SAFETY DATA SHEET

Estradiol Gel Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
4.0	30.09.2023	10608788-00006	Date of first issue: 08.02.2022

Section 1: Identification

Product name : Estradiol Gel Formulation

Manufacturer or supplier's details

Company : Organon & Co.

Address : 30 Hudson Street, 33nd floor
Jersey City, New Jersey, U.S.A 07302

Telephone : +1-551-430-6000

Emergency telephone number : +1-215-631-6999

E-mail address : EHSSTEWARD@organon.com

Recommended use of the chemical and restrictions on use

Recommended use : Pharmaceutical
Restrictions on use : Not applicable

Section 2: Hazard identification

GHS Classification

Flammable liquids : Category 2

Serious eye damage/eye irritation : Category 2

Carcinogenicity : Category 1

Reproductive toxicity : Category 1

Specific target organ toxicity - repeated exposure : Category 1 (Liver, Bone, Blood, Endocrine system)

Hazardous to the aquatic environment - chronic hazard : Category 1

GHS label elements

Hazard pictograms :

Signal word : Danger

Hazard statements : H225 Highly flammable liquid and vapour.

H319 Causes serious eye irritation.
H350 May cause cancer.
H360FD May damage fertility. May damage the unborn child.
H372 Causes damage to organs (Liver, Bone, Blood, Endocrine system) through prolonged or repeated exposure.
H410 Very toxic to aquatic life with long lasting effects.

Precautionary statements : **Prevention:**

P201 Obtain special instructions before use.
P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
P233 Keep container tightly closed.
P241 Use explosion-proof electrical/ ventilating/ lighting equipment.
P242 Use non-sparking tools.
P243 Take action to prevent static discharges.
P264 Wash skin thoroughly after handling.
P270 Do not eat, drink or smoke when using this product.
P273 Avoid release to the environment.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response:

P303 + P361 + P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water.
P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P308 + P313 IF exposed or concerned: Get medical advice/ attention.
P337 + P313 If eye irritation persists: Get medical advice/ attention.
P391 Collect spillage.

Storage:

P403 + P235 Store in a well-ventilated place. Keep cool.
P405 Store locked up.

Disposal:

P501 Dispose of contents/ container to an approved waste disposal plant.

Other hazards which do not result in classification

Vapours may form explosive mixture with air.

Section 3: Composition/information on ingredients

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)
Ethanol#	64-17-5	58.5

Propylene glycol	57-55-6	12.5
Estradiol	50-28-2	0.1

Voluntarily-disclosed substance

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	:	In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. If easy to do, remove contact lens, if worn. Get medical attention.
If swallowed	:	If swallowed, DO NOT induce vomiting. Get medical attention. Rinse mouth thoroughly with water.
Most important symptoms and effects, both acute and delayed	:	Causes serious eye irritation. May cause cancer. May damage fertility. May damage 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 (see section 8).
Notes to physician	:	Treat symptomatically and supportively.

Section 5: Fire-fighting measures

Suitable extinguishing media	:	Water spray Alcohol-resistant foam Carbon dioxide (CO2) Dry chemical
Unsuitable extinguishing media	:	High volume water jet
Specific hazards during fire-fighting	:	Do not use a solid water stream as it may scatter and spread fire. Flash back possible over considerable distance. Vapours may form explosive mixtures with air. Exposure to combustion products may be a hazard to health.
Hazardous combustion products	:	Carbon oxides

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 firefighters	:	In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.
Hazchem Code	:	2YE

Section 6: Accidental release measures

Personal precautions, protective equipment and emergency procedures	:	Remove all sources of ignition. Ventilate the area. Use personal protective equipment. Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).
Environmental precautions	:	Avoid release to the environment. Prevent further leakage or spillage if safe to do so. Prevent spreading over a wide area (e.g. by containment or oil barriers). 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	:	Non-sparking tools should be used. Soak up with inert absorbent material. Suppress (knock down) gases/vapours/mists with a water spray jet. For large spills, provide dyking or other appropriate containment to keep material from spreading. If dyked material can be pumped, store recovered material in appropriate container. Clean up remaining materials from spill with suitable absorbent. 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	:	See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.
Local/Total ventilation	:	If sufficient ventilation is unavailable, use with local exhaust ventilation. Use explosion-proof electrical, ventilating and lighting equipment.
Advice on safe handling	:	Do not get on skin or clothing.

