### Safety data sheet in accordance with regulation (EC) No 1907/2006

Trade name: Adeps marmottae conservatus

Substance number: 260250

Version: 2 / CH

Replaces Version: 1 / CH

Date revised: 06.02.2023

HANSELER

Print date: 06.02.23

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

#### **1.1. Product identifier**

Adeps marmottae conservatus Item No. 26025000

### 1.2. Relevant identified uses of the substance or mixture and uses advised against

### Use of the substance/preparation

Active pharmacutical substance, Manufacture of pharmacutical products

### 1.3. Details of the supplier of the safety data sheet

### Address/Manufacturer

Hänseler AG Industriestrasse 35 9100 Herisau Telephone no. 0041 (0)71 353 58 58 E-mail address of person responsible for this SDS

### 1.4. Emergency telephone number

Switzerland :145 / Abroad +41 (0)44 251 51 51

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

### 2.1. Classification of the substance or mixture

Voluntary product information following the Safety Data Sheet format This product is not classified hazardous in accordance with Regulation (EC) No 1272/2008.

### 2.2. Label elements

### Labelling according to regulation (EC) No 1272/2008

The product does not require a hazard warning label in accordance with Regulation (EC) No 1272/2008.

### 2.3. Other hazards

The Substance does not meet PBT-criteria. This substance does not meet the vPvB-criteria. This substance does not have endocrine disrupting properties with respect to humans. This substance does not have endocrine disrupting properties with respect to non-target organisms.

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

#### Further ingredients \*\*\*

MARMOT OIL CAS No. Concentration Advice: [4]	225234-13-9	>=	95	%
Propane-1,2-diol CAS No. EINECS no. Registration no. Concentration Advice: [4]	57-55-6 200-338-0 01-2119456809-23	<	1	%

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2,6-Di-tert-butyl-p-c CAS No.	128-37-0				
EINECS no.	204-881-4				
Concentration		<	1	%	
[4] Classification (Bog	ulation (EC) No. 1272/2009)				
Classification (Reg	ulation (EC) No. 1272/2008) Aquatic Acute 1	H400			
	Aquatic Chronic 1	H410			
Concentration limits	s (Regulation (EC) No. 1272 Aquatic Acute 1	/2008) M =	1		
	Aquatic Chronic	M =	-		
	1				
6-O-palmitoylascort					
CAS No.	137-66-6				
EINECS no. Concentration	205-305-4	<	1	%	
Advice: [4]			I	70	
	ulation (EC) No. 1272/2008)				
	Eye Irrit. 2	H319			
CAS No.	31566-31-1				
EINECS no.	250-705-4				
Concentration		<	1	%	
Advice: [4]					
Classification (Reg	ulation (EC) No. 1272/2008) Acute Tox. 4	H302			
		11002			
Citric acid, anhydro	us				
CAS No.	77-92-9				
EINECS no. Concentration	201-069-1		1	%	
Advice: [4]		<	1	/0	
	ulation (EC) No. 1272/2008)				
	Eye Irrit. 2	H319			
Nerra					
<b>Note</b> [4] Voluntary inform	ation				
	lation				
SECTION 4: First ai	d measures				
4.1. Description of firs	st aid measures				
After inhalation	( 1.), (				
	ty into fresh air and keep hi	m calm.			
After skin contact	unt innit older innited in a MA1	<b></b>		and weter	
•	uct isn't skin irritating. Wash	off with So	Jap a	and water.	
After eye contact		المتعامية	<b>.</b> 4 .		diaal adviat
	vith eyes rinse thoroughly w	ith plenty of	JT Wa	ater and seek me	aical advice.
After ingestion					
By continuous com	plaints consult a physician.				
SECTION 5: Firefig	hting measures				
JECHON J. FILCING	ining incasules				

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5.1. Extinguishing media

### Suitable extinguishing media

Carbon dioxide, Dry chemical extinguisher, Foam

### Non suitable extinguishing media

Full water jet

5.2. Special hazards arising from the substance or mixture Carbon monoxide (CO); Carbon dioxide (CO2)

### **SECTION 6: Accidental release measures**

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

Pick up with absorbent material (eg sand, kieselgur, acid binder, universal binder, sawdust). Allow to set, pick up mechanically. High risk of slipping due to leakage/spillage of product.

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

### 7.1. Precautions for safe handling

### Advice on safe handling

Observe the usual precautions for handling chemicals.

