SAFETY DATA SHEET

Desogestrel / Ethinyl estradiol Formulation

Version	Revision Date:	MSDS Number:	Date of last issue: 01.04.2015
2.3	02.04.2015	19074-00005	Date of first issue: 06.10.2014

SECTION 1. IDENTIFICATION

Product name : Desogestrel / Ethinyl estradiol Formulation

Manufacturer or supplier's details

Company name of supplier : MSD
Limited

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

Telephone : 908-740-4000

Telefax : 908-735-1496

Emergency telephone : 1-908-423-6000

Recommended use of the chemical and restrictions on use

Recommended use : Pharmaceutical

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification

Carcinogenicity : Category 1A

Reproductive toxicity : Category 1B

Specific target organ systemic toxicity - repeated exposure : Category 1

GHS Label element

Hazard pictograms :

Signal Word : Danger

Hazard Statements : H350 May cause cancer.
H360 May damage fertility or the unborn child.
H372 Causes damage to organs through prolonged or repeated exposure.

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/ fume/ gas/ mist/ vapors/ spray.
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

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Hazardous ingredients

Chemical Name	CAS-No.	Concentration (%)
Starch	9005-25-8	>= 20 - < 30
Stearic acid	57-11-4	>= 5 - < 10
Desogestrel	54024-22-5	>= 0,1 - < 1
Ethinyl Estradiol	57-63-6	< 0,1

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 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 : Contact with dust can cause mechanical irritation or drying of the skin.

delayed		Dust contact with the eyes can lead to mechanical irritation. May cause cancer. May damage fertility or 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 Dry chemical Carbon dioxide (CO2)
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 Nitrogen oxides (NOx)
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.

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 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.

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
Starch	9005-25-8	TWA	10 mg/m3	ACGIH
		TWA (Res-	5 mg/m3	NIOSH REL

		pirable)		
		TWA (total)	10 mg/m3	NIOSH REL
		TWA (total dust)	15 mg/m3	OSHA Z-1
		TWA (respirable fraction)	5 mg/m3	OSHA Z-1
Stearic acid	57-11-4	TWA	10 mg/m3	ACGIH
Desogestrel	54024-22-5	TWA	0,05 µg/m3	Merck
		Wipe limit	0.5 µg/100 cm²	Merck
Ethinyl Estradiol	57-63-6	TWA	0,01 µg/m3	Merck
	Further information: Skin			
		Wipe limit	0.1 µg/100 cm²	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
Material : Impervious 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	:	tablet
Color	:	White to light 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	:	No data available
Evaporation rate	:	No data available
Flammability (solid, gas)	:	No data available
Upper explosion limit	:	No data available
Lower explosion limit	:	No data available
Vapor pressure	:	No data available
Relative vapor density	:	No data available
Density	:	1 g/cm3
Solubility(ies)		
Water solubility	:	No data available
Partition coefficient: n-	:	No data available

octanol/water

Autoignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity Viscosity, dynamic	:	No data available
Explosive properties	:	Not explosive
Oxidizing properties	:	The substance or mixture is not classified as oxidizing.
Molecular weight	:	No data available

SECTION 10. STABILITY AND REACTIVITY

Reactivity	:	Not classified as a reactivity hazard.
Chemical stability	:	Stable under normal conditions.
Possibility of hazardous reactions	:	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
Skin contact
Ingestion
Eye contact

Acute toxicity

Not classified based on available information.

