According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758

# **Cloprostenol Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 08.12.2023
5.0	06.04.2024	9371271-00009	Date of first issue: 27.08.2021

#### **SECTION 1:** Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier		
Trade name	:	Cloprostenol Formulation
Other means of identification	:	ESTRUMATE® (A002698) ESTRUMATE SYNTHETIC PROSTAGLANDIN FOR CATTLE AND HORSES (36076)
1.2 Relevant identified uses of the	he s	substance or mixture and uses advised against
Use of the Sub- stance/Mixture	:	Veterinary product
Recommended restrictions on use	:	Not applicable
1.3 Details of the supplier of the	saf	fety data sheet
Company	:	MSD Walton Manor, Walton MK7 7AJ Milton Keynes - United Kingdom
Telephone	:	+1-908-740-4000
E-mail address of person responsible for the SDS	:	EHSDATASTEWARD@msd.com

#### 1.4 Emergency telephone number

+1-908-423-6000

#### **SECTION 2: Hazards identification**

#### 2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008) as amended by GB-CLP Regulation, UK SI 2019/720, and UK SI 2020/1567)

Not a hazardous substance or mixture.

#### 2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008) as amended by GB-CLP Regulation, UK SI 2019/720, and UK SI 2020/1567)

No hazard pictogram, no signal word, no hazard statement(s), no precautionary statement(s) required

EUH210 Safety data sheet available on request.

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



## **Cloprostenol Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 08.12.2023
5.0	06.04.2024	9371271-00009	Date of first issue: 27.08.2021

#### 2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

#### **SECTION 3: Composition/information on ingredients**

#### 3.2 Mixtures

#### Components

Chemical name	CAS-No.	Classification	Concentration
	EC-No.		(% w/w)
	Index-No.		
	Registration number		
Benzyl alcohol	100-51-6	Acute Tox. 4; H302	>= 1 - < 10
	202-859-9	Acute Tox. 4; H332	
	603-057-00-5	Eye Irrit. 2; H319	
Sodium [1α(Ζ),2β(1E,3R*),3α,5α]-(+/-	55028-72-3	Resp. Sens. 1;	< 0.1
)-7-[2-[4-(3-chlorophenoxy)-3-	259-439-3	H334	
hydroxybut-1-enyl]-3,5-		Repr. 1B; H360F	
dihydroxycyclopentyl]hept-5-enoate		STOT SE 1; H370	
		(Lungs)	
		STOT RE 1; H372	
		(Ovary)	

For explanation of abbreviations see section 16.

#### **SECTION 4: First aid measures**

#### 4.1 Description of first aid measures

Protection of first-aiders	No special precautions are necessa	ary for first aid responders.
If inhaled	If inhaled, remove to fresh air. Get medical attention if symptoms of	occur.
In case of skin contact	Wash with water and soap as a pre Get medical attention if symptoms of	
In case of eye contact	Flush eyes with water as a precauti Get medical attention if irritation de	
If swallowed	If swallowed, DO NOT induce vomi Get medical attention if symptoms of Rinse mouth thoroughly with water.	occur.

**4.2 Most important symptoms and effects, both acute and delayed** None known.

#### 4.3 Indication of any immediate medical attention and special treatment needed

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



# **Cloprostenol Formulation**

Version 5.0	Revision Date: 06.04.2024		DS Number: 71271-00009	Date of last issue: 08.12.2023 Date of first issue: 27.08.2021		
Treat	ment	:	Treat symptomati	cally and supportively.		
SECTION	I 5: Firefighting meas	sur	es			
5.1 Exting	uishing media					
Suitable extinguishing media		:		Alcohol-resistant foam Carbon dioxide (CO2)		
Unsui media	table extinguishing a	:	None known.			
5.2 Specia	al hazards arising from	the	e substance or mi	xture		
Speci fightin	fic hazards during fire- Ig	:	Exposure to com	bustion products may be a hazard to health.		
Hazardous combustion prod- ucts		:	Carbon oxides			
5.3 Advice	e for firefighters					
	al protective equipment efighters	:		ed breathing apparatus for firefighting if nec- onal protective equipment.		
Specific extinguishing meth- ods		:	cumstances and Use water spray	g measures that are appropriate to local cir- the surrounding environment. to cool unopened containers. ged containers from fire area if it is safe to do		

#### 6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions	:	Follow safe handling advice (see section 7) and personal pro- tective equipment recommendations (see section 8).
6.2 Environmental precautions		
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. If spillage enters rivers or watercourses, inform the Environ- ment Agency (emergency telephone number 0800 807060).