### 7.2. Conditions for safe storage, including any incompatibilities

### Requirements for storage rooms and vessels

Keep tightly closed in a dry and cool place.

### Storage classes

Storage class according to TRGS 510	13
Storage category (Switzerland)	NG

Non- combustible solids Other solid hazardous substances without classification/labelling hazardous

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

### 8.1. Control parameters

### Derived No/Minimal Effect Levels (DNEL/DMEL)

### 2,6-Di-tert-butyl-p-cresol

_,• ••••		
Type of value	Derived No Effect Level (DNEL)	
Reference group	Worker	
Duration of exposure	Long term	
Route of exposure	inhalative	
Mode of action	Systemic effects	
Concentration	3.5	mg/m³
Type of value	Derived No Effect Level (DNEL)	
Reference group	Worker	
Duration of exposure	Short term	
Route of exposure	dermal	
Mode of action	Systemic effects	
Concentration	0.5	mg/kg
Propane-1,2-diol		
Type of value	Derived No Effect Level (DNEL)	
Reference group	General Population	



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Duration of exposure	Long term	
Route of exposure	inhalative	
Mode of action	Systemic effects	
Concentration	50	mg/m³
Type of value	Derived No Effect Level (DNEL)	
Reference group	Worker	
Duration of exposure	Long term	
Route of exposure	inhalative	
Concentration	168	mg/m³
Predicted No Effect Conce	ntration (PNEC)	
Citric acid, anhydrous		
Type of value	PNEC	
Туре	Freshwater	
Concentration	0.44	mg/l
Type of value	PNEC	
Туре	Saltwater	
Concentration	0.044	mg/l
Type of value	PNEC	
Туре	Sewage treatment plant (STP)	
Concentration	1000	mg/l
Type of value	PNEC	
Туре	Sediment	
Concentration	34.6	mg/kg
Type of value	PNEC	
Туре	Marine sediment	
Concentration	3.46	mg/kg
Type of value	PNEC	
Type	Soil	
Concentration	33.1	mg/kg
2,6-Di-tert-butyl-p-cresol		
Type of value	PNEC	
Туре	Freshwater	
Concentration	0.199	μg/l
Type of value	PNEC	
Type Concentration	Saltwater	
Concentration	0.0199	μg/l
Type of value	PNEC	
Type Conditions	Water Intermittend	
Concentration	1.99	μg/l
Type of value	PNEC	
Type	Sediment	
Concentration	0.0996	mg/kg
Type of value	PNEC	

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Type Concentration	Marine sediment 0.0096	mg/kg
Type of value Type Concentration	PNEC Soil 0.04769	mg/kg
Propane-1,2-diol Type of value Type Concentration	PNEC Soil 50	mg/kg
Type of value Type Concentration	PNEC Saltwater 26	mg/l
Hand protection Protective gloves Eye protection Not necessary. SECTION 9: Physical an	d chemical properties	
9.1. Information on basic pl Physical state Colour	h <b>ysical and chemical properties</b> liquid yellowish to brownish	
<b>Melting point</b> Value Remarks	0 to 10 Information refers to the main compo	°C nent.
<b>Flash point</b> Value Remarks	290 Information refers to the main compor	°C nent.
Vapour pressure Remarks Density and/or relative de	Not applicable	
Value Remarks	appr. 0.9 Relative Density according specificati	g/cm³ on
SECTION 10: Stability and	nd reactivity	
10.1. Reactivity None known		
<b>10.2. Chemical stability</b> No decomposition if stored	l and applied as directed.	
<b>10.3. Possibility of hazardo</b> No hazardous reactions kr		

