB):

Materials in an HHC4 category are considered extreme health hazards. Health Hazard Categories are intended to be a component of workplace risk assessment. Consult your site safety and industrial hygiene staff for guidance on handling and control strategies.***

S-P OCCUPATIONAL EXPOSURE GUIDELINE (OEG): Internal Occupational Exposure Limit of 1 mcg/m³ (8-hr TWA) for Testosterone Decanoate. Internal Occupational Exposure Limit of 1 mcg/m³ (8-hr TWA) for Testosterone Isocaproate. Internal Occupational Exposure Limit of 1 mcg/m³ (8-hr TWA) for Testosterone Phenyl Propionate. Internal Occupational Exposure Limit of 1 mcg/m³ (8-hr TWA) for Testosterone Propionate. .

EXPOSURE LIMIT VALUES:

INGREDIENT	Greece	Poland	Hungary	Croatia	Turkey
Benzyl Alcohol		NDS 240 mg/m ³			

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):

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.
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.
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.
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.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

INFORMATION ON BASIC PHYSICAL AND CHEMICAL PROPERTIES

FORM:	Viscous liquid
COLOR:	Color not reported
ODOR:	Odor unknown
ODOR THRESHOLD:	Not determined
pH:	Not determined
BOILING POINT / RANGE:	Not determined
MELTING POINT / RANGE:	Not determined
DECOMPOSITION TEMPERATURE:	Not determined
VAPOR PRESSURE:	Not determined
VAPOR DENSITY:	Not determined
SPECIFIC GRAVITY:	Not determined
SOLUBILITY:	
Water:	Not determined
PARTITION COEFFICIENT (log Pow):	Not determined
VISCOSITY:	Not determined
EVAPORATION RATE:	Not determined

FLAMMABILITY DATA:

Flash Point:	Not determined (liquids) or not applicable (solids).
Flammability (solid, gas):	Not determined
UEL:	Not determined
LEL:	Not determined
Autoignition Temperature:	Not determined

SECTION 10. STABILITY AND REACTIVITY**STABILITY/ REACTIVITY:**

Stable under conditions specified in Section 7 of this SDS. No hazardous reactions known.

CONDITIONS AND MATERIALS TO AVOID:

None known.

HAZARDOUS DECOMPOSITION PRODUCTS / REACTIONS:

No dangerous decomposition is expected if used according to manufacturer's specifications.

SECTION 11. TOXICOLOGICAL INFORMATION**LIKELY ROUTES OF EXPOSURE:**

Skin, eye, inhalation, and ingestion.

ACUTE TOXICITY DATA**INHALATION:**

No data available.

SKIN:

Testosterone gels cause slight irritation but to a lesser extent compared to testosterone patches.

Benzyl alcohol: Dermal LD50: 2000 mg/kg (rabbit)

Benzyl alcohol was moderately irritating to the skin of guinea pigs and rabbits.

EYE:

Benzyl alcohol was moderate-highly irritating to eyes.

ORAL:

Testosterone Propionate: Oral LD50: 1000 mg/kg (rat); Oral LD50: 1350 mg/kg (mouse).

Benzyl alcohol: Oral LD50: 1230 mg/kg (rat)

ASPIRATION:

No data available.

DERMAL AND RESPIRATORY SENSITIZATION:

Hypersensitivity reactions, including skin manifestations and anaphylactoid reactions, have occurred rarely with testosterone. Allergic contact dermatitis has been reported with topical administration (e.g., as transdermal systems) of testosterone.

Benzyl alcohol was not a skin sensitizer in guinea pigs.

ADDITIONAL INFORMATION:

Testosterone: Intraperitoneal LDLo: 326 mg/kg (rat). Testosterone Propionate: Subcutaneous LD50: 0.5 g/kg (rat); Subcutaneous LD50: 0.5 g/kg (mouse). The acute toxicity of androgens in general is relatively low.

REPEAT DOSE TOXICITY DATA

SUBCHRONIC / CHRONIC TOXICITY:

Testosterone:

Oral LOEL (17-20 days after conception): 100 mg/kg (female rat).

Oral LOEL (10 days pre-mating): 64 mg/kg (male rat).

Subcutaneous LOEL (14 days pre-mating): 0.7 mg/kg (female rat).