		Do not breathe vapours. Do not swallow. Do not get in eyes. Wash skin thoroughly after handling. Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment Non-sparking tools should be used. Keep container tightly closed. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Take precautionary measures against static discharges. Do not eat, drink or smoke when using this product. Take care to prevent spills, waste and minimize release to the environment.
Hygiene measures	:	If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. Wash contaminated clothing before re-use. The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.
Conditions for safe storage	:	Keep in properly labelled containers. Store locked up. Keep tightly closed. Keep in a cool, well-ventilated place. Store in accordance with the particular national regulations. Keep away from heat and sources of ignition.
Materials to avoid	:	Do not store with the following product types: Self-reactive substances and mixtures Organic peroxides Oxidizing agents Flammable gases Pyrophoric liquids Pyrophoric solids Self-heating substances and mixtures Poisonous gases Explosives

Section 8: Exposure controls/personal protection

Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Ethanol	64-17-5	WES-TWA	1,000 ppm 1,880 mg/m3	NZ OEL
	Further information: Ototoxin			

		STEL	1,000 ppm	ACGIH
Propylene glycol	57-55-6	WES-TWA (particulate)	10 mg/m3	NZ OEL
		WES-TWA (Vapour and particulates)	150 ppm 474 mg/m3	NZ OEL
Estradiol	50-28-2	TWA	0.05 µg/m3 (OEB 5)	Internal
	Further information: Skin			
		Wipe limit	0.5 µg/100 cm²	Internal

Engineering measures : Use closed processing systems or containment technologies to control at source (e.g., glove boxes/isolators) and to prevent leakage of compounds into the workplace.
All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.
No open handling permitted.
Totally enclosed processes and materials transport systems are required.
Operations require the use of appropriate containment technology designed to prevent leakage of compounds into the workplace.

Use explosion-proof electrical, ventilating and lighting equipment.

Personal protective equipment

Respiratory protection : If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.

Filter type : Combined particulates and organic vapour type

Hand protection

Material : Chemical-resistant gloves

Remarks : Consider double gloving. Take note that the product is flammable, which may impact the selection of hand protection.

Eye protection : Wear safety glasses with side shields or goggles.
If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles.
Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.

Skin and body protection : Work uniform or laboratory coat.
Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces.
Use appropriate degowning techniques to remove potentially contaminated clothing.

Section 9: Physical and chemical properties

Appearance	:	gel
Colour	:	opalescent
Odour	:	aromatic
Odour 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	:	22 °C Method: closed cup
Evaporation rate	:	No data available
Flammability (solid, gas)	:	Not applicable
Flammability (liquids)	:	Ignitable (see flash point)
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Vapour pressure	:	No data available
Relative vapour density	:	No data available
Relative density	:	No data available
Density	:	No data available
Solubility(ies) Water solubility	: :	 No data available
Partition coefficient: n-octanol/water	:	Not applicable
Auto-ignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity Viscosity, kinematic	: :	 No data available
Explosive properties	:	Not explosive

Oxidizing properties	:	The substance or mixture is not classified as oxidizing.
Molecular weight	:	No data available
Particle size	:	Not applicable

Section 10: Stability and reactivity

Reactivity	:	Not classified as a reactivity hazard.
Chemical stability	:	Stable under normal conditions.
Possibility of hazardous reactions	:	Highly flammable liquid and vapour. Vapours may form explosive mixture with air. Can react with strong oxidizing agents.
Conditions to avoid	:	Heat, flames and sparks.
Incompatible materials	:	Oxidizing agents
Hazardous decomposition products	:	No hazardous decomposition products are known.

Section 11: Toxicological information

Exposure routes : Inhalation
Skin contact
Ingestion
Eye contact

Acute toxicity

Not classified based on available information.

Components:

Ethanol:

Acute oral toxicity	:	LD50 (Rat): > 5,000 mg/kg Method: OECD Test Guideline 401
Acute inhalation toxicity	:	LC50 (Rat): 124.7 mg/l Exposure time: 4 h Test atmosphere: vapour

Propylene glycol:

Acute oral toxicity	:	LD50 (Rat): 22,000 mg/kg
Acute inhalation toxicity	:	LC50 (Rat): > 44.9 mg/l Exposure time: 4 h Test atmosphere: dust/mist
Acute dermal toxicity	:	LD50 (Rabbit): > 2,000 mg/kg Assessment: The substance or mixture has no acute dermal toxicity

Estradiol:

Acute oral toxicity	:	LD50 (Rat): > 2,000 mg/kg
Acute toxicity (other routes of administration)	:	LD50 (Rat): > 300 mg/kg Application Route: Subcutaneous

Skin corrosion/irritation

Not classified based on available information.

