MSD is a tradename of Merck & Co., Inc., with headquarters in Whitehouse Station, N.J., U.S.A.

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: **OVESTIN 15GR**

SYNONYM(S): OVESTERIN CREAM; PHYSIOGINE CREAM

CHEMICAL NAME: CONTAINS 0.1% ESTRIOL

SDS Number: SP499058

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

EU SUPPLIER/MANUFACTURER: MSD
Molenstraat 110
5342 CC Oss
The Netherlands

INFORMATION: +31 (0)412-661600 (MSD Oss)

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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. 1A (H350)

Classification according to EC Directives 67/548/EEC (substances) or 1999/45/EC (mixtures):
Carc.Cat.1;R45

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

LABEL ELEMENTS

SIGNAL WORD: DANGER

HAZARD STATEMENT(S):
May cause cancer
PRECAUTIONARY STATEMENT(S):
Do not handle until all safety precautions have been read and understood. Obtain special instructions before use. Use personal protective equipment as required. IF exposed or concerned: Get medical attention/advice. Store locked up. Dispose of contents/container to an approved incineration plant.

OTHER HAZARDS

Health-Related Hazards:

May cause effects to:
endocrine system
gastrointestinal tract
cardiovascular system
nervous system
liver
kidney
reproductive system
fetus

LISTED CARCINOGENS

INGREDIENT	CAS NUMBER	IARC	EU
Estriol	50-27-1	1	

1 (IARC): IARC Group 1 - 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: CONTAINS 0.1% ESTRIOL

CHEMICAL FORMULA: ... / C18 H24 O

CHEMICAL COMPOSITION

INGREDIENT	CAS NUMBER	EC NUMBER	REACH REGISTRATION NUMBER	EU CLASSIFICATION	GHS CLASSIFICATION	PERCENT	REASON FOR LISTING
Estriol	50-27-1	200-022-2	Not available	Carc.Cat.1;R45 Repr.Cat.1;R60 Repr.Cat.2;R61 Xn;R48/22	Carc. 1A (H350), Repr. 1A (H360Fd), STOT Rep. 1 (H372)	0.1	Active Pharmaceutical Ingredient Classified
Chlorhexidine Dihydrochloride	3697-42-5	223-026-6	Not available	Xi;R36-38 N;R50-53	Skin Irrit. 2 (H315) Eye Irrit. 2 (H319) Aquatic Acute 1 (H400) Aquatic Chronic 1 (H410)	< 0.1	Classified
Sodium Hydroxide	1310-73-2	215-185-5	x	C; R35	Skin Corr. 1A (H314)	< 0.1	Classified Community workplace exposure limit
Glycerin	56-81-5	200-289-5	x	Not Classified	Not Classified	<20	Community workplace exposure limit
Lactic Acid	50-21-5	200-018-0	x	C;R34	Skin Corr. 1B (H314)	< 1	Classified
Sorbitan Monostearate	1338-41-6	215-664-9	Not available			< 1	Community workplace exposure limit
Cethyl Palmitate	540-10-3	208-736-6	Not available			<5	Classified
Cetyl Alcohol	36653-82-4	253-149-0	x	Xi;R38	Skin Irrit. 2 (H315)	< 5	Classified
Octyl Dodecanol	5333-42-6	226-242-9	x	Xi;R38	Skin Irrit. 2 (H315)	< 10	Classified

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 mixture have not been fully characterized in humans. 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.

Estriol may cause gastrointenstinal tract irritation with abdominal cramps, nausea and vomiting. Prolonged ingestion may have adverse effects such as increased blood pressure, bloating, jaundice (yellow eyes or skin), gall bladder obstruction, weight gain or weight loss, change in sex drive, loss of appetite, swelling due to fluid and salt retention, and central nervous system effects such as headache, migraine, dizziness, mental depression. May cause effects on menstrual edema in females and reversible gynaecomastia in males. May also cause tenderness of breasts and changes in libido.

Based on animal studies, Estriol may cause cancer and adverse reproductive effects and birth defects.