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<b>10.4. Conditions to avoid</b> No hazardous reactions kno	wn.		
<b>10.5. Incompatible materials</b> No decomposition if stored a	ind appli	ed as directed.	
10.6. Hazardous decomposit None known	ion pro	oducts	
SECTION 11: Toxicologic	<u>al inf</u>	ormation	
11.1 Information on hazard c	lasses	as defined in Regulatio	n (EC) No 1272/2008
Acute oral toxicity (Compo			
Citric acid, anhydrous	,		
Species	rat		
LD50		3000	mg/kg
6-O-palmitoylascorbic acid			
Species LD50	rat >	10000	mg/kg
6-O-palmitoylascorbic acid	-	10000	ing/ng
Species	mouse		
LD50		25000	mg/kg
Species LD50	rat >	5000	mg/kg
2,6-Di-tert-butyl-p-cresol	-	3000	ing/kg
Species	Rats (r	nale/female)	
LD50	>	6000	mg/kg
Method	OECD	401	
Propane-1,2-diol	rot		
Species LD50	rat	20000	mg/kg
Propane-1,2-diol			
Species	rat		
LD50		6660	mg/kg
Remarks	intrape	ritoneal	
Propane-1,2-diol Species	mouse		
LD50	modoc	9718	mg/kg
Remarks	intrape	eritoneal	
Acute dermal toxicity (Com	nponen	ts)	
Citric acid, anhydrous	No dot	e evelleble	
Remarks	No dat	a available	
6-O-palmitoylascorbic acid Species	guinea	nia	
LD50	>	3000	mg/kg
Species	Humai		
Duration of exposure Remarks	Bacad	24 h on available data, the classification	ation criteria are not met
2,6-Di-tert-butyl-p-cresol	Daseu	טון מאמוומטוב ממומ, וווב טומסטוווט	ation ontona are not met.
Species	Rats (r	nale/female)	
LD50	>	2000	mg/kg
Method	OECD	402	

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Propane-1,2-diol		
Species	rabbit	
	20800	mg/kg
Acute inhalative toxicity (	Components)	
Citric acid, anhydrous		
Remarks	Harmful by inhalation.	
6-O-palmitoylascorbic acid		
Remarks	No data available.	
Species	Human	
Remarks	Based on available data, the classification	ation criteria are not met.
2,6-Di-tert-butyl-p-cresol Remarks	No data available.	
Propane-1,2-diol		
Remarks	No data available.	
Skin corrosion/irritation (	Components)	
Citric acid, anhydrous		
Species	rabbit	
evaluation	slightly irritant	
Method	OECD 404	
6-O-palmitoylascorbic acid		
Species	rabbit	
evaluation	slightly irritant	
Species	guinea pig	
Remarks	No effect of irritation known.	
2,6-Di-tert-butyl-p-cresol evaluation	non-irritant	
Propane-1,2-diol		
Duration of exposure	7 d	
evaluation	slightly irritant	
Serious eye damage/irrita	tion (Components)	
Citric acid, anhydrous		
Species	rabbit	
evaluation	irritant - risk of serious damage to eye	es
Method	OECD 405	
6-O-palmitoylascorbic acid		
Species	rabbit	
evaluation	non-irritant	
Method	Draize method	
Species Remarks	mammal, species unspecified slightly irritating (Eye)	
2,6-Di-tert-butyl-p-cresol Species	rabbit	
evaluation	non-irritant	
Propane-1,2-diol		
Species	rabbit	
evaluation	slightly irritant	
Sensitization (Component		
Citric acid, anhydrous	,	
Remarks	No data available.	
6-O-palmitoylascorbic acid evaluation	non-sensitizing	

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Remarks	No sensitation effect known.	
Remarks	No sensitation effect known.	
2,6-Di-tert-butyl-p-cresol		
Species	Human	
evaluation	non-sensitizing	
Propane-1,2-diol		
Remarks	No data available.	
	ronic toxicity (Components)	
6-O-palmitoylascorbic acid	Net en l'en ble	
Remarks Remarks	Not applicable Not applicable	
2,6-Di-tert-butyl-p-cresol	Not applicable	
Remarks	No data available	
Propane-1,2-diol		
Remarks	No data available.	
Mutagenicity (Component	s)	
Citric acid, anhydrous	-,	
evaluation	No mutagenicity in the Ames-test.	
Method	in vitro	
Remarks	negative	
6-O-palmitoylascorbic acid		
Remarks	negative	
Remarks	No data available.	
2,6-Di-tert-butyl-p-cresol	No mutogenicity eccording to verious in vitro	tooto
evaluation	No mutagenicity according to various in vitro	lesis.
2,6-Di-tert-butyl-p-cresol Species	Salmonella typhimurium	
evaluation	No mutagenicity in the Ames-test.	
Remarks	negative	
2,6-Di-tert-butyl-p-cresol		
Route of exposure	oral	
Species	rat (male)	
Remarks	negative	
2,6-Di-tert-butyl-p-cresol Route of exposure	intraperitoneal	
Species	mouse	
evaluation	No mutagenicity in the micronucleus test.	
Propane-1,2-diol		
Remarks	No data available.	
Reproduction toxicity (Co	mponents)	
Citric acid, anhydrous		
Remarks	Indications of toxic effects are available from animals.	reproduction studies in
6-O-palmitoylascorbic acid		
evaluation	No negative effects	
Species Remarks	rat Indications of toxic effects are available from animals.	reproduction studies in
2,6-Di-tert-butyl-p-cresol		
Remarks	No data available.	
Propane-1,2-diol		

