according to Regulation (EC) No. 1907/2006



Eqvalan®, oral paste (finished product)

Version	Revision Date:	SDS Number:	Date of last issue: 09.10.2017
3.3	28.02.2018	000000049058	Date of first issue: 11.04.2017

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

1.1 Product identifier Trade name : Eqvalan®, oral paste (finished product) Synonyms : Eqvalan® Oral Paste für Pferde, Ivomec® Vet Paste, Ivomec® Vet Paste 6,42mg, Valaneq, EQUIMEC® Paste, Zimectrine, Equide®, Ivomec® Eprinex, Ivomec P, Panomec® oral paste for horses, Furexel with API: Ivermectin 1.2 Relevant identified uses of the substance or mixture and uses advised against Use of the Sub-: Pharmaceutical stance/Mixture Recommended restrictions Safety Data Sheet only for the professional user. : on use 1.3 Details of the supplier of the safety data sheet Company Boehringer Ing. Pharma GmbH & Co.KG : Binger Str. 173 55216 Ingelheim am Rhein Telephone : +498007790900 E-mail address of person : EHS-Services@Boehringer-Ingelheim.com responsible for the SDS

1.4 Emergency telephone number

Int. Emergency Telephone number: +1 703-527-3887 Chemtrec 24-hours

SECTION 2: Hazards identification

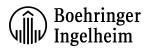
2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008)					
Acute aquatic toxicity , Category 1	H400: Very toxic to aquatic life.				
Chronic aquatic toxicity , Category 1	H410: Very toxic to aquatic life with long lasting effects.				

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

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Haza	ard pictograms	:	¥		
Sign	al word	:	Warnir	ng	
Hazard statements		:	H410	Very toxic	to aquatic life with long lasting effects.
Precautionary statements		:	Preve	ntion:	
			P273	Avoid relea	ase to the environment.
			Respo	Response:	
			P391	P391 Collect spillage.	
			Dispo	sal:	
			P501 dispos	Dispose of al plant.	contents/ container to an approved waste

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.

The pharmacological effect of the medicament has to be considered (see package leaflet). This drug is not subject to the labelling requirements under the Globally Harmonized System (GHS)

SECTION 3: Composition/information on ingredients

3.2 Mixtures

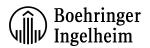
Chemical nature : organic

Hazardous components

Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
Ivermectin	70288-86-7 274-536-0	Acute Tox. 2; H300 Acute Tox. 4; H332 Acute Tox. 3; H311 Aquatic Acute 1; H400 Aquatic Chronic 1; H410	>= 1 - < 2,5

For explanation of abbreviations see section 16.

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SECTION 4: First aid measures

4.1 Description of first aid measures

General advice	:	In the case of accident or if you feel unwell, seek medical ad- vice immediately (show the label where possible). First Aid responders should pay attention to self-protection and use the recommended protective clothing Remove from exposure, lie down. Take off immediately all contaminated clothing. Victim to lie down in the recovery position, cover and keep him warm.
If inhaled	:	Move to fresh air.
In case of skin contact	:	Wash off immediately with plenty of water.
In case of eye contact	:	Rinse immediately with plenty of water for at least 15 minutes. Keep eye wide open while rinsing.
If swallowed	:	Rinse mouth. Drink plenty of water.

4.2 Most important symptoms and effects, both acute and delayed

Risks

: No information available.

4.3 Indication of any immediate medical attention and special treatment needed

Treatment

: Observe the summary of product characteristics of proprietary medicinal products Symptomatic treatment (decontamination, vital functions).

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. Water Dry chemical Foam Carbon dioxide (CO2)

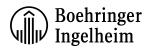
5.2 Special hazards arising from the substance or mixture

Specific hazards during fire-	:	In case of fire and/or explosion do not breathe fumes.	
fighting		Can be released in case of fire:	
		Carbon oxides	
		Product itself is non-combustible.	

5.3 Advice for firefighters

Special protective equipment : In the event of fire, wear self-contained breathing apparatus.

