


SECTION 1: IDENTIFICATION	
1.1 Product identifier	
Product name:	Perlutex 5 mg Tablets
Synonyms:	None
Proper Shipping name:	Not Applicable
Other means of identification:	None
1.2 Relevant identified uses of the substances or mixture and uses advised against	
Recommended uses:	For the symptomatic treatment of clinical signs associated with Pituitary Pars Intermedia Dysfunction (PPID) (Equine Cushing's Disease)
Uses advised against:	Not for human use
1.3 Details of the supplier of the substance or mixture	
Registered company name:	Dechra Ltd
Address:	Snaygill Industrial Estate Keighley Road Skipton North Yorkshire BD23 2RW UK
Telephone:	+44 (0) 1756 791311
Fax:	+44 (0) 1756 798604
Website:	www.dechra.com
1.4 Emergency Telephone Numbers	
	+44 (0) 1756 791311

SECTION 2: HAZARDS IDENTIFICATION	
2.1 Classification of the substance or mixture	
<p style="color: red;">Considered a hazardous mixture according to Reg. (EC) No 1272/2008 and their amendments. Not classified as Dangerous Goods for transport purposes (EU).</p>	
Classification according to regulation (EC) No 1272/2008 [CLP] and amendments (EU)¹	H360 - Reproductive Toxicity Category 1B, H351 - Carcinogenicity Category 2
1. Classified by Chemwatch; 2. Classification drawn from Regulation (EU) No 1272/2008 - Annex VI	

2.2 Label Elements	
Hazard Pictogram:	
Signal Word:	Danger
Hazard statement(s):	
H360	May damage fertility or the unborn child.
H351	Suspected of causing cancer.
Supplementary Statement(s):	
Not applicable	
Precautionary Statement(s) Prevention:	
P201	Obtain special instructions before use.
P280	Wear protective gloves, protective clothing, eye protection and face protection.
Precautionary Statement(s) Response:	
P308+P313	IF exposed or concerned: Get medical advice/ attention.
Precautionary Statement(s) Storage:	
P405	Store locked up.
Precautionary Statement(s) Disposal:	
P501	Dispose of contents/container to authorised hazardous or special waste collection point in accordance with any local regulation.
2.3 Other Hazard Information	
Cumulative effects may result following exposure*. May produce skin discomfort*. Possible respiratory and skin sensitizer*. REACh - Art.57-59: The mixture does not contain Substances of Very High Concern (SVHC) at the SDS print date.	

SECTION 3: INFORMATION ON THE INGREDIENTS

3.1 Substances

See 'Composition of mixtures' in Section 3.2

3.2 Mixtures

1.CAS No 2.EC Number 3.Index Number 4.REACH Number	% Weight	Name	Classification according to regulations (EC) No 1272/2008 [CLP] (EU)
1.64044-51-5 2.200-559-2 3.Not Available 4.Not Available	>60	<u>alpha-lactose</u>	Not Applicable
1.65996-63-6 2.232-679-6 3.Not Available 4.Not Available	10-30	<u>starch</u>	Not Applicable
1.71-58-9 2.200-757-9 3.Not Available 4.Not Available	1-10	<u>medroxyprogesterone acetate</u>	Carcinogenicity Category 2, Reproductive Toxicity Category 1B; H351, H360FD [1]
1.14807-96-6 2.238-877-9 3.Not Available 4.01-2120140278-58-XXXX	1-10	<u>talc</u>	Acute Toxicity (Inhalation) Category 4, Specific Target Organ Toxicity - Single Exposure (Respiratory Tract Irritation) Category 3; H332, H335 [1]
1.9000-70-8 2.232-554-6 3.Not Available 4.Not Available	<1	<u>gelatine</u>	Not Applicable
1.557-04-0 2.209-150-3 3.Not Available 4.Not Available	<1	<u>magnesium stearate</u>	Skin Corrosion/Irritation Category 2, Serious Eye Damage/Eye Irritation Category 2, Specific Target Organ Toxicity - Single Exposure (Respiratory Tract Irritation) Category 3; H315, H319, H335 [1]