#### 6.3 Methods and material for containment and cleaning up

Methods for cleaning up : Soak up with inert absorbent material.

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



# **Cloprostenol Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 08.12.2023
5.0	06.04.2024	9371271-00009	Date of first issue: 27.08.2021
		ment to keep m be pumped, sto Clean up remain bent. Local or nationa posal of this ma employed in the mine which regu Sections 13 and	provide dyking or other appropriate contain- aterial from spreading. If dyked material can re recovered material in appropriate container. hing materials from spill with suitable absor- al regulations may apply to releases and dis- terial, as well as those materials and items e cleanup of releases. You will need to deter- ulations are applicable. d 15 of this SDS provide information regarding hational requirements.

#### 6.4 Reference to other sections

See sections: 7, 8, 11, 12 and 13.

#### **SECTION 7: Handling and storage**

#### 7.1 Precautions for safe handling

		0	
	Technical measures	:	See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.
	Local/Total ventilation		Use only with adequate ventilation.
	Advice on safe handling	:	Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure as- sessment 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 contami- nated 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.
7.2	Conditions for safe storage,	, inc	luding any incompatibilities
	Requirements for storage areas and containers	:	Keep in properly labelled containers. Store in accordance with the particular national regulations.
	Advice on common storage	:	Do not store with the following product types: Strong oxidizing agents Gases
7.3	Specific end use(s)		
	Specific use(s)	:	No data available

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



# **Cloprostenol Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 08.12.2023
5.0	06.04.2024	9371271-00009	Date of first issue: 27.08.2021

#### **SECTION 8: Exposure controls/personal protection**

#### 8.1 Control parameters

#### **Occupational Exposure Limits**

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis	
Sodium $[1\alpha(Z),2\beta(1E,3R^*),$ $3\alpha,5\alpha]-(+/-)-7-[2-[4-(3-chlorophenoxy)-3-hydroxybut-1-enyl]-3,5-dihydroxycyclopen-tyl]hept-5-enoate$	55028-72-3	TWA	0.01 ug/m3 (OEB 5)	Internal	
	Further information: RSEN, Skin				
		Wipe limit	0.1 ug/100 cm2	Internal	

#### Derived No Effect Level (DNEL):

Substance name	End Use	Exposure routes	Potential health ef- fects	Value
Benzyl alcohol	Workers	Inhalation	Long-term systemic effects	22 mg/m3
	Workers	Inhalation	Acute systemic ef- fects	110 mg/m3
	Workers	Skin contact	Long-term systemic effects	8 mg/kg bw/day
	Workers	Skin contact	Acute systemic ef- fects	40 mg/kg bw/day
	Consumers	Inhalation	Long-term systemic effects	5.4 mg/m3
	Consumers	Inhalation	Acute systemic ef- fects	27 mg/m3
	Consumers	Skin contact	Long-term systemic effects	4 mg/kg bw/day
	Consumers	Skin contact	Acute systemic ef- fects	20 mg/kg bw/day
	Consumers	Ingestion	Long-term systemic effects	4 mg/kg bw/day
	Consumers	Ingestion	Acute systemic ef- fects	20 mg/kg bw/day

### Predicted No Effect Concentration (PNEC):

Substance name	Environmental Compartment	Value
Benzyl alcohol	Fresh water	1 mg/l
	Marine water	0.1 mg/l
	Intermittent use/release	2.3 mg/l
	Sewage treatment plant	39 mg/l
	Fresh water sediment	5.27 mg/kg
	Marine sediment	0.527 mg/kg

