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SECTION 1 CHEMICAL PRODUCT AND COMPANY IDENTIFICATION MANUFACTURED BY: MIPHARM S.p.A., MILAN, ITALY FOR 24 HR. EMERGENCY MEDICAL INFORMATION: COLUMBIA LABORATORIES BERMUDA Ltd. 800-424-9300 COLUMBIA LABORATORIES, INC. CHEM TREC USA, CAN, PR: (973) 994-3999 MARKETED BY: 354 EISENHOWER PARKWAY INTERNATIONAL: (973) 994-3999 PLAZA 1, SECOND FLOOR LIVINGSTON, NJ 07039 SUBSTANCE: TESTOSTERONE TRADE NAMES/ SYNONYMS: STRIANT CREATION DATE: MAY 13, 2003 REVISION DATE: \_\_\_\_\_ SECTION 2 COMPOSITION, INFORMATION ON INGREDIENTS COMPONENT: 17BETA-HYDROXYANDROST-4-EN-3-ONE SUBSTANCE CLASS: Androgenic (anabolic) steroids FORMULA: C19 H28 02 CAS NUMBER: 58-22-0 EC NUMBER (EINECS): 200-370-5 PERCENTAGE:

SECTION 3 HAZARDS IDENTIFICATION

MAY CAUSE HARM TO THE UNBORN CHILD. POSSIBLE RISK OF IMPAIRED FERTILITY. LIMITED EVIDENCE OF A CARCINOGENIC EFFECT. HARMFUL BY INHALATION, IN CONTACT WITH SKIN AND IF SWALLOWED.

SECTION 4 FIRST AID MEASURES

ROUTES OF EXPOSURE: Inhalation, ingestion, mucous membrane absorption and skin absorption.

POSSIBLE SYMPTOMS: Symptoms of exposure may include: headache, dizziness, tremor, sweating, gastro-intestinal complaints, nausea, and vomiting, water retention and sodium retention.

POSSIBLE EFFECTS: Effects of overexposure: Harmful by inhalation in contact with skin and if swallowed. Effects as for androgens in general. Androgenic and anabolic activity. Changes in libido. Reversible gynaecomastia in male. Effects on fertility. Effects on menstruation.

GENERAL ADVISE: In all cases of doubt, or when symptoms persist, seek medical attention.

EYE CONTACT: Rinse immediately and as long as possible with plenty of water. Eyelids should be held away from the eyeball to ensure thorough rinsing. Consult a physician immediately.



Page 002 OF 008 SKIN CONTACT: Flush with copious amounts of water for at least 15 minutes while removing contaminated clothing and shoes.

INHALATION: Remove from exposure, fresh air, rest, if breathing is difficult, give oxygen. Obtain medical attention immediately (show this Material Safety Data Sheet).

INGESTION: Only when conscious, rinse mouth, give plenty of water to drink (approx. 500 ml). DO NOT induce vomiting. Seek medical advice.

MEDICAL ADVISE: If swallowed (and when followed by vomiting), there is danger of aspiration.

SECTION 5 FIRE FIGHTING MEASURES

SPECIAL HAZARDS: Emits toxic and corrosive fumes under fire conditions.

PROTECTIVE EQUIPMENT: Wear self-contained breathing apparatus, protective suit, suitable materials.

EXTINGUISING MEDIA: Water, fire extinguishing powder, carbon dioxide of foam.

NON-SUITABLE EXTINGUISHING AGENTS: None.

HAZARDOUS DECOMPOSITION OR COMBUST ON PRODUCTS: None.

OTHER INFORMATION: Evacuate personnel to safe area. In certain concentrations the product may form an explosive dust-air mixture.

SECTION 6 ACCIDENTAL RELEASE MEASURES

PERSONAL PRECAUTIONS: Avoid inhalation of dusts. Use appropriate respiratory protection.

ENVIRONMENTAL PRECAUTIONS: Avoid dust generation. Isolate spill area.

METHODS FOR CLEAING UP: Shovel up. Collect as much as possible in a clean container for (preferable) reuse or disposal. Rinse remnant with plenty of water.