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fo	or firef	ighters		complete suit prot	tecting against chemicals
F	Further	information	:	must not be disch Fire residues and	ated fire extinguishing water separately. This arged into drains. contaminated fire extinguishing water must accordance with local regulations.
SECT		6: Accidental releas	se r	neasures	
6.1 Pe	ersona	al precautions, protec	ctive	e equipment and e	emergency procedures
		al precautions	:	Wear personal pr Ensure adequate	otective equipment.
6.2 Er	nviron	mental precautions			
E	Enviror	mental precautions	:	Do not flush into s	surface water or sanitary sewer system.
6.3 M	ethod	s and material for co	ntai	nment and cleani	ng up
		ls for cleaning up	:		fer to properly labelled containers.
6.4 Re	6.4 Reference to other sections				
For pe	ersona	I protection see section	n 8.	, For disposal cons	iderations see section 13.
SECT		7: Handling and sto	oraç	ge	
7.1 Pr	recaut	ions for safe handlin	a		
		on safe handling	:	Provide sufficient	air exchange and/or exhaust in work rooms.
		on protection against l explosion	:	No special protec product is not flan	tive measures against fire required. The nmable.
F	lygien	e measures	:		I hygiene practice. Wash hands and face d immediately after handling the product. thes separately.
7.2 Co	onditio	ons for safe storage,	inc	luding any incom	patibilities
		ements for storage and containers	:	No special storag	e conditions required.
Д	Advice	on common storage	:	Keep away from f Advice on Segreg	food, drink and animal feedingstuffs. gation
S	Storage	e class (TRGS 510)	:	12, Non-comb.Lic class.	a,,cant be assig.to any of the above stor.
7.3 Sr	pecific	end use(s)			
-	-	c use(s)	:	Consult the techn stance/mixture.	ical guidelines for the use of this sub-
				1/11	

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SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Contains no substances with occupational exposure limit values.

8.2 Exposure controls

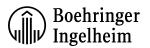
Engineering measures Local exhaust Emergency sprinkling nozzle		
Personal protective equipm Eye protection	ient :	Safety glasses with side-shields
Hand protection Material Break through time Glove thickness Directive Protective index		Nitrile rubber 480 min 0,43 mm Protective gloves against chemicals and micro-organisms Class 6
Skin and body protection	:	Laboratory: laboratory coat; factory: disposable Overall.
Respiratory protection	:	No personal respiratory protective equipment normally re- quired. Breathing apparatus needed only when aerosol or mist is formed. Respiratory protection ABEK2
Protective measures	:	Handle in accordance with good industrial hygiene and safety practice. Avoid contact with skin, eyes and clothing. Only use protective equipment in accordance with nation- al/international regulations. Follow the national regulations about wearing personal protective equipment and the warran- ty given by the manufacturer for the safe function.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance	:	paste
Colour	:	white
Odour	:	almost odourless
Odour Threshold	:	No data available
рН	:	No data available

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	Melting	point/range	:	Not applicable	
	Boiling	point/boiling range	:	185 °C	
	Flash p	point	:	101 °C	
	Evapor	ation rate	:	No data available	9
		explosion limit / Upper ability limit	:	2,6 %(V)	
		explosion limit / Lower ability limit	:	12,6 %(V)	
	Vapour	rpressure	:	0,1 hPa	
	Relativ	e vapour density	:	No data available	9
	Relativ	e density	:	No data available	9
	Bulk de	ensity	:	Not applicable	
	Solubili Wat	ity(ies) ter solubility	:	insoluble	
	Partitio octano	n coefficient: n- I/water	:	No data available	9
	Auto-ig	nition temperature	:	No data available	9
	Decom	position temperature	:	No data available	9
	Viscosi Visc	ity cosity, dynamic	:	No data available	9
	Explos	ive properties	:	Not explosive	
	Oxidizi	ng properties	:	No data available	9
9.2	9.2 Other information Self-ignition		:	not auto-flammal	ble

SECTION 10: Stability and reactivity

10.1 Reactivity

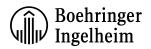
No dangerous reaction known under conditions of normal use.

10.2 Chemical stability

No decomposition if stored and applied as directed.