Ingredients:

Starch:

Acute oral toxicity	:	LD50 (Mouse): > 5.000 mg/kg

Stearic acid:

Acute oral toxicity	:	LD50: > 2.000 mg/kg Method: OECD Test Guideline 401 Assessment: The substance or mixture has no acute oral toxicity
Acute inhalation toxicity	:	LC50 (Rat): > 0,1621 mg/l Exposure time: 4 h Test atmosphere: vapor

Assessment: The substance or mixture has no acute inhalation toxicity

Acute dermal toxicity : LD50 (Rabbit): > 2.000 mg/kg
Assessment: The substance or mixture has no acute dermal toxicity

Desogestrel:
Acute oral toxicity : LD50 (Rat, male and female): > 2.000 mg/kg

LD50 (Mouse, male and female): > 2.000 mg/kg

Ethinyl Estradiol:
Acute oral toxicity : LD50 (Rat): 1.200 mg/kg

LD50 (Rat): 1.200 mg/kg

LD50 (Mouse): 1.737 mg/kg

Skin corrosion/irritation

Not classified based on available information.

Ingredients:

Stearic acid:
Species: Rabbit
Result: No skin irritation

Serious eye damage/eye irritation

Not classified based on available information.

Ingredients:

Stearic acid:
Species: Rabbit
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:

Stearic acid:
Test Type: Buehler Test
Routes of exposure: Skin contact
Species: Guinea pig
Result: negative

Germ cell mutagenicity

Not classified based on available information.

Ingredients:

Stearic acid:
Genotoxicity in vitro : Test Type: Chromosome aberration test in vitro
Method: OECD Test Guideline 473

Result: negative
Remarks: Based on data from similar materials

Desogestrel:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)
Result: negative

Genotoxicity in vivo : Test Type: Micronucleus test
Species: Rat
Application Route: Intraperitoneal
Result: negative

Ethinyl Estradiol:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)
Species: Salmonella typhimurium
Result: negative

: Test Type: Bacterial reverse mutation assay (AMES)
Species: Escherichia coli
Result: negative

: Test Type: Chromosome aberration test in vitro
Species: Human lymphocytes
Result: Equivocal

Genotoxicity in vivo : Test Type: Chromosomal aberration
Species: Mouse
Cell type: Bone marrow
Application Route: Oral
Result: positive

Test Type: Micronucleus test
Species: Mouse
Cell type: Bone marrow
Application Route: Oral
Result: negative

Germ cell mutagenicity - Assessment : Weight of evidence does not support classification as a germ cell mutagen.

Carcinogenicity

May cause cancer.

Ingredients:

Desogestrel:
Species: Rat
Application Route: Oral
Exposure time: 104 weeks
Result: negative

Species: Mouse
Application Route: Oral
Exposure time: 81 weeks
Result: negative

Ethinyl Estradiol:
Species: Rat, (male and female)
Application Route: Oral
Exposure time: 2 Years
NOAEL: 0,05 mg/kg body weight

Result: negative

Species: Monkey, (female)
Application Route: Oral
Exposure time: 10 Years
NOAEL: 5 mg/kg body weight

Result: negative

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 ingredient of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by OSHA.
NTP	No ingredient of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

Reproductive toxicity
May damage fertility or the unborn child.

Ingredients:

Stearic acid:

Effects on fertility	:	Test Type: Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test Species: Rat Application Route: Ingestion Method: OECD Test Guideline 422 Result: negative
Effects on fetal development	:	Test Type: Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test Species: Rat Application Route: Ingestion Method: OECD Test Guideline 422 Result: negative

Desogestrel:

Effects on fertility	:	Test Type: Fertility/early embryonic development Species: Rabbit, female Fertility: Lowest observed adverse effect level Parent: 2 mg/kg body weight Result: positive

Test Type: Fertility/early embryonic development
Species: Rat, female
Fertility: No observed adverse effect level Parent: 0,5 mg/kg body weight
Result: negative

Effects on fetal development : Test Type: Embryo-fetal development
Species: Rabbit, female
Application Route: Oral
Duration of Single Treatment: 12 d
Developmental Toxicity: No observed adverse effect level F1: 1 mg/kg body weight
Result: Embryotoxic effects and adverse effects on the offspring were detected., No teratogenic effects.