INDICATION OF ANY IMMEDIATE MEDICAL ATTENTION AND SPECIAL TREATMENT NEEDED

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

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 IMCOMPATIBILITIES

STORAGE:
Store at 15-25 deg C. Store in adequately sealed container.

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

The following guidance applies to the handling of the active ingredient(s) in this formulation.

CONTROL PARAMETERS

OCCUPATIONAL EXPOSURE BAND (OEB):
OEB 5: <1 mcg/m^3. Materials in an OEB 5 category are considered extreme health hazards. The OEB is a range of airborne concentrations expressed as an 8-hour Time Weighted Average (8-hr. TWA) and is intended to be used with Industrial Hygiene Risk Assessment to assist with industrial hygiene sampling and selection of proper controls for worker protection. Consult your site safety and industrial hygiene staff for guidance on handling and control strategies.

INTERNAL OCCUPATIONAL EXPOSURE LIMIT (8-hr TWA):
0.5 mcg/m^3

Wipe Limit:
5 ug/100 cm2

OEB/OEL NOTATION(S):
This material has a notation of "S" for its ability to cause systemic toxicity through skin absorption.

EXPOSURE LIMIT VALUES:

INGREDIENT	CAS NUMBER	ACGIH TLV (TWA)	ACGIH TLV (STEL / SKIN)	ACGIH TLV (CEIL)
Sodium Hydroxide	1310-73-2			2 mg/m^3
Glycerin	56-81-5	10 mg/m^3		
Sorbitan Monostearate	1338-41-6	10 mg/m^3		

INGREDIENT	CAS NUMBER	EU	Austria	Belgium	Denmark	France
Sodium Hydroxide	1310-73-2		STEL 4 mg/m^3 MAK 2 mg/m^3		Ceiling 2 mg/m^3	VME 2 mg/m^3
Glycerin	56-81-5			TWA 10 mg/m^3		VME 10 mg/m^3
Sorbitan Monostearate	1338-41-6			TWA 10 mg/m^3		

INGREDIENT	CAS NUMBER	Germany	Ireland	Italy	Netherlands
Sodium Hydroxide	1310-73-2		STEL 2 mg/m^3		
Glycerin	56-81-5	MAK 50 mg/m^3 Peak 100 mg/m^3	TWA 10 mg/m^3		
Sorbitan Monostearate	1338-41-6		TWA 10 mg/m^3		

INGREDIENT	CAS NUMBER	Norway	Portugal	Spain	Switzerland	UK:
Sodium Hydroxide	1310-73-2	Ceiling 2 mg/m^3	Ceiling 2 mg/m^3	VLA-EC 2 mg/m^3	STEL 2 mg/m^3 MAK 2 mg/m^3	STEL 2 mg/m^3
Glycerin	56-81-5		TWA 10 mg/m^3	VLA-ED 10 mg/m^3	STEL 100 mg/m^3 MAK 50 mg/m^3	STEL 30 mg/m^3 TWA 10 mg/m^3
Sorbitan Monostearate	1338-41-6		TWA 10 mg/m^3	VLA-ED 10 mg/m^3		

INGREDIENT	Greece	Poland	Hungary	Croatia	Turkey
Sodium Hydroxide	STEL 2 mg/m^3 TWA 2 mg/m^3	NDSCh 1 mg/m^3 NDS 0.5 mg/m^3	STEL 2 mg/m^3 TWA 2 mg/m^3	STEL 2 mg/m^3	
Glycerin	TWA 10 mg/m^3	NDS 10 mg/m^3		TWA 10 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:	Miscible
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

PRODUCT / CHEMICAL NAME	EXPOSURE ROUTE	STUDY DESCRIPTION	RESULT
eSTRIOL	Oral	LD50 (rat)	> 2000 mg/kg

INHALATION:
No data available.

ORAL:
No data available.

EYE:
No data available.

SKIN:
No data available.

ASPIRATION:
No data available.

DERMAL AND RESPIRATORY SENSITIZATION:
No data available.