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Remarks	No data available.	
Carcinogenicity (Compon		
Citric acid, anhydrous	,	
Remarks	No data available.	
6-O-palmitoylascorbic acid		
Remarks	negative	
Species	rat	
Remarks	negative	
2,6-Di-tert-butyl-p-cresol	<b>.</b>	
Remarks	No evidence available on carcinogenicity.	
Propane-1,2-diol	No data available	
Remarks	No data available.	
	<pre>kicity (STOT) (Components)</pre>	
Citric acid, anhydrous Remarks	Not applicable	
6-O-palmitoylascorbic acid		
Remarks	Not applicable	
Remarks	Not applicable	
2,6-Di-tert-butyl-p-cresol	Organau Liver	
Species	Organs: Liver rat	
NOAEL	25 mg/kg	
Duration of exposure	1 d	
Method	Value taken from the literature	
Propane-1,2-diol Remarks	Not applicable	
11.2 Information on other ha	azards	
	perties with respect to humans	
	ave endocrine disrupting properties with resp	act to humans
This substance does not ha	we endocrine disrupting properties with resp	
SECTION 12: Ecological	information ***	
12.1. Toxicity		
Fish toxicity (Components	5)	
Citric acid, anhydrous	,	
Species	golden orfe (Leuciscus idus)	
LC50	440 to 760 mg	g/l
Duration of exposure	96 h	-
6-O-palmitoylascorbic acid		
Species	Salmo gairdneri	
LC50	51 mỹ 96 h	g/l
Duration of exposure Remarks	96 h No data available.	
Komuno		
2 6-Di-tert-butyl-p-cresol	Oryzias latipes	
2,6-Di-tert-butyl-p-cresol Species		
<b>2,6-Di-tert-butyl-p-cresol</b> Species LC50	5.3 mg	g/l
Species LC50		g/l
Species LC50 <b>Propane-1,2-diol</b> Species		g/I
Species LC50 <b>Propane-1,2-diol</b>	5.3 mg	-

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Daphnia toxicity (Compone	ente)			
Citric acid, anhydrous				
EC5	485		mg/l	
Source	Entosiphon sulc	atum (Literaturwert)		
Citric acid, anhydrous	Destais moone			
Species EC50	Daphnia magna 120	l	mg/l	
Duration of exposure	72	h	mg/i	
6-O-palmitoylascorbic acid				
Remarks	No data availab	le.		
Remarks	No data availab	le.		
2,6-Di-tert-butyl-p-cresol				
EC50	0.48		mg/l	
Duration of exposure Method	48 OECD 201	h		
	OECD 201			
2,6-Di-tert-butyl-p-cresol NOEC	0.15		mg/l	
Duration of exposure	48	h	iiig/i	
Propane-1,2-diol				
Species	Daphnia			
NOEC	13020		mg/l	
Propane-1,2-diol				
Species	Daphnia magna	l		
EC50 Duration of exposure	> 10000 48	h	mg/l	
•		11		
Algae toxicity (Component	.5)			
Citric acid, anhydrous	0			
Species IC5	Scenedesmus o 640	quadricauda	mg/l	
Duration of exposure	7	d	iiig/i	
Citric acid, anhydrous	-	-		
Species IC5	Microcystis aeru 80	uginosa (blue alge)	mg/l	
6-O-palmitoylascorbic acid			-	
Remarks	No data availab			
Remarks	No data availab	le.		
2,6-Di-tert-butyl-p-cresol				
EC50	> 0.4	Ŀ	mg/l	
Duration of exposure	72	h		
Propane-1,2-diol Remarks	No data availab	ام		
		IG.		
Bacteria toxicity (Compone	51115)			
Citric acid, anhydrous	. 40000			
EC5 Duration of exposure	> 10000 16	h	mg/l	
6-O-palmitoylascorbic acid	10			
Remarks	No data availab	le.		
Remarks	No data availab			
2,6-Di-tert-butyl-p-cresol				
EC50	1.7		mg/l	
2,6-Di-tert-butyl-p-cresol				
· · ·				