Test Type: Embryo-fetal development
Species: Rat, female
Application Route: Oral
Embryo-fetal toxicity.: Lowest observed adverse effect concentration Parent: 0,125 mg/kg body weight
Result: No teratogenic effects.

Reproductive toxicity - Assessment : Clear evidence of adverse effects on sexual function and fertility, based on animal experiments., Some evidence of adverse effects on development, based on animal experiments.

Ethinyl Estradiol:

Effects on fertility : Species: Hamster
Fertility: Lowest observed adverse effect level Parent: 6,3 mg/kg body weight
Symptoms: Effects on fertility.
Result: positive

Effects on fetal development : Test Type: Four-generation reproduction toxicity study
Species: Rat
Application Route: Oral
Dose: > 0.006 milligram per kilogram
Developmental Toxicity: Lowest observed adverse effect concentration F1: > 0,006 mg/kg body weight
Symptoms: Specific developmental abnormalities.

Test Type: Two-generation reproduction toxicity study
Species: Rat, male and female
Application Route: Oral
Developmental Toxicity: Lowest observed adverse effect concentration F1: 0,005 mg/kg body weight
Symptoms: Specific developmental abnormalities.

Reproductive toxicity - Assessment : Clear evidence of adverse effects on sexual function and fertility, based on animal experiments., Clear evidence 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 through prolonged or repeated exposure.

Ingredients:

Ethinyl Estradiol:
Assessment: Shown to produce significant health effects in animals at concentrations of 10 mg/kg bw or less.

Repeated dose toxicity

Ingredients:

Stearic acid:
Species: Rat
NOAEL: 1.000 mg/kg
Application Route: Ingestion
Exposure time: 42 d
Method: OECD Test Guideline 422

Desogestrel:
Species: Rat, female
LOAEL: 0,00625 mg/kg
Application Route: Oral
Target Organs: Reproductive organs, Pituitary gland

Species: Rat
LOAEL: 0,005 mg/kg
Application Route: Oral
Exposure time: 52 Weeks
Number of exposures: daily
Target Organs: Reproductive organs, Pituitary gland

Species: Dog
LOAEL: 0,00625 mg/kg
Application Route: Oral
Exposure time: 26 Weeks
Number of exposures: daily
Target Organs: Reproductive organs, Prostate

Species: Dog
LOAEL: 0,005 mg/kg
Application Route: Oral
Exposure time: 52 Weeks
Number of exposures: daily
Target Organs: Reproductive organs

Ethinyl Estradiol:
Species: Rat
NOAEL: 0,25 mg/kg
LOAEL: 0,5 mg/kg
Application Route: Oral
Exposure time: 2 Weeks
Target Organs: Liver

Species: Rabbit
LOAEL: 0,015 mg/kg
Application Route: Oral
Exposure time: 20 Weeks
Target Organs: Liver

Species: Dog
NOAEL: 0,04 mg/kg
LOAEL: 0,2 mg/kg
Application Route: Oral
Exposure time: 95 d
Target Organs: Blood

Species: Rat, male and female
NOAEL: 0,0015 mg/kg
LOAEL: 0,005 mg/kg
Application Route: Oral
Exposure time: 2 y
Target Organs: Reproductive organs, Mammary gland, Liver

Aspiration toxicity

Not classified based on available information.

Experience with human exposure

Ingredients:

Desogestrel:

Ingestion : Symptoms: Headache, changes in libido, Dizziness, Nausea, Vomiting, Diarrhea, water retention, sodium retention, Gastrointestinal discomfort, mental depression, amenorhea, insomnia, impaired glucose tolerance, pulmonary embolism

Ethinyl Estradiol:

Ingestion : Symptoms: Abdominal pain, Nausea, Vomiting, Diarrhea, Headache, Dizziness, mood swings, Edema, liver function change, water retention, hair loss, gynecomastia, effects on menstruation

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Ingredients:

Stearic acid:

Toxicity to fish : LC50 (Leuciscus idus (Golden orfe)): > 10.000 mg/l
Exposure time: 48 h

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): > 4,8 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 202
Remarks: No toxicity at the limit of solubility.