1. Classified by Chemwatch; 2. Classification drawn from Regulation (EU) No 1272/2008 - Annex VI; 3. Classification drawn from C&L; * EU IOELVs available; [e] Substance identified as having endocrine disrupting properties

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

Eye contact:	Accidental spillage on the eyes should be washed off immediately with plenty of water. Remove contact lenses if possible. Seek medical
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	advice if pain and irritation persists and show the package leaflet or the label to the medical practitioner.
Skin contact:	In the case of contact with skin, wash with soap and water. If irritation persists, seek medical advice. Wash hands after use.
Inhalation:	Inhalation is highly unlikely due to the nature of the product and how it is packaged and administered. If irritation or difficulty in breathing occurs, remove the patient from the contaminated area. Seek medical advice if irritation persists and show the package leaflet or the label to the medical practitioner.
Ingestion:	If swallowed, do not induce vomiting. If vomiting occurs, lean patient forward or place on left side (head-down position, if possible) to maintain open airway and prevent aspiration and immediately give water. Give water to rinse out mouth, then provide liquid slowly and as much as casualty can comfortably drink. If discomfort persists, seek medical advice and show the package leaflet or the label to medical practitioner.
4.2 Most important symptoms and effects, both acute and delayed See Section 11	
4.3 Indication of immediate medical attention and special treatment needed Treat symptomatically.	

SECTION 5: FIRE FIGHTING MEASURES

5.1 Extinguishing media

There is no restriction on the type of extinguisher which may be used. Use extinguishing media suitable for surrounding area.

5.2 Special hazards arising from the substance or mixture

Fire incompatibility: Avoid contamination with oxidising agents i.e. nitrates, oxidising acids, chlorine bleaches, pool chlorine etc. as ignition may result.

5.3 Special protective actions for fire-fighters:

Firefighting: Alert Fire Brigade and tell them location and nature of hazard. Wear breathing apparatus plus protective gloves in the event of a fire. Prevent, by any means available, spillage from entering drains or water courses. Use fire fighting procedures suitable for surrounding area. **DO NOT** approach containers suspected to be hot. Cool fire exposed containers with water spray from a protected location. If safe to do so, remove containers from path of fire. Equipment should be thoroughly decontaminated after use

Fire/explosion hazard: Combustible solid which burns but propagates flame with difficulty
On combustion, may emit toxic fumes of carbon monoxide.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

See section 8

6.2 Environmental Precautions

See section 12

6.3 Methods and material for containment and cleaning up

Spills are unlikely due to the nature of the product and how it is packaged

Minor Spills:	Clean up all spills immediately. Avoid breathing vapours and contact with skin and eyes. Control personal contact with the substance, by using protective equipment. Place in a suitable, labelled container for waste disposal.
Major Spills:	Clear area of personnel and move upwind. Alert Fire Brigade and tell them location and nature of the hazard. Prevent, by any means available, spillage from entering drains or water course.

6.4 Reference to other sections

Personal Protective Equipment advice is contained in Section 8 of the SDS.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Safe Handling:	Wear suitable protection gloves and clothing when handling the product. Avoid all personal contact, including inhalation. When handling, DO NOT eat, drink or smoke. Always wash hands with water after handling. Observe manufacturer's storage and handling recommendations.
Fire and explosion protection	See section 5
Other Information:	Store in original containers. Keep containers securely sealed. Store in a cool, dry area protected from environmental extremes. Keep out of the reach and sight of children. Observe manufacturer's storage and handling recommendations contained within this SDS. For major quantities: Consider storage in bunded areas - ensure storage areas are isolated from sources of community water (including stormwater, ground water, lakes and streams).. Ensure that accidental discharge to air or water is the subject of a contingency disaster management plan; this may require consultation with local authorities

7.2 Conditions for safe storage, including any incompatibilities

Suitable Container:	Cardboard box containing 60 or 160 tablets in cold-formed nylon/aluminium foil/UPVC. The lidding material is aluminium foil with a vinyl heat seal coating.
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Storage incompatibility:	Avoid reaction with oxidising agents
7.3 Specific end uses See section 1	