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



## **Cloprostenol Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 08.12.2023	
5.0	06.04.2024	9371271-00009	Date of first issue: 27.08.2021	
. IL		Soil	0.456 mg/kg	

## 8.2 Exposure controls

#### **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.

#### Personal protective equipment

Eye/face 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.
Material	:	Chemical-resistant gloves
Remarks Skin and body protection	:	Consider double gloving. 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.
Respiratory protection	:	If adequate local exhaust ventilation is not available or expo- sure assessment demonstrates exposures outside the rec- ommended guidelines, use respiratory protection. Equipment should conform to BS EN 14387
Filter type	:	Organic vapour type (A)

#### **SECTION 9: Physical and chemical properties**

#### 9.1 Information on basic physical and chemical properties

pH : 5.6 - 6.1 (20 - 25 °C) Melting point/freezing point : No data available Initial boiling point and boiling : No data available	Appearance Colour Odour Odour Threshold	:	Aqueous solution clear No data available No data available
	рН	:	5.6 - 6.1 (20 - 25 °C)
Initial boiling point and boiling : No data available	Melting point/freezing point	:	No data available
51 5	01 0	:	No data available
range Flash point : No data available	0	:	No data available

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



# **Cloprostenol Formulation**

Ver 5.0	sion	Revision Date: 06.04.2024		S Number: 71271-00009	Date of last issue: 08.12.2023 Date of first issue: 27.08.2021
	Evapor	ation rate	:	No data available	2
	Flamma	ability (solid, gas)	:	Not applicable	
		explosion limit / Upper bility limit	:	No data available	
		explosion limit / Lower bility limit	:	No data available	)
	Vapour	pressure	:	No data available	)
	Relative	e vapour density	:	No data available	)
	Relative	e density	:	1	
	Density	,	:	No data available	)
	Partitio octanol	er solubility n coefficient: n-	:	soluble Not applicable No data available	9
	-	position temperature	:	No data available	
	Viscosi Visc	ty osity, kinematic	:	No data available	
	Explosi	ve properties	:	Not explosive	
	Oxidizir	ng properties	:	The substance of	mixture is not classified as oxidizing.
9.2	Other in	formation			
	Flamma	ability (liquids)	:	No data available	
	Molecu	lar weight	:	No data available	)
	Particle	size	:	Not applicable	

#### **SECTION 10: Stability and reactivity**

#### 10.1 Reactivity

Not classified as a reactivity hazard.

#### 10.2 Chemical stability

Stable under normal conditions.

#### 10.3 Possibility of hazardous reactions

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



# **Cloprostenol Formulation**

Version 5.0	Revision Date: 06.04.2024		S Number: 71271-00009	Date of last issue: 08.12.2023 Date of first issue: 27.08.2021
Hazaro	dous reactions	:	Can react with st	rong oxidizing agents.
	<b>itions to avoid</b> ions to avoid	:	None known.	
	apatible materials als to avoid	:	Oxidizing agents	
	dous decomposition p zardous decomposition			
SECTION	11: Toxicological in	for	mation	
	nation on toxicologica ation on likely routes of ure		ects Inhalation Skin contact Ingestion Eye contact	
	toxicity assified based on availa	ble	information.	
<u>Produ</u>	<u>ct:</u>			
Acute	oral toxicity	:	Acute toxicity esti Method: Calculati	mate: > 2,000 mg/kg on method
Acute	inhalation toxicity	:	Acute toxicity esti Exposure time: 4 Test atmosphere: Method: Calculati	h dust/mist
<u>Comp</u>	onents:			
Benzy	l alcohol:			
Acute	oral toxicity	:	LD50 (Rat): 1,620	mg/kg
Acute	inhalation toxicity	:	LC50 (Rat): > 4.1 Exposure time: 4 Test atmosphere: Method: OECD T	h dust/mist
	m [1α(Z),2β(1E,3R*),3α roxycyclopentyl]hept∹			hlorophenoxy)-3-hydroxybut-1-enyl]-3,5-
	oral toxicity		LD50 (Rat): > 25	mg/kg tality observed at this dose.
	toxicity (other routes of istration)	:	LD50 (Rat): > 50 Application Route	