SECTION 7 HANDLING AND STORAGE

SAFE HANDLING ADVISE: Avoid inhalation of dusts. Avoid contact with eyes, skin or clothing. Wash hands and/or face before taking a break or leaving work. Never weigh out in the storage room. Avoid exposure to women especially during pregnancy and lactation.

MEASURES TO PREVENT FIRE AND EXPLOSIONS: Avoid dust generation. Take precautionary measures against static discharges.

REQUIREMENTS FOR STORAGE: Store in well closed containers, at 15°-25° C.



Page 003 OF 008 OTHER INFORMATION: Do not eat, drink or smoke in application area. Keep working clothes separately and do not take them home.

SECTION 8 EXPOSURE CONTROLS, PERSONAL PROTECTION

OCCUPATIONAL EXPOSURE LIMITS

EXPOSURE LIMITS: No exposure limit has been established.

#### ADDITIONAL RECOMMENDATION ON TECHNICAL SYSTEM DESIGN

TECHNICAL MEASURES: Avoid inhalation of dusts. Ensure good ventilation and local exhaust ventilation of the working area. If these measures are not sufficient, suitable respiratory protection must be worn.

#### PERSONAL PROTECTION

RESPIRATORY: Use appropriate respiratory protection. EYE: Wear safety goggles. HAND: Wear suitable gloves. SKIN & BODY: Wear suitable protective clothing, special overalls, tight fitting at neck, ankles and wrists and head covered. Change daily. After handling bulk quantities, showering is recommended.

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SECTION 9 PHYSICAL AND CHEMICAL PROPERTIES
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FORM: crystal(s) crystal powder PHYSICAL STATE: Solid COLOR: White to creamy white ODOR: Odorless

BOILING POINT: Not Applicable

MELTING POINT: 152° - 157° C

FLAMMABILITY: Not Applicable

FLASH POINT: Not Applicable

AUTO-IGNITION TEMPERATURE: Not Applicable

EXPLOSIVE PROPERTIES: Lower, not applicable Upper, not applicable

EXPLOSION LIMITS: Lower, not applicable Upper, not applicable

VAPOR PRESSURE: Not Applicable

DENSITY (Specific Gravity): Not Determined



BULK DENSITY: Not Determined

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SOLUBILITY: Soluble in/with alcohol 0.2 g/ml SOLUBILITY: in/with dehydrated alcohol 0.17 g/ml SOLUBILITY: in/with chloroform 0.5 g/ml SOLUBILITY: in/with ether 0.01 g/ml SOLUBILITY: soluble in/with dioxane and vegetable oils SOLUBILITY: slightly soluble in/with ethyl oleate SOLUBILITY IN WATER: insoluble

RELATIVE VAPOR DENSITY AIR=1: Not Applicable

pH (QUANT): Not Applicable

PARTITION COEFFICIENT: Not Determined

VISCOSOTY: Not Applicable

OXIDIZING PROPERTIES: Not Applicable

SADT: Not Applicable

SPECIFIC CONDUCTIVITY: Not Applicable

SECTION 10 STABILITY AND REACTIVITY

CONDITIONS TO AVOID: None

MATERIALS TO AVOID: None

HAZARDOUS DECOMPOSITION PRODUCTS: None

STABILITY: Stable under recommended storage and handling conditions.

SECTION 11 TOXICOLOGICAL INFORMATION

#### ACUTE TOXICITY

LD50 ORAL DOSE: No data available

LD50 ORAL RAT DOSE: 1000 mg/kg INFORM. APPLIES TO: Testosterone Propionate

LD50 DERMAL DOSE: No data available

LC50 INHALATION: DOSE: No data available

LDLo INTRAPERITONEAL RAT DOSE: 326 mg/kg



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# ACUTE TOXICITY (irritation, sensitization, etc.)

IRRITATION SKIN RESULTS: No data available

IRRITATION EYE RESULTS: No data available

IRRITATION RESPIRATORY RESULTS: No data available

SENSITIZATION RESULTS: No data available

# DELAYED OR CHRONIC TOXICOLOGICAL EFFECTS

#### CARCINOGENICITY

TDLo ORAL MOUSE SYMPTOMS: tumorigenic effects DOSE: 6240 mg/kg PERIOD: 52 day(s) continuous

TDLo SUBCUTANEOUS MOUSE SYMPTOMS: Tumorigenic effects DOSE: 30 mg/kg PERIOD: 5 day(s) intermittent

REPRODUCTIVE EFFECTS: SYMPTOMS: Experimental teratogen. Reproductive disorder(s) in human and experimental animal.

