Safety Data Sheet for Drug Products (US)

Date of issue: 04-JUL-2019
Replaces version of:
ESTRADIOL 0.1MG/24H 8TTS V1 US

Section 1: Identification

Product name	ESTRADIOL 0.1MG/24H 8TTS V1 US
Chemical Class	Steroid derivative
Generic Name	Estradiol
Pharmacological Action	estrogene, Hormone-releasing hormone
Usage	Drug product (pharmaceutical bulk, primary packed, finished product, pharmaceutical intermediate)
Company name	Novartis Pharma AG 4002 Basel Switzerland Tel: +41 61 324 11 11, email: sds.support@novartis.com
Emergency phone number	CHEMTEL (International) +1 813 676 1670 (365/24/7)

Section 2: Hazards identification

For side effects, which could also have impact for people working with this substance, please refer to the Patient Information Leaflet.

Section 3: Composition / information on ingredients

For classification of declared components, see section 15, "Regulatory Information"

Chemical Name	Contains:	CAS Number
Estradiol	0.2 - 0.4 mg/cm2	35380-71-3

Remaining components are inert ingredients.

For TLV values of declared components, see Section 8, Exposure controls / Personal

Section 4: First aid measures

First aid measures for drug products

Inhalation	Remove the victim from danger zone, avoid further exposure.
Skin Contact	Remove contaminated clothing. Rinse contaminated skin immediately with plenty of water and soap and seek medical advice.
Eye Contact	Immediately rinse eyes thoroughly with running water as long as possible (approx. 15 min). Take injured quickly to factory medical center or call an ambulance (code word: eye accident).
Ingestion	If swallowed, seek medical advice immediately and show this container or label.
Notes to Physician	General measures to eliminate the substance and to reduce absorption.

Section 5: Fire fighting measures

Suitable Extinguishing Media	Water spray or fog, foam, dry chemical powder, CO2, dry sand
Unsuitable Extinguishing Media	No restrictions
Protective equipment for firefighters	Wear self-contained breathing apparatus and fire protective suite.

Section 6: Accidental release measures

Personal precautions	Avoid contact with skin, eyes and clothing.
Environmental precautions	Must not be released into sewers, drains or wells.

Methods for cleaning	Transfer large quantities into a container. Clean up the rest with absorbent material and discharge properly.

Section 7: Handling and storage

No special handling requirements for normal use of this material.
Store in a dry and cool place and observe special instructions from supplier.

Section 8: Exposure controls / Personal protection

Occupational Exposure Limit (OEL)
no data available

TLV values of declared components
Contains:
Estradiol

List type	Value	Unit	
Occupational Exposure Limit (OEL)	0.1	µg/m3	HHA Database

Personal protection for open handling

Health care personnel		Safety glasses (EN166) Disposable fine dust protection mask (EN149); Double disposable gloves (EN374) Disposable dust-proof lab coat

Section 9: Physical and chemical properties

Formulation	plaster
Flash Point	not applicable

Section 10: Stability and reactivity

Under the normal conditions of use, the product is stable.

Section 11: Toxicological information

Acute Toxicity	Data of Estradiol LD50: 1200 mg/kg Route: oral Species: rat
Irritation, Corrosion	Data of Estradiol Skin (Species: rabbit) non irritant
Sensitisation	Data of Estradiol Skin (Species: guinea pig) not sensitizing
Mutagenicity	Data of Estradiol Negative with and without metabolic activation (AMES-Test (reverse mutation assay)) in vitroCell: Strains of Salmonella typhimurium and Escherichia coli. Data of Estradiol Negative (DNA Damage and Repair, Unscheduled DNA Synthesis in Mammalian Cells in vitro) in vitroCell: Rat hepatocytes Data of Estradiol Negative (Mouse Lymphoma Mutagenicity Assay in vitro) in vitroCell: Lymphoma cells L5178Y of the mouse Data of Estradiol Negative (DNA Damage and Repair, Unscheduled DNA Synthesis in vivo) in vivo, Species: rat, Cell: Liver cells Data of Estradiol