10.3 Possibility of hazardous reactions

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Hazardous reactions		: No dangerous reaction	known under conditions of normal use
0.4 Cond	litions to avoid		
Condi	tions to avoid	: Extremes of temperatur	re and direct sunlight.
0.5 Incon	npatible materials		
Mater	ials to avoid	: No data available	
	rdous decompositio Ita available	products	
SECTION	I 11: Toxicological	nformation	
1.1 Inform	mation on toxicologi	al effects	
	e toxicity		
	assified based on ava	able information.	
<u>Produ</u> Acute	<u>uct:</u> oral toxicity	: Acute toxicity estimate:	> 2.000 mg/kg
	-	Method: Calculation met	thod
Acute	inhalation toxicity	: Acute toxicity estimate: Exposure time: 4 h Test atmosphere: dust/n Method: Calculation met	nist
Acute	dermal toxicity	: Acute toxicity estimate: Method: Calculation met	
<u>Comp</u>	oonents:		
lverm	ectin:		
Acute	oral toxicity	: LD50 (Mouse): = 25 mg/	/kg
		LD50 (Rat): = 50 mg/kg	
Acute	inhalation toxicity	: LC50 (Rat): > 5,11 mg/l Exposure time: 1 h Test atmosphere: dust/n Assessment: The compo short term inhalation.	nist onent/mixture is moderately toxic after
Acute	dermal toxicity	: LD50 (Rabbit, male and	female): = 406 mg/kg
Skin	corrosion/irritation		
	assified based on ava	able information.	
Comr	oonents:		

Ivermectin:

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Species: Rabbit Result: No skin irritation

Serious eye damage/eye irritation

Not classified based on available information.

Components:

Ivermectin:

Species: Rabbit Result: Mild eye irritation

Respiratory or skin sensitisation

Skin sensitisation

Not classified based on available information.

Respiratory sensitisation

Not classified based on available information.

Components:

Ivermectin: Remarks: No data available

Germ cell mutagenicity

Not classified based on available information.

Components:

Ivermectin:

Genotoxicity in vitro	:	Test Type: Ames-test Test system: Salmonella typhimurium Result: negative
		Test Type: Mouse lymphoma assay Result: negative
		Test Type: Unscheduled DNA synthesis Test system: fibroblast cell line Result: negative
Genotoxicity in vivo	:	Remarks: No data available

Carcinogenicity

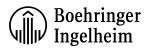
Not classified based on available information.

Components:

Ivermectin:

Remarks: No data available

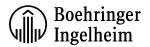
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	•	Juctive toxicity ssified based on availa	able	information.			
<u>C</u>	ompo	onents:					
lv	verme	ctin:					
Ef	ffects	on fertility	:	Remarks: No data	a available		
	ffects nent	on foetal develop-	:	Remarks: No data	a available		
	eprod essme	luctive toxicity - As- ent	:	 No toxicity to reproduction Animal testing did not show any effects on foetal develop- ment. 			
		single exposure					
		ssified based on availa onents:	able	information.			
	verme						
		ks: No data available					
		_					
		 repeated exposure ssified based on availa 	ahle	information			
			1010				
	<u>Components:</u> Ivermectin:						
		ks: No data available					
A	spira	tion toxicity					
No	ot cla	ssified based on availa	able	information.			
<u>C</u> (ompo	onents:					
	verme						
No	o data	a available					
Fu	urthe	r information					
<u>C</u>	ompo	onents:					
lv	verme	ctin:					
Re	emarl	ks: No data available					

according to Regulation (EC) No. 1907/2006



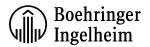
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SECTION 12: Ecological information

12.1 Toxicity **Components:** Ivermectin: Toxicity to fish LC50 (Oncorhynchus mykiss (rainbow trout)): 0,003 mg/l : Exposure time: 96 h LC50 (Lepomis macrochirus (Bluegill sunfish)): 0,0053 mg/l Exposure time: 96 h Toxicity to algae Remarks: No data available : M-Factor (Acute aquatic tox- : 100 icity) Toxicity to microorganisms : Remarks: No data available Toxicity to fish (Chronic tox-Remarks: No data available : icity) Toxicity to daphnia and other : EC50: 0,0017 mg/l aquatic invertebrates (Chron-Exposure time: 10 d Species: Hyallela azteca (Amphipod) ic toxicity) NOEC: 0,00021 mg/l Exposure time: 10 d Species: Hyallela azteca (Amphipod) M-Factor (Chronic aquatic 100 : toxicity) 12.2 Persistence and degradability **Components:** Ivermectin: : Remarks: No data available Biodegradability 12.3 Bioaccumulative potential **Components:** Ivermectin: Bioaccumulation : Remarks: No data available