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



# **Cloprostenol Formulation**

0	Revision Date: 06.04.2024	SDS Number: 9371271-00009	Date of last issue: 08.12.2023 Date of first issue: 27.08.2021			
		LD50 (Rat): > 5 Application Rot	i0 mg/kg ute: Intramuscular			
LD50 (Rat): 5 mg/kg Application Route: Intravenous Remarks: No mortality observed at this dose.						
	LD50 (Mouse): 350 mg/kg Application Route: Intramuscular					
LD50 (Mouse): 54.7 mg/kg Application Route: Intravenous						
			): 0.0025 - 0.025 mg/kg ute: Intramuscular Lungs			
		Symptoms: Dia	rrhoea, Vomiting, Rapid respiration			
			): 0.0013 mg/kg ute: Intramuscular ovaries			
Not c	corrosion/irritation classified based on av ponents:	ailable information.				
Benz	yl alcohol:					
Benz Spec Meth Resu	ies od	: Rabbit : OECD Test Gu : No skin irritatio				
Spec Meth Resu <b>Sodi</b>	ies od llt <b>um [1α(Ζ),2β(1Ε,3</b> ℝ*	: OECD Test Gu : No skin irritatio ),3α,5α]-(+/-)-7-[2-[4-(3				
Spec Meth Resu <b>Sodi</b>	ies od llt um [1α(Ζ),2β(1E,3R* droxycyclopentyl]he	: OECD Test Gu : No skin irritatio ),3α,5α]-(+/-)-7-[2-[4-(3 pt-5-enoate: : Not classified d	n			
Spec Meth Resu Sodia dihya Rema	ies od llt um [1α(Z),2β(1E,3R* droxycyclopentyl]he arks ous eye damage/eye	<ul> <li>OECD Test Gu</li> <li>No skin irritatio</li> </ul> ),3α,5α]-(+/-)-7-[2-[4-(3) pt-5-enoate: <ul> <li>Not classified d</li> <li>Can be absorbed</li> <li>irritation</li> </ul>	n <b>-chlorophenoxy)-3-hydroxybut-1-enyl]-3,5-</b> ue to lack of data.			
Spec Meth Resu Sodi dihyo Rema Seric Not c	ies od llt um [1α(Z),2β(1E,3R* droxycyclopentyl]he arks ous eye damage/eye classified based on av	<ul> <li>OECD Test Gu</li> <li>No skin irritatio</li> </ul> ),3α,5α]-(+/-)-7-[2-[4-(3) pt-5-enoate: <ul> <li>Not classified d</li> <li>Can be absorbed</li> <li>irritation</li> </ul>	n <b>-chlorophenoxy)-3-hydroxybut-1-enyl]-3,5-</b> ue to lack of data.			
Spec Meth Resu Sodi dihyo Rema Seric Not c <u>Com</u>	ies od llt um [1α(Z),2β(1E,3R* droxycyclopentyl]he arks ous eye damage/eye classified based on av ponents:	<ul> <li>OECD Test Gu</li> <li>No skin irritatio</li> </ul> ),3α,5α]-(+/-)-7-[2-[4-(3) pt-5-enoate: <ul> <li>Not classified d</li> <li>Can be absorbed</li> <li>irritation</li> </ul>	n <b>-chlorophenoxy)-3-hydroxybut-1-enyl]-3,5-</b> ue to lack of data.			
Spec Meth Resu Sodi dihyo Rema Seric Not c <u>Com</u>	ies od llt um [1α(Z),2β(1E,3R* droxycyclopentyl]he arks ous eye damage/eye classified based on av <u>ponents:</u> cyl alcohol:	<ul> <li>OECD Test Gu</li> <li>No skin irritatio</li> </ul> ),3α,5α]-(+/-)-7-[2-[4-(3) pt-5-enoate: <ul> <li>Not classified d</li> <li>Can be absorbed</li> <li>irritation</li> </ul>	n <b>-chlorophenoxy)-3-hydroxybut-1-enyl]-3,5-</b> ue to lack of data.			
Spec Meth Resu Sodiu dihyo Rema Seric Not c <u>Com</u> Benz	ies od llt um [1α(Z),2β(1E,3R* droxycyclopentyl]he arks bus eye damage/eye classified based on av ponents: cyl alcohol: ies od	<ul> <li>OECD Test Gu</li> <li>No skin irritatio</li> <li>),3α,5α]-(+/-)-7-[2-[4-(3)</li> <li>pt-5-enoate:         <ul> <li>Not classified d Can be absorbe</li> </ul> </li> <li>irritation         <ul> <li>ailable information.</li> <li>Rabbit</li> <li>OECD Test Gu</li> </ul> </li> </ul>	n -chlorophenoxy)-3-hydroxybut-1-enyl]-3,5- lue to lack of data. ed through skin.			
Spec Metha Resu Sodiu dihyo Rema Seric Not c Com Benz Spec Metha Resu Sodiu	ies od llt um [1α(Z),2β(1E,3R* droxycyclopentyl]he arks ous eye damage/eye elassified based on av ponents: cyl alcohol: ies od llt	<ul> <li>OECD Test Gu</li> <li>No skin irritatio</li> </ul> ),3α,5α]-(+/-)-7-[2-[4-(3) :pt-5-enoate: <ul> <li>Not classified d</li> <li>Can be absorbed</li> </ul> irritation ailable information.   : Rabbit <ul> <li>OECD Test Gu</li> <li>Irritation to eye</li> </ul> ),3α,5α]-(+/-)-7-[2-[4-(3)	n -chlorophenoxy)-3-hydroxybut-1-enyl]-3,5- lue to lack of data. ed through skin. ideline 405			