Toxicity to algae	:	EC50 (Pseudokirchneriella subcapitata (green algae)): > 0,9 mg/l Exposure time: 72 h Method: OECD Test Guideline 201 Remarks: No toxicity at the limit of solubility.
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	:	NOEC (Daphnia magna (Water flea)): > 0,22 mg/l Exposure time: 21 d Method: OECD Test Guideline 211 Remarks: No toxicity at the limit of solubility.
Toxicity to bacteria	:	EC10 (Pseudomonas putida): 883 mg/l Exposure time: 16 h
Desogestrel:		
Toxicity to fish	:	LC50 (Oncorhynchus mykiss (rainbow trout)): 4 mg/l Exposure time: 96 h Method: FDA 4.11 Remarks: Based on data from similar materials LC50 (Lepomis macrochirus (Bluegill sunfish)): 1,3 mg/l Exposure time: 96 h Method: OECD Test Guideline 203 Remarks: No toxicity at the limit of solubility. Based on data from similar materials
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia magna (Water flea)): > 3,9 mg/l Exposure time: 48 h Method: OECD Test Guideline 202 Remarks: No toxicity at the limit of solubility. Based on data from similar materials
Toxicity to fish (Chronic toxicity)	:	NOEC (Pimephales promelas (fathead minnow)): 0,059 mg/l Exposure time: 32 d Method: OECD Test Guideline 210 Remarks: Based on data from similar materials
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	:	NOEC (Daphnia magna (Water flea)): 1,2 mg/l Exposure time: 21 d Remarks: Based on data from similar materials
M-Factor (Chronic aquatic toxicity)	:	1
Toxicity to bacteria	:	EC50: > 1.000 mg/l Exposure time: 3 h Test Type: Respiration inhibition Method: OECD Test Guideline 209 Remarks: Based on data from similar materials NOEC: 70,8 mg/l Exposure time: 3 h Test Type: Respiration inhibition Remarks: Based on data from similar materials

Ethinyl Estradiol:

Toxicity to fish : LC50 (Lepomis macrochirus (Bluegill sunfish)): 1,6 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 203

Toxicity to algae : EC50 (Pseudokirchneriella subcapitata (green algae)): > 6,7 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

Toxicity to fish (Chronic toxicity) : NOEC (Pimephales promelas (fathead minnow)): 0,01 µg/l
Exposure time: 35 d
Method: OECD Test Guideline 210

NOEC (Zebrafish): 0,00031 µg/l
Exposure time: 339 d

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (Daphnia magna (Water flea)): 0,75 mg/l
Exposure time: 21 d
Method: OECD Test Guideline 211

M-Factor (Chronic aquatic toxicity) : 100.000

Toxicity to bacteria : EC50: > 1.000 mg/l
Exposure time: 3 h
Test Type: Respiration inhibition
Method: OECD Test Guideline 209

NOEC: 24,9 mg/l
Exposure time: 3 h
Test Type: Respiration inhibition
Method: OECD Test Guideline 209

Persistence and degradability

Ingredients:

Stearic acid:

Biodegradability : Result: Readily biodegradable.
Biodegradation: 93 %
Exposure time: 28 d
Method: OECD Test Guideline 301B

Desogestrel:

Stability in water : Hydrolyzis: < 10 %(5 d)
Remarks: Based on data from similar materials

Bioaccumulative potential

Ingredients:

Stearic acid:

Bioaccumulation : Species: Fish
Bioconcentration factor (BCF): 238 - 288
Remarks: Based on data from similar materials

Partition coefficient: n-octanol/water	:	log Pow: > 5

Desogestrel:

Bioaccumulation	:	Species: Lepomis macrochirus (Bluegill sunfish) Bioconcentration factor (BCF): 128 Remarks: Based on data from similar materials
Partition coefficient: n-octanol/water	:	log Pow: 3,5