REPEAT DOSE TOXICITY DATA

SUBCHRONIC / CHRONIC TOXICITY:
Estriol: Hamsters were given subcutaneous implants of 20 mg pellets of estriol, reimplanted every 150 days to ensure constant absorption, for 318-601 days. After latent periods of 396-593 days, 6/11 animals developed tumors in one or both kidneys. Oral dosing of dogs with 80 mg/day of estriol succinate for 1 year produced testicular atrophy, diminished penis size in males and enlarged vulvas with purvulent discharge and slightly enlarged nipples in females. Oral dosing of dogs with 2 - 10 mg/day of estriol for 13 - 26 weeks produced dose dependent estrogenic effects on reproductive organs.

REPRODUCTIVE / DEVELOPMENTAL TOXICITY:
Estriol: Administration of 0.1 umol estriol to Wistar rats from days 16 to 19 of gestation induced partial feminization of male fetuses. Oral dosing of female rats with 0.0084 mg/kg of oestriol 1 day pre-mating produced maternal effects. Oral dosing of female rats with 5 mg/kg of oestriol 5 days after conception produced effects on fertility. Oral studies on rats with 1 mg/kg/day during days 6 - 15 of pregnancy produced no embryonic mortality or teratogenic effects, while doses >= 2 mg/kg/day produced rib abnormalities.

Subcutaneous studies on female rats with 0.05 mg/kg oestriol 1 day after conception produced effects on fertility. Subcutaneous studies on male mice with 100 mg/kg oestriol 10 days pre-mating produced paternal effects and effects on fertility.***

MUTAGENICITY / GENOTOXICITY:
Estriol: Negative in a micronucleus test in rats. Not mutagenic in Salmonella/microsome mutagenicity test.

CARCINOGENICITY:
Estriol: Female rats, 50-55 days received 5 mg estriol; 48 h later, all animals received 20 mg DMBA by oral gavage. The implants were removed from 15 animals after 14 days. At the termination of the experiment at 180 days, the incidence of mammary tumors was 60% after two weeks of estriol treatment and 20% with continuous estriol treatment. Groups virgin Sprague Dawley rats, 40 to 50 days of age, were irradiated. Crystalline sodium chloride pellets containing estriol (638 +175 ug per month) were implanted subcutaneously into the anterior dorsal area each month of life. Control rats were irradiated without estriol treatment. Estriol treatment began one to three days before irradiation or 5, 13 or 15 days after irradiation. Of 142 irradiated controls, 93 developed mammary carcinomas; two thirds of the tumors appeared more than 300 days after irradiation. When estriol administration was begun one to three days before or five days after irradiation, no significant reduction in mammary carcinoma incidence (29/54 controls versus 50/113 estriol treated) was observed.

Classification according to EC Directive 1272/2008:
Carc. 1A (H350).

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

See Section 4 for human health symptoms and effects.

SECTION 12. ECOLOGICAL INFORMATION

ECOTOXICITY DATA

This product has not been tested for ecotoxicity.

PERSISTENCE AND DEGRADABILITY

Biodegradation Results: No data available.

BIOACCUMULATIVE POTENTIAL

Partition Coefficient (log Pow) Results: 2.81

MOBILITY IN SOIL

Soil Adsorption/Desorption Results: No data available.

PBT and vPvB ASSESSMENT

Assessment is not required for PBT or vPVB..

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

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
Estriol	Not listed.	Not listed.	WGK 2
Chlorhexidine Dihydrochloride	Not listed.	Not listed.	Not listed.
Sodium Hydroxide	Not listed.	142	Not listed.
Glycerin	Not listed.	116	Not listed.
Lactic Acid	Not listed.	Not listed.	Not listed.
Sorbitan Monostearate	Not listed.	Not listed.	5623
Cethyl Palmitate	660	Not listed.	Not listed.
Cetyl Alcohol	656	Not listed.	Not listed.
Octyl Dodecanol	656	Not listed.	Not listed.

Ozone Depleting Substance(s)

INGREDIENT	Listing
Estriol	Not listed.
Chlorhexidine Dihydrochloride	Not listed.
Sodium Hydroxide	Not listed.
Glycerin	Not listed.
Lactic Acid	Not listed.
Sorbitan Monostearate	Not listed.
Cethyl Palmitate	Not listed.
Cetyl Alcohol	Not listed.
Octyl Dodecanol	Not listed.