SECTION 8: EXPOSURE CONTROLS / PERSONAL PROTECTION

8.1 Control parameters

Ingredient	SNELs Exposure Pattern Worker	PNECs Compartment
talc	Dermal 43.2 mg/kg bw/day (Systemic, Chronic) Inhalation 2.16 mg/m ³ (Systemic, Chronic) Dermal 4.54 mg/cm ² (Local, Chronic) Inhalation 3.6 mg/m ³ (Local, Chronic) Inhalation 2.16 mg/m ³ (Systemic, Acute) Inhalation 3.6 mg/m ³ (Local, Acute) <i>Dermal 21.6 mg/kg bw/day (Systemic, Chronic)* Inhalation 1.08 mg/m³ (Systemic, Chronic)*</i> <i>Oral 160 mg/kg bw/day (Systemic, Chronic)* Dermal 2.27 mg/cm² (Local, Chronic)* Inhalation 1.8 mg/m³ (Local, Chronic)* Inhalation 1.08 mg/m³ (Systemic, Acute)* Oral 160 mg/kg bw/day (Systemic, Acute)*</i> <i>Inhalation 1.8 mg/m³ (Local, Acute)*</i>	597.97 mg/L (Water (Fresh)) 141.26 mg/L (Water - Intermittent release) 597.97 mg/L (Water (Marine)) 31.33 mg/kg sediment dw (Sediment (Fresh Water)) .13 mg/kg sediment dw (Sediment (Marine))

* Values for General Population

OCCUPATIONAL EXPOSURE LIMITS (OEL)

INGREDIENT DATA

Source	Ingredient	Material name	TWA	STEL	Peak	Notes
Germany Recommended Exposure Limits - MAK Values	talc	Dust, general threshold limit value (inhalable fraction)	4 mg/m ³	Not Available	Not Available	see section Vf and g
	talc	Dust, general threshold limit value (respirable fraction) (biopersistent granular dusts)	0.3 mg/m ³	2.4 mg/m ³	Not Available	except for ultrafine particles; see section Vh; see section Vf; for dusts with a density of 1 g/cm ³ ; Preg gr: C; Carc cat: 4
	Magnesium stearate	Dust, general threshold limit value (inhalable fraction)	4 mg/m ³	Not Available	Not Available	see section Vf and g

	Magnesium stearate	Dust, general threshold limit value (respirable fraction) (biopersistent granular dusts)	0.3 mg/m ³	2.4 mg/m ³	Not Available	except for ultrafine particles; see section Vh; see section Vf; for dusts with a density of 1 g/cm ³ ; Preg gr: C; Carc cat: 4
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EMERGENCY LIMITS:

Ingredient	TEEL-1	TEEL-2	TEEL-3
starch	30 mg/m ³	330 mg/m ³	2,000 mg/m ³


Ingredient	Original IDLH	Revised IDLH
All ingredients	Not available	Not available

Occupational Exposure Banding

Ingredient	Occupational Exposure Band Rating	Occupational Exposure Band Limit
medroxyprogesterone acetate	C	> 0.1 to ≤ mg/m ³ of air

Occupational exposure banding is a process of assigning chemicals into specific categories or bands based on a chemical's potency and the adverse health outcomes associated with exposure. The output of this process is an occupational exposure band (OEB), which corresponds to a range of exposure concentrations that are expected to protect worker health.

8.2 Exposure controls

Appropriate engineering controls:	Engineering controls are used to remove a hazard or place a barrier between the worker and the hazard. Well-designed engineering controls can be highly effective in protecting workers and will typically be independent of worker interactions to provide this high level of protection. Process controls which involve changing the way a job activity or process is done to reduce the risk. Enclosure and/or isolation of emission source which keeps a selected hazard "physically" away from the worker and ventilation that strategically "adds" and "removes" air in the work environment.
Personal protection:	
Eye and face protection:	Safety glasses with side shields. Chemical goggles. Contact lenses may pose a special hazard; soft contact lenses may absorb and concentrate irritants
Skin protection:	See hand protection below
Hands/ feet protection:	The material may produce skin sensitisation in predisposed individuals. Care must be taken, when removing gloves and other protective equipment, to avoid all possible skin contact. Contaminated leather items, such as shoes, belts and watch-bands should be removed and destroyed
Body protection:	See Other protection below
Other protection:	Overalls, P.V.C apron, barrier cream, skin cleansing cream, eye wash