	Negative (Micronucleus Test) in vivo, Species: rat, Cell: Bone marrow
	Data of Estradiol Positive (Chromosome Aberration Study) in vitroCell: Cultured peripheral human lymphocytes
Chronic Effects	Data of Estradiol Pharmacological effects (Repeated Dose Toxicity) Route: percutaneous Species: rat, Organ: Female reproductive system Duration: 13 weeks
	Data of Estradiol Evidence for tumour promotion (Repeated Dose Toxicity) Route: intramuscular Species: dog, Organ: Female reproductive system Duration: 52 weeks
	Data of Estradiol Carcinogen (Carcinogenesis) Route: percutaneous Species: rat
	Data of Estradiol Carcinogen (Carcinogenesis) Route: oral Species: hamster, Organ: Kidneys Duration: 9 months
	Data of Estradiol Carcinogen (Carcinogenesis) Route: subcutaneous Species: mouse, Organ: Female reproductive system Duration: 20 months
Reproduction Toxicity	Data of Estradiol No teratogenicity at maternally non toxic dose (Embryo-Fetal Development) NOEL: > 0.001 mg/kg/d Route: subcutaneous Species: rat
	Data of Estradiol No teratogenicity at maternally non toxic dose (Embryo-Fetal Development) NOEL: 0.0003 mg/kg/d Route: subcutaneous Species: rabbit

Toxicological Hazard Classification

Acute Toxicity (oral):	Data of Estradiol Cat.4
Acute Toxicity (dermal):	Data of Estradiol not classifiable
Acute Toxicity (inhalation):	Data of Estradiol not classifiable
Eye Corrosion / Irritation:	Data of Estradiol not classifiable
Skin Corrosion / Irritation:	Data of Estradiol not classified
Respiratory sensitizer	Data of Estradiol not classifiable
Skin sensitizer:	Data of Estradiol not classified
Germ cell mutation:	Data of Estradiol not classifiable

Carcinogenicity:	Data of Estradiol Cat.2
Reproductive toxicity:	Data of Estradiol Cat.1B dev.,fert.&lact.
Specific organ toxicity (single dose), not lethal:	Data of Estradiol not classifiable
Specific organ toxicity (repeated exposure):	Data of Estradiol not classifiable
Aspiration Hazard:	Data of Estradiol not applicable

Carcinogenicity listing

Data of Estradiol
IARC Carcinogens

Data of Estradiol
National Toxicology Program (NTP) Report on Carcinogens (1998)
Anticipated human carcinogen

Section 12: Ecological information

Fish acute toxicity	Data of Estradiol LC50: > 0.5 mg/l Species: rainbow trout (salmo gairdneri, oncorhynchus mykiss) Exp. time: 96 hours
Aquatic invertebrate acute toxicity	no data available
Algae Toxicity	no data available
Bacterial Respiration Inhibition	no data available
Biological Elimination	no data available
Partition Coefficient	Data of Estradiol log Pow: 3.3 (Temperature: 20 °C)
Biological accumulation	no data available
Soil and Sludge Sorption/Desorption	no data available
PBT assessment	no data available
Other adverse effects	no data available

Section 13: Disposal considerations

Disposal Requirements	Fill into suitable waste receptacles, seal and label them properly. Incineration in an approved, controlled furnace with combustion gas scrubbing and emission gas control. Local regulations should be adhered to.

Section 14: Transport information

Regulation	IMDG-Code:	ICAO/IATA-DGR:
UN Number	0	0
UN Proper Shipping Name	-	-
Transport Hazard Class(es)		
Transport Label(s)		

Packing group	
Environmental Hazard	
Additional Information	

Special Precaution for User

Transport within user's premises: always transport in closed containers that are upright and secure. Ensure that persons transporting the product know what to do in the event of an accident or spillage.

Temperature Conditions for Transport Transport condition: TEMPCONTROL: Transport + intermediate storage below 30°C

Section 15: Regulatory information

Chemical characterisation of the substance / preparation:

Chemical Name	Contains:	CAS Number	Picto	Signal Word	Classification
Estradiol	0.2 - 0.4 mg/cm2	35380-71-3		D	H302, H351, H360df/362, H401

Regulatory lists of declared components
Contains:
Estradiol

List type	assessment	Date
IARC Carcinogens National Toxicology Program (NTP) Report on Carcinogens	Anticipated human carcinogen	1998

Toxic Substances Control Act Not listed or exempted

Remaining components are inert ingredients.

Section 16: Other information

Abbreviations used

H302: Harmful if swallowed.
H351: Suspected of causing cancer.
H360df/362: May damage fertility and the unborn child. May cause harm to breast-fed children.
H401: Toxic to aquatic life.(in EU not leading to classification as hazardous)

Recipient .

Product should be stored, handled and used in accordance with good industrial hygiene practices and in conformity with legal regulations. The information contained herein is based on the present state of our knowledge and is intended to describe our products from the point of view of safety requirements. It should therefore not be construed as guaranteeing specific properties.