Persistent Organic Pollutants

INGREDIENT	Listing
Estriol	Not listed.
Chlorhexidine Dihydrochloride	Not listed.
Sodium Hydroxide	Not listed.
Glycerin	Not listed.
Lactic Acid	Not listed.
Sorbitan Monostearate	Not listed.
Cethyl Palmitate	Not listed.
Cetyl Alcohol	Not listed.
Octyl Dodecanol	Not listed.

EU Import and Export Restrictions

INGREDIENT	Requires PIC Notification	Requires Export Notification	Export Ban
Estriol	Not listed.	Not listed.	Not listed.
Chlorhexidine Dihydrochloride	Not listed.	Not listed.	Not listed.
Sodium Hydroxide	Not listed.	Not listed.	Not listed.
Glycerin	Not listed.	Not listed.	Not listed.
Lactic Acid	Not listed.	Not listed.	Not listed.
Sorbitan Monostearate	Not listed.	Not listed.	Not listed.
Cethyl Palmitate	Not listed.	Not listed.	Not listed.
Cetyl Alcohol	Not listed.	Not listed.	Not listed.
Octyl Dodecanol	Not listed.	Not listed.	Not listed.

SEVESO II EU Directive

INGREDIENT	Listing
Estriol	Not listed.
Chlorhexidine Dihydrochloride	Not listed.
Sodium Hydroxide	Not listed.
Glycerin	Not listed.
Lactic Acid	Not listed.
Sorbitan Monostearate	Not listed.
Cethyl Palmitate	Not listed.
Cetyl Alcohol	Not listed.
Octyl Dodecanol	Not listed.

REACH

INGREDIENT	Subject to Authorization	Candidate List for Authorization	Potential Substances of High Concern	Restrictions
Estriol	Not listed.	Not listed.	Not listed.	Not listed.
Chlorhexidine Dihydrochloride	Not listed.	Not listed.	Not listed.	Not listed.
Sodium Hydroxide	Not listed.	Not listed.	Not listed.	Not listed.
Glycerin	Not listed.	Not listed.	Not listed.	Not listed.
Lactic Acid	Not listed.	Not listed.	Not listed.	Not listed.
Sorbitan Monostearate	Not listed.	Not listed.	Not listed.	Not listed.
Cethyl Palmitate	Not listed.	Not listed.	Not listed.	Not listed.
Cetyl Alcohol	Not listed.	Not listed.	Not listed.	Not listed.
Octyl Dodecanol	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).

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SDS CREATION DATE: 19-Aug-2011

SUPERSEDES DATE: 19-Aug-2011

SIGNIFICANT CHANGES (EU SUBFORMAT): Hazard classification, Risk and safety phrases, Wipe Limit, Toxicology data

DEFINITIONS (referred to under Sections 2 and 3):

CLP Classifications:	• Carc. 1A (H350) • Repr. 1B (H360Fd) - May damage fertility. Suspected of damaging the unborn child. • STOT Rep. 1 (H372) - Causes damage to organs through prolonged or repeated exposure. • Skin Irrit. 2 (H315) - Causes skin irritation. • Eye Irrit. 2 (H319) - Causes seroius eye irritation. • Aquatic Acute 1 (H400) - Very toxic to aquatic life. • Aquatic Chronic 1 (H410) - Very toxic to aquatic life with long lasting effects. • Skin Corr. 1B (H314) - Causes severe skin burns and eye damage • Skin Corr. 1A (H314) - Causes severe skin burns and eye damage.	• May cause cancer
Risk Phrases:	• R45 - May cause cancer. • R60 - May impair fertility. • R61 - May cause harm to the unborn child. • R35 - Causes severe burns. • R34 - Causes burns. • R36/38 - Irritating to eyes and skin. • R48/22 - Harmful: danger of serious damage to health by prolonged exposure if swallowed. • R50/53 - Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.	

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)