Thermal hazards:	Not applicable
Respiratory protection:	Respirators may be necessary when engineering and administrative controls do not adequately prevent exposures.
8.3 Environmental exposure controls See Section 12	

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance: White tablets
Container: Cardboard box containing 60 or 160 tablets in cold-formed nylon/aluminium foil/UPVC.
Physical state: Solid
Odor: Odourless
Melting point / freezing point (degrees C): Not available
Initial boiling point and boiling range: Not applicable
Flash Point: Not applicable
Evaporation rate Not applicable
Flammability: Not available
Upper/lower flammability or explosive limits: Not available
Vapor pressure: Not applicable
Specific Gravity: Not available
Solubility in water and solvents (mg/L): Not available
Auto ignition temperature (degrees C): Not available
Decomposition temperature (degrees C): Not available
Viscosity: (degrees C): Not available
Explosive properties: Not available
Oxidizing properties: Not available
Partition Coefficient: Not available
Taste: Not available
Surface tension: Not available
Volatile component: Not available
Gas group: Not available
pH: 3 Not available
VOC g/L: Not available

9.2 Other information

Not available

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity	See Section 7.
10.2 Chemical stability	Product is considered stable. Unstable in the presence of incompatible materials Hazardous polymerisation will not occur.

10.3 Possibility of hazardous reactions	See Section 7.
10.4 Conditions to avoid	See Section 7.
10.5 Incompatible materials	See section 7.
10.6 Hazardous decomposition	See Section 5.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Inhalation:	The material is not thought to produce adverse health effects or irritation of the respiratory tract (as classified by EC Directives using animal models). Nevertheless, good hygiene practice requires that exposure be kept to a minimum and that suitable control measures be used in an occupational setting.
Ingestion:	The material has NOT been classified by EC Directives or other classification systems as "harmful by ingestion". This is because of the lack of corroborating animal or human evidence. The material may still be damaging to the health of the individual, following ingestion, especially where pre-existing organ (e.g. liver, kidney) damage is evident.
Skin contact:	The material may produce mild skin irritation; limited evidence or practical experience suggests, that the material either: produces mild inflammation of the skin in a substantial number of individuals following direct contact, and/or produces significant, but mild, inflammation when applied to the healthy intact skin of animals (for up to four hours), such inflammation being present twenty-four hours or more after the end of the exposure period
Eye contact:	Although the material is not thought to be an irritant (as classified by EC Directives), direct contact with the eye may cause transient discomfort characterised by tearing or conjunctival redness
Chronic:	On the basis, primarily, of animal experiments, concern has been expressed that the material may produce carcinogenic or mutagenic effects; in respect of the available information, however, there presently exists inadequate data for making a satisfactory assessment.

	Toxicity	Irritation
Perlutex 5 mg Tablet	Not available	Not Available
alpha-lactose	Oral(rat) LD ₅₀ : >10000 mg/kg ^[2]	Not Available
starch	Not Available	Skin(human): 0.3 mg/3d-I mild
medroxyprogesterone acetate	Oral(dog) LD ₅₀ : >5000 mg/kg ^[2]	Not Available
talc		

	Dermal (rat) LD50 >2000 mg/kg ^[1] Inhalation (rat) LC ₅₀ :>2.1 mg/kg ^[1] Oral (mouse) LD ₅₀ >5000 mg/kg ^[1]	Eye: no adverse effect observed (not irritating) ^[1] Skin (human): 0.3 mg/3d-I mild Skin: no adverse effect observed (not irritating) ^[1]
gelatine	Toxicity	Irritation
	Not available	Not Available
magnesium stearate	Toxicity	Irritation
	Oral(rat) LD ₅₀ : >10000 mg/kg ^[2]	Not available
1. Value obtained from Europe ECHA Registered Substances - Acute toxicity 2.* Value obtained from manufacturer's SDS. Unless otherwise specified data extracted from RTECS - Register of Toxic Effect of chemical Substances		
Acute Toxicity ✘		Carcinogenicity ✔
Skin Irritation/Corrosion ✘		Reproductivity ✔
Serious Eye Damage/Irritation ✘		STOT – Single Exposure ✘
Respiratory or Skin Sensitization ✘		STOT – Repeated Exposure ✘
Mutagenicity ✘		Aspiration Hazard ✘
✘ - Data either not available or does not fill the criteria for classification ✔ - Data available to make classification		
11.2 Information on toxicological effects Not available		