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



# **Cloprostenol Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 08.12.2023
5.0	06.04.2024	9371271-00009	Date of first issue: 27.08.2021

#### Respiratory or skin sensitisation

#### Skin sensitisation

Not classified based on available information.

#### Respiratory sensitisation

Not classified based on available information.

#### **Components:**

#### **Benzyl alcohol:**

Test Type	: Maximisation Test
Exposure routes	: Skin contact
Species	: Guinea pig
Method	: OECD Test Guideline 406
Test Type Exposure routes Species Method Result	: negative

# Sodium $[1\alpha(Z), 2\beta(1E, 3R^*), 3\alpha, 5\alpha]-(+/-)-7-[2-[4-(3-chlorophenoxy)-3-hydroxybut-1-enyl]-3, 5-dihydroxycyclopentyl]hept-5-enoate:$

Result : Sensitiser

#### Germ cell mutagenicity

Not classified based on available information.

#### **Components:**

#### Benzyl alcohol:

Genotoxicity in vitro	: Test Type: Bacterial reverse mutation assay (AMES) Result: negative
Genotoxicity in vivo	: Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay) Species: Mouse Application Route: Intraperitoneal injection Result: negative

# Sodium $[1\alpha(Z), 2\beta(1E, 3R^*), 3\alpha, 5\alpha]-(+/-)-7-[2-[4-(3-chlorophenoxy)-3-hydroxybut-1-enyl]-3, 5-dihydroxycyclopentyl]hept-5-enoate:$

Genotoxicity in vitro	: Test Type: Bacterial reverse mutation assay (AMES) Result: negative
	Test Type: In vitro mammalian cell gene mutation test Test system: mouse lymphoma cells Result: negative
	Test Type: Chromosomal aberration Test system: Human lymphocytes Result: equivocal
Genotoxicity in vivo	: Test Type: Micronucleus test Species: Mouse Cell type: Bone marrow