Components:

Ethanol:

Species	:	Rabbit
Method	:	OECD Test Guideline 404
Result	:	No skin irritation

Propylene glycol:

Species	:	Rabbit
Method	:	OECD Test Guideline 404
Result	:	No skin irritation

Serious eye damage/eye irritation

Causes serious eye irritation.

Components:

Ethanol:

Species	:	Rabbit
Result	:	Irritation to eyes, reversing within 21 days
Method	:	OECD Test Guideline 405

Propylene glycol:

Species	:	Rabbit
Result	:	No eye irritation
Method	:	OECD Test Guideline 405

Estradiol:

Result	:	No eye irritation

Respiratory or skin sensitisation

Skin sensitisation

Not classified based on available information.

Respiratory sensitisation

Not classified based on available information.

Components:

Ethanol:

Test Type	:	Local lymph node assay (LLNA)
Exposure routes	:	Skin contact
Species	:	Mouse
Result	:	negative

Propylene glycol:

Test Type	:	Maximisation Test
Exposure routes	:	Skin contact
Species	:	Guinea pig
Result	:	negative

Estradiol:

Exposure routes	:	Skin contact
Species	:	Guinea pig
Assessment	:	Does not cause skin sensitisation.
Result	:	negative

Chronic toxicity

Germ cell mutagenicity

Not classified based on available information.

Components:

Ethanol:

Genotoxicity in vitro	:	Test Type: In vitro mammalian cell gene mutation test Result: negative Test Type: Bacterial reverse mutation assay (AMES) Result: negative
Genotoxicity in vivo	:	Test Type: Rodent dominant lethal test (germ cell) (in vivo) Species: Mouse Application Route: Ingestion Result: equivocal

Propylene glycol:

Genotoxicity in vitro	:	Test Type: Bacterial reverse mutation assay (AMES) Result: negative Test Type: Chromosome aberration test in vitro Method: OECD Test Guideline 473 Result: negative
Genotoxicity in vivo	:	Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay) Species: Mouse

Application Route: Intraperitoneal injection
Result: negative

Estradiol:

Genotoxicity in vitro	:	Test Type: DNA damage and repair, unscheduled DNA synthesis in mammalian cells (in vitro) Test system: mammalian cells Result: positive Test Type: Chromosome aberration test in vitro Test system: mammalian cells Result: positive Test Type: Chromosomal aberration Test system: mammalian cells Result: positive
Genotoxicity in vivo	:	Test Type: Chromosomal aberration Species: Rat Cell type: Bone marrow Result: negative Test Type: Chromosomal aberration Species: Mouse Cell type: Bone marrow Result: negative

Carcinogenicity

May cause cancer.

Components:

Propylene glycol:

Species	:	Rat
Application Route	:	Ingestion
Exposure time	:	2 Years
Result	:	negative

Estradiol:

Species	:	Mouse
Application Route	:	Ingestion
Exposure time	:	24 Months
LOAEL	:	100 µg/kg
Result	:	positive
Target Organs	:	female reproductive organs

Species	:	Rat
Application Route	:	Subcutaneous
Exposure time	:	13 weeks
LOAEL	:	20 mg/kg body weight
Result	:	positive

Target Organs	:	Endocrine system
Carcinogenicity - Assessment	:	Positive evidence from human epidemiological studies

Reproductive toxicity

May damage fertility. May damage the unborn child.

Components:

Ethanol:

Effects on fertility	:	Test Type: Two-generation reproduction toxicity study Species: Mouse Application Route: Ingestion Result: negative

Propylene glycol:

Effects on fertility	:	Test Type: Two-generation reproduction toxicity study Species: Mouse Application Route: Ingestion Result: negative
Effects on foetal development	:	Test Type: Embryo-foetal development Species: Mouse Application Route: Ingestion Result: negative

Estradiol:

Effects on fertility	:	Test Type: One-generation reproduction toxicity study Species: Rat Application Route: Ingestion Fertility: LOAEL: 0.5 mg/kg body weight Result: Effects on fertility Test Type: One-generation reproduction toxicity study Species: Rat Duration of Single Treatment: 90 d Fertility: LOAEL: 0.69 mg/kg body weight Result: Effects on fertility Test Type: Two-generation study Species: Mouse Application Route: Oral Fertility: LOAEL: 0.1 mg/kg body weight Result: Effects on fertility
Effects on foetal development	:	Test Type: Embryo-foetal development Species: Mouse, female Application Route: Subcutaneous Teratogenicity: LOAEL: 4 mg/kg body weight Symptoms: Malformations were observed. Result: positive, Teratogenic effects