Subcutaneous LOEL (21 day pre-mating): 8.4 mg/kg (male rat).

Testosterone Propionate:

Subcutaneous TDLo (26 weeks intermittent): 1560 mg/kg (rat).

Intraperitoneal LD50 (26 weeks intermittent): 3900 mg/kg (rat).

Intramuscular TDLo (14 days pre-mating): 4.286 mg/kg (male human).

Intramuscular TDLo (6 days pre-mating): 3 mg/kg (female human).

Parenteral TDLo (24 days pre-mating): 8.57 mg/kg (male human).

TDLo (31 days pre-mating): 18.5 mg/kg (female human).

Oral TDLo (49 days pre-mating): 24.5 mg/kg (male rabbit).

Subcutaneous TDLo (1 day pre-mating): 0.05 mg/kg (female rat).

(20 day pre-mating): 0.2 mg/kg (male rat).

REPRODUCTIVE / DEVELOPMENTAL TOXICITY:

Testosterone:

Oral LOEL (8-12 days post-conception): 15 mg/kg (female mouse). Effects were seen on newborn.

Subcutaneous LOEL (5 days pre-mating): 10 mg/kg (female mouse). Effects were seen on fertility with maternal toxicity.

Testosterone/ Testosterone Propionate: Daily subcutaneous injections for 4-8 days of total doses of 0.5-80 mg testosterone into rats between days 10 and 20 of gestation and of total doses of 1-55 mg testosterone propionate between days 12 and 19 of gestation resulted in resorptions, necrosis, lethality, post-partum mortality and various degrees of masculinization in female offspring. The effects were correlated directly with dosage and period of administration.

Injection of 100 mg testosterone propionate on day 14 of gestation into rats induced small or absent mammary glands in male and female offspring and absence of nipples in 100% of females only.

A single subcutaneous injection of 4 mg/kg of testosterone to rats between days 5 and 8 of gestation prevented implantation. Injections on days 9-11 produced fetal loss or delayed parturition in rats.

Injection of 20 mg/kg on days 1, 5 or 9 led to fetal loss in all animals treated.

Testosterone administration to rats during pregnancy is detrimental to the development and subsequent function of the reproductive system of female progeny. Testosterone may cause fetal harm when administered to pregnant women. Androgens in general are contraindicated during pregnancy. Studies in humans have shown that androgens cause masculinization of the external genitalia of the female fetus, including clitoromegaly and abnormal vaginal development. The degree of masculinization is dose related.

Androgenic effects including clitoral hypertrophy, labial fusion, abnormal vaginal development, and persistence of a urogenital sinus have occurred in the female offspring of women who were given androgens during pregnancy. The degree of masculinization is related to the amount of drug given to the woman and the age of the fetus; masculinization is most likely to occur in a female fetus when exposure to androgens occurs during the first trimester.

Testosterone Propionate is an experimental teratogen. Exposure to testosterone propionate resulted in reproductive effects in humans and experimental animals.

Subcutaneous TDLo (1 day pre-mating): 0.5 mg/kg (male rabbit). Testosterone propionate showed effects on fertility.

Subcutaneous TDLo (16- 20 days post conception): 25 mg/kg (female rabbit). Testosterone propionate showed specific developmental abnormalities.

MUTAGENICITY / GENOTOXICITY:

Testosterone/ testosterone propionate induced morphological transformation of Syrian hamster embryo cells. The transformation frequencies induced by testosterone/testosterone propionate were less than one-half that induced by benzo[a]pyrene (positive control) at 1 microgram/ml. None of these steroids induced significant increases in frequencies of chromosome aberrations or aneuploidy. Gene mutations were not observed for testosterone at the HPRT or Na⁺/K⁺ATPase locus. (Carcinogenesis 1995 Jun; 16 (6): 1329-33).

at concentrations of 1-100 ug/ml had weak transforming activity, but with no dose-response relationship, in Syrian hamster embryo cells (Lasne et al., 1990).

enhances prostatic carcinogenesis, perhaps by generating estradiol through peripheral conversion (Han et al., 1995).