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EC0	500	ma/l	
Duration of exposure	30 min	mg/l	
2,6-Di-tert-butyl-p-cresol			
Species	activated sludge		
EC50	> 10000	mg/l	
Duration of exposure	3 h	Ũ	
Propane-1,2-diol			
Remarks	No data available.		
12.2. Persistence and degra	adability		
Physico-chemical elimina	•		
Citric acid, anhydrous			
Remarks	No data available.		
6-O-palmitoylascorbic acid			
Remarks	No data available.		
Remarks	No data available.		
2,6-Di-tert-butyl-p-cresol			
Remarks	No data available.		
Propane-1,2-diol			
Remarks	No data available.		
Biodegradability (Compo			
Citric acid, anhydrous	-		
Value	98	%	
Duration of test	2 d		
evaluation	Readily eliminable from water		
6-O-palmitoylascorbic acid	l		
Value	48	%	
Duration of test	28 d		
evaluation	not readily degradable		
Method	OECD 302B/ISO 9888/EEC 88/302,0	)	
Remarks	No data available.		
2,6-Di-tert-butyl-p-cresol			
Value	< 10	%	
Duration of test	20 d		
evaluation Method	not readily degradable OECD 301D		
	OECD 301D		
Propane-1,2-diol Remarks	No data available.		
Ready degradability (Con			
	iponenta)		
Citric acid, anhydrous Value	98	%	
Duration of test	2 d	70	
Method	OECD 302B/ISO 9888/EEC 88/302,0	)	
6-O-palmitoylascorbic acid			
Method	OECD 302B/ISO 9888/EEC 88/302,0	)	
Remarks	Not readily biodegradable.		
Remarks	No data available.		
2,6-Di-tert-butyl-p-cresol			
Remarks	Not readily biodegradable.		
Propane-1,2-diol			

-			SWISS PHARM	1A
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Chemical oxygen demand (	COD) (Compon	ients)		
Citric acid, anhydrous Value	728		mg/g	
Biochemical oxygen demar	nd (BOD5) (Com	nponents)		
Citric acid, anhydrous				
Value Duration of test	526 5	d	mg/g	
	-	ŭ		
12.3. Bioaccumulative potent				
Octanol/water partition coe	fficient (log Po	w) (Compone	nts)	
Citric acid, anhydrous log Pow	-1.72			
Temperature	20	°C		
6-O-palmitoylascorbic acid				
log Pow Method	6.0 calculated			
12.4. Mobility in soil				
Mobility in soil (Component	ts)			
<b>2,6-Di-tert-butyl-p-cresol</b> The product is insoluble and	sinks in water.			
2,6-Di-tert-butyl-p-cresol Adsorbs on soil.				
2,6-Di-tert-butyl-p-cresol Immobile				
12.5. Results of PBT and vPv	B assessment	t		
Results of PBT and vPvB as	ssessment ***			
The Substance does not mee This substance does not mee		а.		
12.6 Endocrine disrupting pro	operties			
Endocrine disrupting prope	-	ect to the env	rionment	
	•		with respect to non-target organisms.	
SECTION 13: Disposal co	nsiderations	5		
13.1. Waste treatment metho		-		
Disposal recommendations		·+		
May be reused after working	-			
Disposal recommendations				
Contaminated packaging sho taken for reuse.	ould be emptied as	s far as possible	and after appropriate cleansing may be	

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	Land transport ADR/RID	Marine transport IMDG/GGVSee	Air transport ICAO/IATA
14.1. UN number	The product does not constitute a	The product does not constitute a	The product does not constitute
	hazardous substance in land	hazardous substance in sea	a hazardous substance in air
	transport.	transport.	transport.

### **SECTION 15: Regulatory information \*\*\***

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

### Water Hazard Class (Germany) \*\*\*

Water Hazard Class	Not water hazardous		
(Germany) Remarks	Derivation of WGK according to Annex 1 No. 5.2 AwSV		

### **SECTION 16: Other information**

### Supplemental information

Relevant changes compared with the previous version of the safety data sheet are marked with: \*\*\* This information is based on our present state of knowledge. However, it should not constitute a guarantee for any specific product properties and shall not establish a legally valid relationship.