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



# **Cloprostenol Formulation**

ersion 0	Revision Date: 06.04.2024	-	S Number: 71271-00009	Date of last issue: 08.12.2023 Date of first issue: 27.08.2021
			Application Rou Result: negative	te: Intraperitoneal
	i <b>nogenicity</b> lassified based on avai	lable	information.	
Com	ponents:			
Benz	yl alcohol:			
Speci Applio Expos Metho Resu	cation Route sure time od		Mouse Ingestion 103 weeks OECD Test Gui negative	deline 451
	um [1α(Z),2β(1E,3R*),; łroxycyclopentyl]hep			chlorophenoxy)-3-hydroxybut-1-enyl]-3,5
Rema		:		ue to lack of data.
<u>Com</u>	lassified based on avai ponents: yl alcohol:	lable	information.	
	ts on fertility	:	Species: Rat Application Rou Result: negative	
Effect ment	ts on foetal develop-	:	Test Type: Emb Species: Mouse Application Rou Result: negative	te: Ingestion
	um [1α(Z),2β(1E,3R*),; łroxycyclopentyl]hep			chlorophenoxy)-3-hydroxybut-1-enyl]-3,5
	ts on fertility	:	Test Type: Thre Species: Rat Application Rou General Toxicity	e-generation study te: Oral v F1: NOAEL: 0.015 mg/kg body weight

Result: Animal testing did not show any effects on fertility. Species: Cattle Application Route: Intramuscular General Toxicity - Parent: LOAEL: 0.16 µg/kg Result: positive Remarks: Abortion

Fertility: NOAEL: > 0.04 mg/kg body weight

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



# **Cloprostenol Formulation**

Version 5.0	Revision Date: 06.04.2024	SDS Number: 9371271-00009	Date of last issue: 08.12.2023 Date of first issue: 27.08.2021	
Effects	s on foetal develop-	Teratogenicity: Result: No tera Test Type: Dev Species: Rat Application Ro	it ute: Subcutaneous NOAEL: 0.250 μg/kg togenic effects velopment ute: Oral NOAEL: 100 μg/kg	
Repro sessm	ductive toxicity - As- ient	: May damage fe	ertility.	
STOT	- single exposure			

Not classified based on available information.

#### **Components:**

Sodium  $[1\alpha(Z), 2\beta(1E, 3R^*), 3\alpha, 5\alpha]-(+/-)-7-[2-[4-(3-chlorophenoxy)-3-hydroxybut-1-enyl]-3, 5-dihydroxycyclopentyl]hept-5-enoate:$ 

Target Organs Assessment		Lungs
Assessment	÷	Causes damage to organs.

#### STOT - repeated exposure

Not classified based on available information.

#### Components:

Sodium  $[1\alpha(Z), 2\beta(1E, 3R^*), 3\alpha, 5\alpha]-(+/-)-7-[2-[4-(3-chlorophenoxy)-3-hydroxybut-1-enyl]-3, 5-dihydroxycyclopentyl]hept-5-enoate:$ 

	Target Organs Assessment	Ovary Causes damage to organs through prolonged or repeated
I		exposure.

#### Repeated dose toxicity

#### Components:

#### **Benzyl alcohol:**

Species NOAEL Application Route Exposure time Method	:	Rat
NOAEL	:	1.072 mg/l
Application Route	:	inhalation (dust/mist/fume)
Exposure time	:	28 Days
Method	:	OECD Test Guideline 412

# Sodium $[1\alpha(Z), 2\beta(1E, 3R^*), 3\alpha, 5\alpha]-(+/-)-7-[2-[4-(3-chlorophenoxy)-3-hydroxybut-1-enyl]-3, 5-dihydroxycyclopentyl]hept-5-enoate:$

Species NOAEL LOAEL	: Rat
NOAEL	: 0.05 mg/kg
LOAEL	: 0.15 mg/kg

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



# **Cloprostenol Formulation**

Version 5.0	Revision Date: 06.04.2024	SDS Number: 9371271-00009	Date of last issue: 08.12.2023 Date of first issue: 27.08.2021	
Expos	cation Route sure time t Organs	: Oral : 3 Months : Ovary		
Expos		: Rat : 0.0125 mg/kg : Subcutaneous : 30 Days : Ovary		
Expos	EL	: Monkey : 0.05 mg/kg : 0.15 mg/kg : Oral : 3 Months : Heart, Testis		

#### Aspiration toxicity

Not classified based on available information.