		Test Type: One-generation reproduction toxicity study Species: Rat Application Route: Subcutaneous Teratogenicity: LOAEL: 2.5 µg/kg body weight Symptoms: Reduced body weight Result: positive, Embryotoxic effects and adverse effects on the offspring were detected. Test Type: Embryo-foetal development Species: Rat Application Route: Subcutaneous Developmental Toxicity: LOAEL: 0.2 mg/kg body weight Symptoms: Early Resorptions / resorption rate, Reduced number of viable fetuses, Reduced body weight Result: Embryotoxic effects and adverse effects on the offspring were detected only at high maternally toxic doses
Reproductive toxicity - Assessment	:	May damage fertility. May damage the unborn child.

STOT - single exposure

Not classified based on available information.

STOT - repeated exposure

Causes damage to organs (Liver, Bone, Blood, Endocrine system) through prolonged or repeated exposure.

Components:

Estradiol:

Target Organs	:	Liver, Bone, Blood, Endocrine system
Assessment	:	Causes damage to organs through prolonged or repeated exposure.

Repeated dose toxicity

Components:

Ethanol:

Species	:	Rat
NOAEL	:	1,280 mg/kg
LOAEL	:	3,156 mg/kg
Application Route	:	Ingestion
Exposure time	:	90 Days

Propylene glycol:

Species	:	Rat, male
NOAEL	:	>= 1,700 mg/kg
Application Route	:	Ingestion
Exposure time	:	2 yr

Estradiol:

Species	:	Rat
LOAEL	:	>= 0.17 mg/kg
Application Route	:	Ingestion
Exposure time	:	90 d
Target Organs	:	Mammary gland, Ovary, Uterus (including cervix), Liver, Bone, Endocrine system, Blood, Testis

Aspiration toxicity

Not classified based on available information.

Experience with human exposure

Components:

Estradiol:

Inhalation	:	Symptoms: tingling, Nose bleeding
Skin contact	:	Symptoms: Skin irritation, Redness, pruritis
Ingestion	:	Symptoms: Headache, Gastrointestinal disturbance, Dizziness, Vomiting, Diarrhoea, water retention, liver function change, changes in libido, breast tenderness, menstrual irregularities

Section 12: Ecological information

Ecotoxicity

Components:

Ethanol:

Toxicity to fish	:	LC50 (Pimephales promelas (fathead minnow)): > 1,000 mg/l Exposure time: 96 h
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Ceriodaphnia (water flea)): > 1,000 mg/l Exposure time: 48 h
Toxicity to algae/aquatic plants	:	ErC50 (Chlorella vulgaris (Fresh water algae)): 275 mg/l Exposure time: 72 h EC10 (Chlorella vulgaris (Fresh water algae)): 11.5 mg/l Exposure time: 72 h
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	:	NOEC (Daphnia magna (Water flea)): 9.6 mg/l Exposure time: 9 d
Toxicity to microorganisms	:	EC50 (Pseudomonas putida): 6,500 mg/l Exposure time: 16 h

Propylene glycol:

Toxicity to fish	:	LC50 (Oncorhynchus mykiss (rainbow trout)): 40,613 mg/l Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Ceriodaphnia dubia (water flea)): 18,340 mg/l Exposure time: 48 h
Toxicity to algae/aquatic plants	:	ErC50 (Skeletonema costatum (marine diatom)): 19,300 mg/l Exposure time: 72 h Method: OECD Test Guideline 201
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	:	NOEC (Ceriodaphnia dubia (water flea)): 13,020 mg/l Exposure time: 7 d
Toxicity to microorganisms	:	NOEC (Pseudomonas putida): > 20,000 mg/l Exposure time: 18 h

Estradiol:

Toxicity to fish	:	LC50 (Oryzias latipes (Japanese medaka)): 3.9 mg/l Exposure time: 96 h
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia magna (Water flea)): 2.7 mg/l Exposure time: 48 h
Toxicity to algae/aquatic plants	:	NOEC (Pseudokirchneriella subcapitata (green algae)): 1.7 mg/l Exposure time: 72 h Method: OECD Test Guideline 201 EC50 (Pseudokirchneriella subcapitata (green algae)): > 1.7 mg/l Exposure time: 72 h Method: OECD Test Guideline 201
Toxicity to fish (Chronic toxicity)	:	NOEC (Oryzias latipes (Japanese medaka)): 0.000003 mg/l Exposure time: 160 d Method: OECD Test Guideline 210
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	:	NOEC (Daphnia magna (Water flea)): 0.2 mg/l Exposure time: 21 d
M-Factor (Chronic aquatic toxicity)	:	1,000
Toxicity to microorganisms	:	EC50: > 100 mg/l Exposure time: 3 h Test Type: Respiration inhibition Method: OECD Test Guideline 209 NOEC: 100 mg/l Exposure time: 3 h Test Type: Respiration inhibition Method: OECD Test Guideline 209

Persistence and degradability

Components:

Ethanol:

Biodegradability	:	Result: Readily biodegradable. Biodegradation: 84 % Exposure time: 20 d

Propylene glycol:

Biodegradability	:	Result: Readily biodegradable. Biodegradation: 98.3 % Exposure time: 28 d Method: OECD Test Guideline 301F

Estradiol:

Biodegradability	:	Result: rapidly degradable Biodegradation: 84 % Exposure time: 24 hrs

Bioaccumulative potential

Components:

Ethanol:

Partition coefficient: n-octanol/water	:	log Pow: -0.35

Propylene glycol:

Partition coefficient: n-octanol/water	:	log Pow: -1.07 Method: Regulation (EC) No. 440/2008, Annex, A.8

Estradiol:

Partition coefficient: n-octanol/water	:	log Pow: 4.01

Mobility in soil

Components:

Estradiol:

Distribution among environmental compartments	:	log Koc: 3.81

Other adverse effects

No data available

Section 13: Disposal considerations

Disposal methods

Waste from residues	:	Do not dispose of waste into sewer. Dispose of in accordance with local regulations.
Contaminated packaging	:	Empty containers should be taken to an approved waste handling site for recycling or disposal. Empty containers retain residue and can be dangerous. Do not pressurize, cut, weld, braze, solder, drill, grind, or expose such containers to heat, flame, sparks, or other sources of ignition. They may explode and cause injury and/or death. If not otherwise specified: Dispose of as unused product.

Section 14: Transport information

International Regulations

UNRTDG

UN number	:	UN 1170
Proper shipping name	:	ETHANOL SOLUTION
Class	:	3
Packing group	:	II
Labels	:	3
Environmentally hazardous	:	yes

IATA-DGR

UN/ID No.	:	UN 1170
Proper shipping name	:	Ethanol solution
Class	:	3
Packing group	:	II
Labels	:	Flammable Liquids
Packing instruction (cargo aircraft)	:	364
Packing instruction (passenger aircraft)	:	353

IMDG-Code

UN number	:	UN 1170
Proper shipping name	:	ETHANOL SOLUTION (Estradiol)
Class	:	3
Packing group	:	II
Labels	:	3
EmS Code	:	F-E, S-D
Marine pollutant	:	yes

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

National Regulations

NZS 5433

UN number	:	UN 1170

Proper shipping name	:	ETHANOL SOLUTION
Class	:	3
Packing group	:	II
Labels	:	3
Hazchem Code	:	2YE
Marine pollutant	:	yes

Special precautions for user

The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

Section 15: Regulatory information

Safety, health and environmental regulations/legislation specific for the substance or mixture

HSNO Approval Number

HSR100425 Pharmaceutical Active Ingredients Group Standard

HSW Controls

Certified handler certificate not required.
Tracking hazardous substance not required.
Refer to the Health and Safety at Work (Hazardous Substances) Regulations 2017, for further information.

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

AICS	:	not determined
DSL	:	not determined
IECSC	:	not determined

Section 16: Other information

Revision Date	:	30.09.2023

Further information

Sources of key data used to compile the Safety Data Sheet	:	Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, http://echa.europa.eu/

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

Date format	:	dd.mm.yyyy

Full text of other abbreviations

ACGIH	:	USA. ACGIH Threshold Limit Values (TLV)
NZ OEL	:	New Zealand. Workplace Exposure Standards for Atmospher-

ic Contaminants

ACGIH / STEL	:	Short-term exposure limit
NZ OEL / WES-TWA	:	Workplace Exposure Standard - Time Weighted average

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.

NZ / EN