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

Ingredient	Endpoint	Test duration (hr)	Species	Value	Source
Perlutex 5 mg Tablet	Not available	Not available	Not available	Not available	Not available
alpha-lactose	Not available	Not available	Not available	Not available	Not available
starch	Not available	Not available	Not available	Not available	Not available
medroxyprogesterone acetate	Not available	Not available	Not available	Not available	Not available
Talc	LC ₅₀	96h	Fish	89581.016mg/l	2
	NOEC(EC _x)	720h	Algae/other aquatic plants	918.089mg/l	2

	EC ₅₀	96h	Algae/other aquatic plants	7202.7mg/l	2
gelatine	Not available	Not available	Not available	Not available	Not available
magnesium stearate	Not available	Not available	Not available	Not available	Not available

Legend: Extracted from 1. IUCLID Toxicity Data 2. Europe ECHA Registered Substances - Ecotoxicological Information - Aquatic Toxicity 3. EPIWIN Suite V3.12 (QSAR) - Aquatic Toxicity Data (Estimated) 4. US EPA, Ecotox database - Aquatic Toxicity Data 5. ECETOC Aquatic Hazard Assessment Data 6. NITE (Japan) - Bioconcentration Data 7. METI (Japan) - Bioconcentration Data 8. Vendor Data

Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
DO NOT discharge into sewer or waterways.

12.2 Persistence and degradability

Ingredient	Persistence: Water/Soil	Persistence: Air
alpha-lactose	LOW	LOW
medroxyprogesterone acetate	HIGH	HIGH

12.3 Bioaccumulative potential

Ingredient	Bioaccumulative Potential
alpha-lactose	LOW (LogKOW = -5.1249)
medroxyprogesterone acetate	MEDIUM (LogKOW = 4.0871)

12.4 Mobility in Soil

Ingredient	Mobility
alpha-lactose	LOW (KOC = 10)
medroxyprogesterone acetate	LOW (KOC = 5721)

12.5 Results of PBT and vPvB assessment

	P	B	T
Relevant available data	Not Available	Not Available	Not Available
PBT	✘	✘	✘
vPvB	✘	✘	✘
PBT Criteria fulfilled?	No		
vPvB	No		

12.6. Endocrine Disruption Properties

Not Available

12.7 Other adverse effects

Not Available

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods	
Product / packaging disposal:	Any unused veterinary medicinal product or waste material derived from such veterinary medicinal products should be disposed of in accordance with national requirements. DO NOT allow wash water from cleaning or process equipment to enter drains.
Waste Treatment Options:	Not Available
Sewage Disposal Options:	Not Available

SECTION 14: TRANSPORT INFORMATION

Labels required		
Marine pollutant:	NO	
Land transport (ADR): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS		
14.1 UN Number	Not Applicable	
14.2 UN Proper Shipping Name	Not Applicable	
14.3 Transport hazard class(es)	Class Subrisk	Not Applicable Not Applicable
14.4 Packing group	Not Applicable	
14.5 Environmental hazards	Not Applicable	
14.6 Special precautions for user	Hazard Identification (Kemler) Classification code Hazard label Special provisions Limited quantity Tunnel Restriction Code	Not Applicable Not Applicable Not Applicable Not Applicable Not Applicable Not Applicable
Air transport (ICAO-IATA / DGR): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS		
14.1 UN Number	Not Applicable	
14.2 UN Proper Shipping Name	Not Applicable	
14.3 Transport hazard class(es)	ICAO/IATA Class ICAO / IATA Subrisk ERG Code	Not Applicable Not Applicable Not Applicable
14.4 Packing group	Not Applicable	
14.5 Environmental hazards	Not Applicable	

