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

Trade name: Primulae radicis extr liq 1/1

Substance number: 126851

Version: 1 / CH Replaces Version: - / CH Date revised: 06.08.2019

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Print date: 06.08.19

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

1.1. Product identifier

Primulae radicis extr liq 1/1 Item No. 12685100

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

Use of the substance/preparation

Medicinal product

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 sdb@haenseler.ch 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

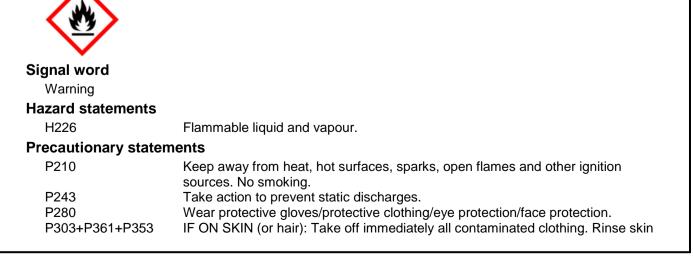
Classification (Regulation (EC) No. 1272/2008)

Classification (Regulation (EC) No. 1272/2008) Flam. Liq. 3 H226 The product is classified and labelled in accordance with Regulation (EC) No 1272/2008 For explanation of abbreviations see section 16.

2.2. Label elements

Labelling according to regulation (EC) No 1272/2008

Hazard pictograms



	_	. ,		7/2006		SWISS PHARMA
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P403+P233 P501.3	with water [or shower]. Store in a well-ventilated place. Keep container tightly cl Disposal in compliance with local and national regulation					
ECTION 3: Compos	sition/inforn	nation of	on ing	gredie	<u>nts</u>	
3.2. Mixtures						
Chemical characteria Alcoholic solution Extract of herbal drug Medicinal products						
Further ingredients						
Water CAS No. EINECS no. Concentration Advice: [4]	7732-18-5 231-791-2		>=	50	%	
Ethanol						
CAS No.	64-17-5					
EINECS no. Concentration Advice: [4]	200-578-6 >=	25	<	50	%	
Classification (Regula	ation (EC) No. 12	72/2008)				
	Flam. Liq. 2		H225			
Methanol CAS No. EINECS no. Registration no.	67-56-1 200-659-6 01-211943330	7-44-XXX	x			
Concentration Advice: [4]	01211040000	7 ++ ////	<	1	%	
Classification (Regulation)		72/2008)				
	Flam. Liq. 2 Acute Tox. 3 Acute Tox. 3 Acute Tox. 3 STOT SE 1		H225 H301 H311 H331 H370			
Concentration limits	(Regulation (EC) STOT SE 1 STOT SE 2	No. 1272/ H370 H371	>=	10 3 < 10		
Note						
[4] Voluntary informa	tion					

The product is an article within the meaning of Article 3 No. 3 of the REACH Regulation and thus not to be labelled according to the CLP regulation. The compilation of the Safety Data sheet is not required according to Article 31 REACH Regulation for articles and is done on a voluntary basis.

SECTION 4: First aid measures

4.1. Description of first aid measures General information



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If you feel unwell, seek medical advice (show the label where possible). Take off contaminated clothing and shoes immediately.

After inhalation

Ensure supply of fresh air. In the event of symptoms take medical treatment. Irregular breathing/no breathing: artificial respiration.

After skin contact

Wash immediately with plenty of water for several minutes. Consult a doctor if skin irritation persists.

After eye contact

Separate eyelids, wash the eyes thoroughly with water (15 min.). In case of irritation consult an oculist.

After ingestion

Consult a physician if necessary. Rinse out mouth and give plenty of water to drink.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media

Water spray jet, Carbon dioxide, Alcohol-resistant foam, Dry powder, Extinguishing measures to suit surroundings

Non suitable extinguishing media

Full water jet

5.2. Special hazards arising from the substance or mixture

In the event of a fire, toxic and combustible gases can be formed. In the event of fire the following can be released: Carbon monoxide (CO); Carbon dioxide (CO2)

5.3. Advice for firefighters

Special protective equipment for fire-fighting

Wear full protective suit. Use self-contained breathing apparatus.

Other information

Cool endangered containers with water spray jet.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Ensure adequate ventilation. Remove persons to safety. Keep away sources of ignition.

6.2. Environmental precautions

Do not discharge into the drains/surface waters/groundwater.

6.3. Methods and material for containment and cleaning up

Take up with absorbent material (eg sand, kieselguhr, universal binder). Send in suitable containers for recovery or disposal. Clean up affected area.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Advice on safe handling

Keep away from heat and sources of ignition. Take action to prevent static discharges.

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 rooms must be properly ventilated.