Ethinyl Estradiol:

Bioaccumulation	:	Species: Lepomis macrochirus (Bluegill sunfish) Bioconcentration factor (BCF): 264 Method: OECD Test Guideline 305
Partition coefficient: n-octanol/water	:	log Pow: 4,15

Mobility in soil

No data available

Other adverse effects

No data available

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods

Waste from residues	:	Dispose of in accordance with local regulations.
Contaminated packaging	:	Dispose of as unused product. Empty containers should be taken to an approved waste handling site for recycling or disposal.

SECTION 14. TRANSPORT INFORMATION

International Regulation

UNRTDG

UN number	:	UN 3077
Proper shipping name	:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Ethinyl Estradiol, Desogestrel)
Class	:	9
Packing group	:	III
Labels	:	9

IATA-DGR

UN/ID No.	:	UN 3077
Proper shipping name	:	Environmentally hazardous substance, solid, n.o.s.

(Ethinyl Estradiol, Desogestrel)

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. (Ethinyl Estradiol, Desogestrel)
Class	:	9
Packing group	:	III
Labels	:	9
EmS Code	:	F-A, S-F
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. (Ethinyl Estradiol, Desogestrel)
Class	:	9
Packing group	:	III
Labels	:	CLASS 9
ERG Code	:	171
Marine pollutant	:	yes (Ethinyl Estradiol, Desogestrel)
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 311/312 Hazards : Chronic Health Hazard

SARA 302 : No chemicals in this material are subject to the reporting requirements of SARA Title III, Section 302.

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

Lactose	63-42-3	70 - 90 %
Starch	9005-25-8	20 - 30 %
Stearic acid	57-11-4	5 - 10 %
Ethinyl Estradiol	57-63-6	0 - 0,1 %

New Jersey Right To Know

Lactose	63-42-3	70 - 90 %
Starch	9005-25-8	20 - 30 %
Stearic acid	57-11-4	5 - 10 %
Polyvinyl pyrrolidone	9003-39-8	1 - 5 %

California Prop 65 WARNING! This product contains a chemical known in the State of California to cause cancer.

Ethinyl Estradiol	57-63-6

The ingredients of this product are reported in the following inventories:

AICS : not determined

DSL : not determined

IECSC : not determined

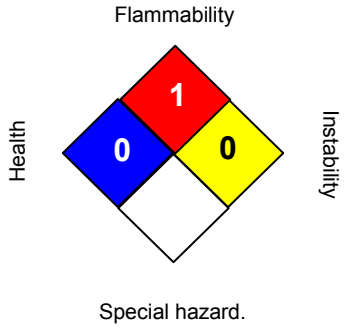
Inventories

AICS (Australia), DSL (Canada), IECSC (China), REACH (European Union), ENCS (Japan), ISHL (Japan), KECI (Korea), NZIoC (New Zealand), PICCS (Philippines), TCSI (Taiwan), TSCA (USA)

SECTION 16. OTHER INFORMATION

Further information

NFPA:



HMIS III:

HEALTH	0*
FLAMMABILITY	1
PHYSICAL HAZARD	0

0 = not significant, 1 =Slight,
2 = Moderate, 3 = High
4 = Extreme, * = Chronic

Full text of other abbreviations

ACGIH	:	USA. ACGIH Threshold Limit Values (TLV)
NIOSH REL	:	USA. NIOSH Recommended Exposure Limits
OSHA Z-1	:	USA. Occupational Exposure Limits (OSHA) - Table Z-1 Limits for Air Contaminants
ACGIH / TWA	:	8-hour, time-weighted average
NIOSH REL / TWA	:	Time-weighted average concentration for up to a 10-hour workday during a 40-hour workweek
OSHA Z-1 / TWA	:	8-hour time weighted average
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	:	02.04.2015

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

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