14.6 Special precautions for user	Special provisions Cargo Only Packing Instructions Cargo Only Maximum Qty / Pack Passenger and Cargo Packing Instructions Passenger and Cargo Maximum Qty / Pack Passenger and Cargo Limited Quantity Packing Instructions Passenger and Cargo Limited Maximum Qty / Pack	Not Applicable Not Applicable Not Applicable Not Applicable Not Applicable Not Applicable Not Applicable
Sea transport (IMDG-Code / GGVSee): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS		
14.1 UN Number	Not Applicable	
14.2 UN Proper Shipping Name	Not Applicable	
14.3 Transport hazard class(es)	IMDG Class IMDG Subrisk	Not Applicable Not Applicable
14.4 Packing group	Not Applicable	
14.5 Environmental hazards	Not Applicable	
14.6 Special precautions for user	EMS Number Special provisions Limited Quantities	Not Applicable Not Applicable Not Applicable
Inland waterways transport (ADN): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS		
14.1 UN Number	Not Applicable	
14.2 UN Proper Shipping Name	Not Applicable	
14.3 Transport hazard class(es)	9	Not Applicable
14.4 Packing group	Not Applicable	
14.5 Environmental hazards	Not Applicable	
14.6 Special precautions for user	Classification code Special provisions Limited Quantity Equipment required Fire cones number	Not Applicable Not Applicable Not Applicable Not Applicable Not Applicable
14.7 Transport in bulk according to Annex II of MARPOL and the IBC code Not Applicable		
14.8 Transport in bulk in accordance with MARPOL Annex V and the IMSBC Code Not Available for any ingredient		

14.9 Transport in bulk in accordance with the ICG Code

Not Available for any ingredient

SECTION 15: REGULATORY INFORMATION

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

Alpha-lactose

Europe EC Inventory / EU - European Inventory of Existing Commercial Chemical Substances (EINECS)

Starch

Europe EC Inventory / EINECS / Germany Classification of Substances Hazardous to Waters (WGK)

Medroxyprogesterone acetate

Chemical Footprint Project - Chemicals of High Concern List / Europe EC Inventory / EINECS / Germany Institute for Occupational Safety Social Accident Insurance (IFA) / List of the carcinogenic, mutagenic and reproduction (CMR) substances (German) / Germany TRGS 905 - List of Carcinogenic, Mutagenic or Reproductive Toxic Substances (German) / International Agency for Research on Cancer (IARC) - Agents Classified by the IARC Monographs / International Agency for Research on Cancer (IARC) - Agents Classified by the IARC Monographs - Group 2B: Possibly carcinogenic to humans

Talc

Chemical Footprint Project - Chemicals of High Concern List / Europe EC Inventory / EINECS / WGK / Germany Recommended Exposure Limits - MAK Values / Germany Recommended Exposure Limits - MAK Values - Carcinogens / Germany Recommended Exposure Limits - MAK Values - Pregnancy Risk Group Classifications & Germ Cell Mutagens / International Agency for Research on Cancer (IARC) - Agents Classified by the IARC Monographs / International Agency for Research on Cancer (IARC) - Agents Classified by the IARC Monographs - Group 2B: Possibly carcinogenic to humans

Gelatine

Europe EC Inventory / EINECS

Magnesium stearate

Europe EC Inventory / EINECS / WGK / Germany Recommended Exposure Limits - MAK Values / Germany Recommended Exposure Limits - MAK Values - Carcinogens / Germany Recommended Exposure Limits - MAK Values - Pregnancy Risk Group Classifications & Germ Cell Mutagens

This safety data sheet is in compliance with the following EU legislation and its adaptations - as far as applicable - : Directives 98/24/EC, - 92/85/EEC, - 94/33/EC, - 2008/98/EC, - 2010/75/EU; Commission Regulation (EU) 2020/878; Regulation (EC) No 1272/2008 as updated through ATPs.

15.2 Chemical Safety Assessment

Product regulated as a veterinary product and is prescribed by veterinarians.