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Storage classes				
Storage class according to TRG Storage category (Switzerland)	S 510 3 3		ammable liquid ammable liquid	
SECTION 8: Exposure cont	rols/person	al protec	<u>tion</u>	
8.1. Control parameters				
Exposure limit values				
Ethanol				
List	SUVA			
Туре	MAK			
Value	960 mg/		500	ppm(V)
Short term exposure limit Pregnancy group: S; Status: 2	1920 mg, 017: Remarks:		1000 ormalKT HU: IN	ppm(V) IRS. NIOSH
8.2. Exposure controls	- ,	, - ,	,	-,
General protective and hygier	ne measures			
Avoid any contact with the body food-stuffs, beverages and feed	. Observe the us	sual precautio	ns for handling (chemicals. Keep away from
Respiratory protection	-3100K3.			
necessary; Do not breathe vapo	ours dust or aero	sol Provide	adequate ventils	ation
Hand protection				
-	loves / resistant	to chomicals		
Eye protection	1070371031314111	to chemicals		
Tightly fitting safety glasses				
Body protection				
Fire-resistant protective clothing	Y			
	9			
ECTION 9: Physical and cl	hemical pro	perties		
9.1. Information on basic physi		nical prope	rties	
Form Colour	liquid, clear red-brown			
Odour	characteristic			
Initial boiling point and boilin				
Value	> 78		°C	
Source	GESTIS-Stoffd	latenbank	C	
Flash point		atombaria		
Value	> 24		°C	
Source	GESTIS-Stoffd	latenbank	0	
Vapour pressure				
Value	< 5.8		kPa	
Density				
Value	0.905	to 1	.050	
Value				
Remarks	Relative Densi	iv accordino s	Decincation	

Risk of ignition or formation of inflammable gases or vapours with: Air

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			/ 011	Filin date. 00.00.
10.2. Chemical stability No decomposition if stored	and appl	ied as directed.		
10.3. Possibility of hazardo Keep away from sources o			osition if stored and ap	oplied as directed.
10.4. Conditions to avoid Heat				
10.5. Incompatible materials Alkaline metals, Ammonia,		s, Oxidising agents		
10.6. Hazardous decompos Hazardous determin decon gases/vapours			noxide, Carbon dioxide	e, Flammable
SECTION 11: Toxicologi	cal inf	ormation		
11.1. Information on toxicol	ogical e	effects		
Acute oral toxicity (Comp	onents)			
Ethanol				
Species	rat			
LD50	Tovios	7060	mg/kg	~ 710 1070
Source	TUXICC	nogy and Applied Pha	armacology. Vol. 16, P	y. 710, 1970.
Ethanol Species	rat			
LD50	Tat	10470	mg/kg	
Acute dermal toxicity (Co	mponen	nts)		
Ethanol				
Species	rabbit			
LD50	-	15800	mg/kg	
Acute inhalative toxicity (Compor	nents)		
Ethanol				
Species LC50	rat	30000	mg/m³	
Duration of exposure		4 h	mg/m-	
Administration/Form	Vapor	S		
Skin corrosion/irritation (Compon	nents)		
Ethanol evaluation	non-irr	ritant		
Serious eye damage/irrita	tion			
Remarks	Eye co	ontact with the produc	t may lead to irritation.	
Serious eye damage/irrita	tion (Co	omponents)		
Ethanol evaluation	irritant			
Mutagenicity (Component	ts)			
Ethanol				
evaluation	No mu	utagenicity in the Ame	es-test.	
Experience in practice				
The solvent vapours cause nervous system and can ca				

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feeling. Liver damage is poss	ible.					
Other information						
When handled appropiately, effects are known. Product specific toxicological			xperience w	ith this produ	uct, no adverse health	
SECTION 12: Ecological in	nformation					
12.2. Persistence and degrad Biodegradability (Compone	•					
	ints)					
Ethanol evaluation	Readily biodegr	adable				
Chemical oxygen demand (
Ethanol		2				
Value	0.93	to	1.67	mg/g		
12.5. Results of PBT and vPv	B assessmen	nt				
Evaluation of persistance a	nd bioaccumu	lation p	otential			
The product contains no PBT	or vPvB substar	nces.				
Evaluation of persistance a	nd bioaccumu	lation p	ootential (C	component	:s)	
Ethanol		_				
The Substance doesn't meet	s PBT/vPvB-crite	rions				
12.6. Other adverse effects						
General information / ecolo	•••		_			
Do not allow undiluted produce system. For this subsection the system of the subsection the subsection the system of the subsection the system of the system						
SECTION 13: Disposal co	nsideration	<u>s</u>				
13.1. Waste treatment metho	ds					
Disposal recommendations	for the produ	ct				
Disposal in compliance with I	ocal and national	regulati	ons.			
Disposal recommendations	for packaging	J				
Dispose of as unused produc	t.					
SECTION 14: Transport in	formation					
	lonnation					

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	Land transport ADR/RID	Marine transport IMDG/GGVSee	Air transport ICAO/IATA						
Tunnel restriction code	D/E								
14.1. UN number	1293	1293	1293						
14.2. UN proper shipping name	TINCTURES, MEDICINAL (Ethanol)	TINCTURES, MEDICINAL (Ethanol)	TINCTURES, MEDICINAL (Ethanol)						
14.3. Transport hazard class(es)	3	3	3						
Label		*	*						
14.4. Packing group	III	111	111						
Limited Quantity	51								
Transport category	3								

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SECTION 15: Regulatory information

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

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

Water Hazard Class (Germany)

Water Hazard Class WGK 1 (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.