CARCINOGENICITY:

Testosterone Cyclopentyl Propionate has limited evidence of carcinogenic effect. Testosterone Propionate has limited evidence of a carcinogenic effect. It is an experimental carcinogen, experimental tumorigen and experimental neoplastigen. There is sufficient evidence of carcinogenicity in experimental animal (IARC).

Testosterone Propionate: Subcutaneous TDLo: 10 mg/kg (rat). Showed tumorigenic effects.

Implantation TDLo (48 weeks continuous): 432 mg/kg (rat). Showed tumorigenic effects.

Implantation TDLo (65 weeks intermittent): 5200 mg/kg (rat). Showed tumorigenic effects.

Testosterone has limited evidence of a carcinogenic effect. It is an experimental carcinogen, experimental tumorigen and experimental neoplastigen. There is sufficient evidence of carcinogenicity in experimental animal (IARC) and limited evidence of carcinogenicity in humans. (IARC). Androgenic (anabolic steroids as a whole are classified as probably carcinogenic to humans (IARC). Evidence of a carcinogenic effect is insufficient to classify this compound as probably carcinogenic to humans (DECOS). This compound is classified as a suspect carcinogen to humans (DECOS).

Classification according to EC Directive 1272/2008:

Carc. 2 (H351). Repr. 1B (H360Df). Acute Tox. 4 (H332).

Classification criteria have not been met for the following endpoints due to lack of data, inconclusive data, technical impossibility to obtain the data, or data which are conclusive although insufficient for classification (available information to support classification criteria is given in Section 4 or Section 11 of this data sheet):

Eye damage or irritation. Skin sensitization. Skin corrosion or irritation. Respiratory sensitization. Mutagenicity. Specific target organ toxicity (STOT) - Single Exposure. Specific target organ toxicity (STOT) - Repeated Exposure. Aspiration hazard.

See Section 4 for human health symptoms and effects.

SECTION 12. ECOLOGICAL INFORMATION**ECOTOXICITY DATA**

Benzyl Alcohol is not expected to be harmful to aquatic organisms.

INGREDIENT ECOTOXICITY

Benzyl alcohol: 96-hr LC50 (fathead minnow): 460 mg/L

PERSISTENCE AND DEGRADABILITY**Biodegradation Results:**

Benzyl Alcohol underwent 70% of theoretical biological oxygen demand in 5 days under aerobic conditions. It is readily biodegradable.

BIOACCUMULATIVE POTENTIAL**Partition Coefficient (log Pow) Results:**

Log Kow = 1.1 (Benzyl Alcohol)

Bioaccumulative Potential (Ingredient Data):

Benzyl Alcohol is not expected to bioaccumulate.

MOBILITY IN SOIL

Benzyl Alcohol is expected to be mobile in soil.

Soil Adsorption/Desorption Results:

Koc = < 5-29 (Benzyl Alcohol).

PBT and vPvB ASSESSMENT

This product is not expected to be a PBT or vPvB compound..

OTHER ADVERSE EFFECTS**ENVIRONMENTAL FATE AND EFFECTS:**

No data available.

SECTION 13. DISPOSAL CONSIDERATIONS**WASTE TREATMENT METHODS**

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

SECTION 15. REGULATORY INFORMATION

SAFETY, HEALTH AND ENVIRONMENTAL REGULATIONS/LEGISLATION SPECIFIC FOR THE SUBSTANCE OR MIXTURE

Germany, Water Endangering Classes (WGK)

INGREDIENT	Annex 1	Annex 2 - Water Hazard Classes	Annex 3
Testosterone Isocaproate	Not listed.	Not listed.	WGK 3
Testosterone Propionate	Not listed.	Not listed.	WGK 3
Testosterone Phenyl Propionate	Not listed.	Not listed.	WGK 3
Testosterone Decanoate	Not listed.	Not listed.	WGK 3
Benzyl Alcohol	Not listed.	216	Not listed.

Ozone Depleting Substance(s)

INGREDIENT	Listing
Testosterone Isocaproate	Not listed.
Testosterone Propionate	Not listed.
Testosterone Phenyl Propionate	Not listed.
Testosterone Decanoate	Not listed.
Benzyl Alcohol	Not listed.

Persistent Organic Pollutants

INGREDIENT	Listing
Testosterone Isocaproate	Not listed.
Testosterone Propionate	Not listed.
Testosterone Phenyl Propionate	Not listed.
Testosterone Decanoate	Not listed.
Benzyl Alcohol	Not listed.