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12.4 Mobi	lity in soil			
Com	ponents:			
lvern	nectin:			
	bution among environ- al compartments	:	Remarks: No data	a available
12.5 Resu	ilts of PBT and vPvB a	sse	ssment	
Prod	uct:			
Asse	ssment	:	to be either persis	ixture contains no components considered stent, bioaccumulative and toxic (PBT), or nd very bioaccumulative (vPvB) at levels of
12.6 Othe	r adverse effects			
Com	ponents:			
lvern	nectin:			
Addit matic	ional ecological infor- n	:	No data available	
SECTION	N 13: Disposal consid	dera	ations	

13.1 Waste treatment methods		
Product	:	Dispose of in accordance with local regulations.
Contaminated packaging	:	Packs that cannot be cleaned should be disposed of in the same manner as the contents. Uncontaminated packaging can be recycled.

SECTION 14: Transport information

14.1 UN number

Not regulated as a dangerous good

14.2 UN proper shipping name

Not regulated as a dangerous good

14.3 Transport hazard class(es)

Not regulated as a dangerous good

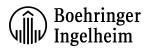
14.4 Packing group

Not regulated as a dangerous good

14.5 Environmental hazards

Not regulated as a dangerous good

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14.6 Special precautions for user

Not applicable

REACH

DSL

14.7 Transport in bulk according to Annex II of Marpol and the IBC Code

Not applicable for product as supplied.

SECTION 15: Regulatory information

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

REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59).	:	Not applicable
Regulation (EC) No 1005/2009 on substances that deplete the ozone layer	:	Not applicable
Regulation (EC) No 850/2004 on persistent organic pol- lutants	:	Not applicable
Regulation (EC) No 649/2012 of the European Parlia- ment and the Council concerning the export and import of dangerous chemicals	:	Ivermectin

Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances. Quantity 2

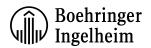
Quantity 1

E1		ENVIRONMENTAL HAZARDS	100 t	200 t
Water contaminating class (Germany)	:	WGK 3 highly water endang	ering	
TA Luft List (Germany)	:	Total dust: Not applicable Inorganic substances in pow Not applicable Inorganic substances in vap Not applicable Organic Substances: Not applicable Carcinogenic substances: Not applicable Mutagenic: Not applicable Toxic to reproduction: Not applicable		rm:
The components of this pro	duo	ct are reported in the follow	ing inventories:	

This product contains the following components that are not
on the Canadian DSL nor NDSL.

: Not in compliance with the inventory

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			Titanoxid	
AICS		:	Not in compliance	e with the inventory
NZIoC		:	Not in compliance	e with the inventory
ENCS		:	Not in compliance	e with the inventory
ISHL		:	Not in compliance	e with the inventory
KECI		:	Not in compliance	e with the inventory
PICCS	3	:	Not in compliance	e with the inventory
IECSC	;	:	Not in compliance	e with the inventory
TCSI		:	Not in compliance	e with the inventory
TSCA		:	Not On TSCA Inv	entory

15.2 Chemical safety assessment

SECTION 16: Other information

Full text of H-Statements

H311 : H332 : H400 :	Fatal if swallowed. Toxic in contact with skin. Harmful if inhaled. Very toxic to aquatic life.
H410 :	Very toxic to aquatic life with long lasting effects.

Full text of other abbreviations

Acute Tox.	:	Acute toxicity
Aquatic Acute	:	Acute aquatic toxicity
Aquatic Chronic	:	Chronic aquatic toxicity

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - European Agreement concerning the International Carriage of Dangerous Goods by Road: AICS - Australian Inventory of Chemical Substances: 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; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration



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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 International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TRGS - Technical Rule for Hazardous Substances; TSCA - Toxic Substances Control Act (United States); UN - United Nations; vPvB - Very Persistent and Very Bioaccumulative

Further information

Training advice	:	Provide adequate information, instruction and training for operators.
Other information	:	Vertical lines in the left hand margin indicate an amendment from the previous version.
Sources of key data used to compile the Safety Data Sheet	:	The specifications are based on own tests and/or literature data.
Classification of the mixtur	e:	Classification procedure:
Aquatic Acute 1	H4	00 Calculation method

•		
Aquatic Chronic 1	H410	Calculation method

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

DE / EN