ECHA SUMMARY

Ingredient	CAS number	Index No	ECHA Dossier
medroxyprogesterone acetate	71-58-9	Not Available	Not Available

Harmonisation (C&L Inventory)	Hazard Class and Category Code(s)	Pictograms Signal Word Code(s)	Hazard Statement Code(s)
1	Carc. 2	GHS08; Wng	H351
Harmonisation Code 1 = The most prevalent classification. Harmonisation Code 2 = The most severe classification			
15.3 Classification of Substances and Mixtures into Water Hazard Classes			
Name	WGK	Score	Source
Alpha-lactose	non-hazardous to waters	0	Calculated
Starch	1		From Regulation
Medroxyprogesterone acetate	1	2	Calculated
Talc	non-hazardous to waters		From Regulation
Gelatine	non-hazardous to waters	0	Calculated
Magnesium stearate	non-hazardous to waters		From Regulation
National Inventory		Status	
Australía – AICS / Australia Non-Industrial Use		Yes	
Canada – DSL		Yes	
Canada – NDSL		No (alpha-lactose; medroxyprogesterone acetate; talc; gelatine; magnesium stearate)	
China – IECSC		No (medroxyprogesterone acetate)	
Europe - EINEC / ELINCS / NLP		Yes	
Japan – ENCS		No (gelatine)	
Korea – KECI		No (medroxyprogesterone acetate)	
New Zealand – NZIoC		Yes	
Philippines – PICCS		No (medroxyprogesterone acetate)	
USA – TSCA		Yes	
Taiwan – TCSI		Yes	
Mexico – INSQ		Yes	
Vietnam – NCI		Yes	
Russia – FBEPH		No (medroxyprogesterone acetate)	
Yes = All ingredients are on the inventory No = Not determined or one or more ingredients are not on the inventory and are not exempt from listing (see specific ingredients in brackets)			

SECTION 16: OTHER INFORMATION

Classification of the preparation and its individual components has drawn on official and authoritative sources as well as independent review by the Chemwatch Classification committee using available literature references. The SDS is a Hazard Communication tool and should be used to assist in the Risk Assessment. Many factors determine whether the reported Hazards are Risks in the workplace or other settings. Risks may be determined by reference to Exposures Scenarios. Scale of use, frequency of use and current or available engineering controls must be considered.

For detailed advice on Personal Protective Equipment, refer to the following EU CEN Standards:

EN 166 Personal eye-protection
EN 340 Protective clothing
EN 374 Protective gloves against chemicals and micro-organisms
EN 13832 Footwear protecting against chemicals
EN 133 Respiratory protective devices

Definitions and abbreviations

PC—TWA: Permissible Concentration-Time Weighted Average
PC—STEL: Permissible Concentration-Short Term Exposure Limit
IARC: International Agency for Research on Cancer
ACGIH: American Conference of Governmental Industrial Hygienists
STEL: Short Term Exposure Limit
TEEL: Temporary Emergency Exposure Limit.
IDLH: Immediately Dangerous to Life or Health Concentrations
ES: Exposure Standard
OSF: Odour Safety Factor
NOAEL :No Observed Adverse Effect Level
LOAEL: Lowest Observed Adverse Effect Level
TLV: Threshold Limit Value
LOD: Limit Of Detection
OTV: Odour Threshold Value
BCF: BioConcentration Factors
BEI: Biological Exposure Index
AIIIC: Australian Inventory of Industrial Chemicals
DSL: Domestic Substances List
NDSL: Non-Domestic Substances List
IECSC: Inventory of Existing Chemical Substance in China
EINECS: European INventory of Existing Commercial chemical Substances
ELINCS: European List of Notified Chemical Substances
NLP: No-Longer Polymers
ENCS: Existing and New Chemical Substances Inventory
KECI: Korea Existing Chemicals Inventory
NZIoC: New Zealand Inventory of Chemicals
PICCS: Philippine Inventory of Chemicals and Chemical Substances
TSCA: Toxic Substances Control Act
TCSI: Taiwan Chemical Substance Inventory
INSQ: Inventario Nacional de Sustancias Químicas
NCI: National Chemical Inventory
FBEPH: Russian Register of Potentially Hazardous Chemical and Biological Substances



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