#### Components:

# Sodium $[1\alpha(Z), 2\beta(1E, 3R^*), 3\alpha, 5\alpha]-(+/-)-7-[2-[4-(3-chlorophenoxy)-3-hydroxybut-1-enyl]-3, 5-dihydroxycyclopentyl]hept-5-enoate:$

Not applicable

#### Experience with human exposure

Components:

# Sodium $[1\alpha(Z), 2\beta(1E, 3R^*), 3\alpha, 5\alpha]-(+/-)-7-[2-[4-(3-chlorophenoxy)-3-hydroxybut-1-enyl]-3, 5-dihydroxycyclopentyl]hept-5-enoate:$

General Information	<ul> <li>Target Organs: Uterus (including cervix) Symptoms: Embryo-foetal toxicity, foetal mortality, menstrual irregularities, miscarriage Target Organs: Lungs Symptoms: Asthma, bronchospasm</li> </ul>
Inhalation	<ul> <li>Target Organs: Lungs</li> <li>Symptoms: bronchospasm, Asthma</li> <li>Remarks: May cause sensitisation of susceptible persons by inhalation of aerosol or dust.</li> <li>Target Organs: Uterus (including cervix)</li> </ul>
Skin contact	<ul> <li>Symptoms: Embryolethal effects, menstrual irregularities</li> <li>Target Organs: Lungs</li> <li>Symptoms: bronchospasm</li> <li>Remarks: Can be absorbed through skin.</li> <li>Target Organs: Uterus (including cervix)</li> <li>Symptoms: Embryolethal effects</li> </ul>

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



## **Cloprostenol Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 08.12.2023
5.0	06.04.2024	9371271-00009	Date of first issue: 27.08.2021

#### **SECTION 12: Ecological information**

#### 12.1 Toxicity

#### **Components:**

Benzyl	alcohol:
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Toxicity to fish	:	LC50 (Pimephales promelas (fathead minnow)): 460 mg/l Exposure time: 96 h
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia magna (Water flea)): 230 mg/l Exposure time: 48 h Method: OECD Test Guideline 202
Toxicity to algae/aquatic plants	:	EC50 (Pseudokirchneriella subcapitata (green algae)): 770 mg/l Exposure time: 72 h Method: OECD Test Guideline 201
		NOEC (Pseudokirchneriella subcapitata (green algae)): 310 mg/l Exposure time: 72 h Method: OECD Test Guideline 201
Toxicity to daphnia and other aquatic invertebrates (Chron- ic toxicity)	:	NOEC: 51 mg/l Exposure time: 21 d Species: Daphnia magna (Water flea) Method: OECD Test Guideline 211

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#### Ecotoxicology Assessment

Acute aquatic toxicity	:	Toxic effects cannot be excluded
Chronic aquatic toxicity	:	Toxic effects cannot be excluded

#### 12.2 Persistence and degradability

#### **Components:**

#### **Benzyl alcohol:**

Biodegradability	: Result: Readily biodegradable. Biodegradation: 92 - 96 %
	Exposure time: 14 d

#### 12.3 Bioaccumulative potential

#### Components:

#### Benzyl alcohol:

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Version 5.0	Revision Date: 06.04.2024		DS Number: 871271-00009	Date of last issue: 08.12.2023 Date of first issue: 27.08.2021	
Partition coefficient: n- octanol/water		:	log Pow: 1.05		
<b>12.4 Mobility in soil</b> No data available					
12.5 Result	ts of PBT and vPvB a	sse	ssment		
Produ	<u>ct:</u>				
Assessment		:	This substance/mixture contains no components considere to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels o 0.1% or higher.		
12.6 Other adverse effects					
Produ Endoc tial	<u>ct:</u> rine disrupting poten-	:	ered to have end	nixture does not contain components consid- ocrine disrupting properties for environment REACH Article 57(f).	