EU Import and Export Restrictions

INGREDIENT	Requires PIC Notification	Requires Export Notification	Export Ban
Testosterone Isocaproate	Not listed.	Not listed.	Not listed.
Testosterone Propionate	Not listed.	Not listed.	Not listed.
Testosterone Phenyl Propionate	Not listed.	Not listed.	Not listed.
Testosterone Decanoate	Not listed.	Not listed.	Not listed.
Benzyl Alcohol	Not listed.	Not listed.	Not listed.

SEVESO II EU Directive

INGREDIENT	Listing
Testosterone Isocaproate	Not listed.
Testosterone Propionate	Not listed.
Testosterone Phenyl Propionate	Not listed.
Testosterone Decanoate	Not listed.
Benzyl Alcohol	Not listed.

REACH

INGREDIENT	Subject to Authorization	Candidate List for Authorization	Potential Substances of High Concern	Restrictions
Testosterone Isocaproate	Not listed.	Not listed.	Not listed.	Not listed.

Testosterone Propionate	Not listed.	Not listed.	Not listed.	Not listed.
Testosterone Phenyl Propionate	Not listed.	Not listed.	Not listed.	Not listed.
Testosterone Decanoate	Not listed.	Not listed.	Not listed.	Not listed.
Benzyl Alcohol	Not listed.	Not listed.	Not listed.	Not listed.

CHEMICAL SAFETY ASSESSMENT

A Chemical Safety Assessment has not been done.

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 SDS:

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

MERCK SDS HELPLINE:

+1 (908) 473-3371 (Worldwide)
Monday to Friday, 9am to 5pm (US Eastern Time)

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SUPERSEDES DATE:

28-Jul-2011

SIGNIFICANT CHANGES (EU SUBFORMAT):

Conversion, New regional format

DEFINITIONS (referred to under Sections 2 and 3):

CLP Classifications:	• Carc. 2 (H351) • Repr. 1B (H360Df) • Acute Tox. 4 (H332) • Acute Tox. 4 (H302) - Harmful if swallowed.	• Suspected of causing cancer • May damage the unborn child. Suspected of damaging fertility • Harmful if inhaled
Risk Phrases:	• R61 - May cause harm to the unborn child. • R62 - Possible risk of impaired fertility. • R40 - Limited evidence of a carcinogenic effect. • R20 - Harmful by inhalation. • R20/22 - Harmful by inhalation and if swallowed.	

GLOSSARY:

IARC - International Agency for Research on Cancer, IARC Group 1 or 2A.
 NTP - National Toxicology Program
 ACGIH - American Conference of Governmental Industrial Hygienists
 ADR - International Carriage of Dangerous Goods by Road
 API - Active Pharmaceutical Ingredient
 CAS - Chemical Abstract Service
 CLP - Classification, Labeling and Packaging
 DOT - Department of Transportation
 EC - European Council
 ETAC - Estimated Target Airborne Concentration
 GHS - Globally Harmonized System
 HEPA - High Efficiency Particulate Arresting
 HHC - Health Hazard Category
 HPA - Hypothalamic Pituitary Adrenal
 IATA - International Air Transport Association
 IMO - International Maritime Organization
 IP - Intraperitoneal Injection
 LD50 - Lethal Dose, 50%
 LC50 - Lethal Concentration, 50%
 LOEL - Lowest Observed Effect Level
 NEL - No Effect Level
 NOAEL - No Adverse Effect Level
 NOEL - No Observe Effect Level
 OEG - Occupational Exposure Guideline
 PBT - Persistent BioaccumulativeToxic
 PG - Packing Group
 PIC - Prior Informed Consent
 PPE - Personal Protective Equipment
 REACH - Registration, Evaluation, Authorization and Restriction of Chemical Substances
 RPE - Respiratory Protective Equipment
 SCBA - Self Contained Breathing Apparatus
 STOT - Specific Target Organ Toxicity
 TSCA - Toxic Substances Control Act
 TWA - Time Weighted Average
 UN - United Nations
 vPvB - Very Persistent andVery Bioaccumulative
 WGK - Water Hazard Class (Germany)