TDLo UNREPORTED WOMEN DOSE: 34.6 mg/kg PERIOD: 7-13 week(s) after conception

TDLo ORAL RAT-FEMALE DOSE: 100 mg/kg PERIOD: 17-20 day(s) after conception

TDLo ORAL RAT-MALE DOSE: 64 mg/kg PERIOD: 10 day(s) pre-mating

TDLo SUBCUTANEOUS RAT-FEMALE DOSE: 0.7 mg/kg PERIOD: 14 day(s) pre-mating

TDLo SUBCUTANEOUS RAT-MALE DOSE: 8.4 mg/kg PERIOD: 21 day(s) pre-mating

TDLo ORAL MOUSE-FEMALE DOSE: 15 g/kg



PERIOD: 8-12 day(s) after conception

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TDLo SUBCUTANEOUS MOUSE-FEMALE DOSE: 10 mg/kg PEROIOD: 5 day(s) pre-mating

#### OTHER TOXICOLOGICAL INFORMATION

GENOTOXICITY: Limited evidence of a carcinogen effect. Experimental carcinogen. Experimental neoplastigen. Human mutagenic data. Sufficient evidence of carcinofenicity in experimental animal (IARC). Limited evidence of carcinogenicity in human (IARC). Androgenic (anabolic) steroids: The group as a whole is classified as probably carcinogenic to human (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).

OTHER INFORMATION: RTECS No: XA3030000 (TESTOSTERONE) N.I. Sax et al. (9Ed), 1995 Matindale "The Extra Pharmacopoeia" (30Ed), J.E.F. Reynolds, 1993. IARC Monographs, Volume 50, 1990; RTECS No: XA3115000 (TESTERONE PROPIONATE). DECOS (Dutch Expert Committee on Occupational Standards), "Scientific Documentation on the Dutch list of occupational carcinogens (II)", RA2/95, 1995.

SECTION 12 ECOLOGICAL INFORMATION

#### PERSISTENCE AND DEGRADATION

No data available.

#### MOBILITY

No data available.

#### BIOACCUMULATIVE POTENTIAL

Partition coefficient: Not determined

No data available.

#### ECOTOXICITY

No data available

BIOCHEMICAL OXYGEN DEMAND

No data available

### AOX

Concentration: No data available



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# SECTION 13 DISPOSAL CONSIDERATIONS

PRODUCT: According to local regulations: controlled incineration, controlled landfill.

CONTAMINATED PACKAGING: According to local regulations: controlled incineration, controlled landfill.

OTHER INFORMATION: Non-contained containers can be treated like domestic garbage. According to local regulations.

SECTION 14 TRANSPORT INFORMATION

TRANSPORTATION/ ADDITIONAL INFORMATION: No dangerous good, according to national and international transport regulations.

SECTION 15 REGULATORY INFORMATION

CLASSIFICATION: EU directives and own criteria

HAZARD SYMBOL(S)



T -Toxic

RISK PHRASES: (R61) May cause harm to the unborn child (R62) Possible risk of impaired fertility (R40) Limited evidence of a carcinogenic effect. (R20/21/22) Harmful by inhalation, in contact with skin and if swallowed
<pre>SAFETY PHRASES: (S53) Avoid exposure - obtain special instructions before use. (S22) Do no breathe dust. (S36/37) Wear suitable protective clothing and gloves (S38) In case of insufficient ventilation, wear suitable respiratory equipment (S45) In case of accident or if you feel unwell, seek medical advise immediately (show the label where possible)</pre>
ADDITIONAL INFORMATION
NATIONAL REGULATIONS WGK (Germany): 3
SECTION 16 OTHER INFORMATION



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This information only concerns the above mentioned product and does not need to be valid if used with each other product(s) or in any process. The information is correct and complete to our best present knowledge and is given in good faith, but without warranty. It remains the user's own responsibility to make sure that the information is appropriate and complete for his special use of this product.