#### **SECTION 13: Disposal considerations**

#### 13.1 Waste treatment methods

Product	:	Dispose of in accordance with local regulations. According to the European Waste Catalogue, Waste Codes are not product specific, but application specific. Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities. Do not dispose of waste into sewer.
Contaminated packaging	:	Empty containers should be taken to an approved waste han- dling site for recycling or disposal. If not otherwise specified: Dispose of as unused product.

#### **SECTION 14: Transport information**

#### 14.1 UN number

ADN	:	Not regulated as a dangerous good
ADR	:	Not regulated as a dangerous good
RID	:	Not regulated as a dangerous good
IMDG	:	Not regulated as a dangerous good
ΙΑΤΑ	:	Not regulated as a dangerous good
14.2 UN proper shipping name		
ADN	:	Not regulated as a dangerous good
ADR	:	Not regulated as a dangerous good
RID	:	Not regulated as a dangerous good

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Version 5.0	Revision Date: 06.04.2024	SDS Num 9371271-0		Date of last issue: 08.12.2023 Date of first issue: 27.08.2021
IMD	3	: Not ree	oulated as	a dangerous good
ΙΑΤΑ	L .		-	a dangerous good
14.3 Tran	sport hazard class(es		-	
ADN		: Not ree	oulated as	a dangerous good
ADR			-	a dangerous good
RID				a dangerous good
IMDO	G		-	a dangerous good
ΙΑΤΑ	L .		-	a dangerous good
14.4 Pacl	king group	·	-	
ADN		: Not reg	nulated as	a dangerous good
ADR			-	a dangerous good
RID			-	a dangerous good
IMD	3			a dangerous good
IATA	(Cargo)		-	a dangerous good
	(Passenger)		-	a dangerous good
14.5 Environmental hazards Not regulated as a dangerous good				
-	cial precautions for us	ser		
14.7 Tran	sport in bulk accordi	ng to Annex	II of Marpo	ol and the IBC Code
Rem	arks	: Not ap	plicable for	r product as supplied.
SECTIO	N 15: Regulatory inf	ormation		
15.1 Safe ture	ty, health and enviror	mental regu	lations/leg	gislation specific for the substance or mix-
	EU provisions transpos	ed through re	tained EU	law
UK F	REACH List of restriction		)	: Not applicable

UK REACH List of restrictions (Annex 17)	:	Not applicable
UK REACH Candidate list of substances of very high	:	Not applicable
concern (SVHC) for Authorisation		
The Persistent Organic Pollutants Regulations (retained	:	Not applicable
Regulation (EU) 2019/1021 as amended for Great Brit-		
ain)		
Regulation (EC) No 1005/2009 on substances that de-	:	Not applicable
plete the ozone layer		
UK REACH List of substances subject to authorisation	:	Not applicable
(Annex XIV)	•	
GB Export and import of hazardous chemicals - Prior		Not applicable
	·	Not applicable
Informed Consent (PIC) Regulation		
Control of Major Accident Hazards Regulations 2015 (CC	IVIA	H)
Not applicable		

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

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

#### 15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

rmation
: Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.
nts
: Harmful if swallowed.
: Causes serious eye irritation.
: Harmful if inhaled.
<ol> <li>May cause allergy or asthma symptoms or breathing difficul- ties if inhaled.</li> </ol>
: May damage fertility.
: Causes damage to organs.
: Causes damage to organs through prolonged or repeated exposure.

#### Full text of other abbreviations

Acute Tox. :	Acute toxicity
Eye Irrit. :	Eye irritation
Repr. :	Reproductive toxicity
Resp. Sens. :	Respiratory sensitisation
STOT RE :	Specific target organ toxicity - repeated exposure
STOT SE :	Specific target organ toxicity - single exposure

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by Road; AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA -European Chemicals Agency; EC-Number - European Community number; 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; 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;



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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; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of very high concern; TCSI - Taiwan Chemical Substance Inventory; 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

#### Further information

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

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