

SAFETY DATA SHEET



.EQVALAN DUO, OSOPA/ 1/15.5+77.5MG/G CZ EQVALAN DUO # ML CZ SK

605-120

EN

Version	Revision Date:	SDS Number:	Date of last issue: -
1.0	04/07/2022	000000049057	Date of first issue: 04/07/2022

SECTION 1. IDENTIFICATION

Product name : .EQVALAN DUO, OSOPA/ 1/15.5+77.5MG/G CZ EQVALAN DUO # ML CZ SK

Product code : 000000000000143043 000000000000143043

Synonyms : Zimectrin® Gold, Ivomec Comp Paste, Eqvalan Gold, Endoxin, Furexel Combi Oral Paste, Molemec Plus
with active ingredient: Ivermectin and Praziquantel

Manufacturer or supplier's details

Company name of supplier : Boehringer Ing. Pharma GmbH & Co.KG

Address : Binger Straße 173
Ingelheim 55216
Germany

Telephone : +498007790900

Prepared by : EHS-Services@Boehringer-Ingelheim.com

Emergency telephone number : Int. Emergency Telephone number: +1 703-527-3887
German Emergency Telephone number: +49800 1817059

Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product

Restrictions on use : Safety Data Sheet only for the professional user., For veterinary use only, Refer to the product insert for complete instructions on usage

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with the OSHA Hazard Communication Standard (29 CFR 1910.1200)

Acute toxicity (Oral) : Category 4

Eye irritation : Category 2A

Skin sensitisation : Category 1

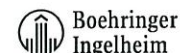
Reproductive toxicity : Category 2

Effects on or via lactation

Specific target organ toxicity : Category 1 (Central nervous system)
- repeated exposure (Oral)

GHS label elements

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Hazard pictograms



Signal word

: Danger

Hazard statements

: H302 Harmful if swallowed.
H317 May cause an allergic skin reaction.
H319 Causes serious eye irritation.
H361 Suspected of damaging fertility or the unborn child.
H362 May cause harm to breast-fed children.
H372 Causes damage to organs (Central nervous system) through prolonged or repeated exposure if swallowed.

Precautionary statements

Prevention:

P201 Obtain special instructions before use.
P202 Do not handle until all safety precautions have been read and understood.
P260 Do not breathe mist or vapours.
P263 Avoid contact during pregnancy/ while nursing.
P264 Wash skin thoroughly after handling.
P270 Do not eat, drink or smoke when using this product.
P272 Contaminated work clothing must not be allowed out of the workplace.
~~P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.~~

Response:

P301 + P312 + P330 IF SWALLOWED: Call a POISON CENTER/ doctor if you feel unwell. Rinse mouth.
P302 + P352 IF ON SKIN: Wash with plenty of soap and water.
P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P308 + P313 IF exposed or concerned: Get medical advice/ attention.
P333 + P313 If skin irritation or rash occurs: Get medical advice/ attention.
P337 + P313 If eye irritation persists: Get medical advice/ attention.
P363 Wash contaminated clothing before reuse.

Storage:

P405 Store locked up.

Disposal:

P501 Dispose of contents/ container to an approved waste disposal plant.

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Other hazards

This drug is not subject to the labelling requirements under the Globally Harmonized System (GHS)

The pharmacological effect of the medicament has to be considered (see package leaflet).

This product does not contain titanium dioxide in its respirable form and would not be considered carcinogenic; however, upon crushing, grinding or other processing that could result in the generation of respirable particulates, the Category 2 carcinogenic classification would apply.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Chemical nature : Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)
Glycerol formal	Not Assigned	>= 70 - < 90
praziquantel	55268-74-1	>= 5 - < 10
titanium dioxide	13463-67-7	>= 1 - < 5
Ivermectin	70288-86-7	>= 1 - < 5

Actual concentration is withheld as a trade secret

SECTION 4. FIRST AID MEASURES

- General advice : In the case of accident or if you feel unwell, seek medical advice immediately.
(show the package insert 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.
- Most important symptoms and effects, both acute and delayed : Harmful if swallowed.
May cause an allergic skin reaction.
Causes serious eye irritation.
Suspected of damaging fertility or the unborn child.
May cause harm to breast-fed children.
Causes damage to organs through prolonged or repeated exposure if swallowed.

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Notes to physician : Observe the summary of product characteristics of proprietary medicinal products
Treat symptomatically.

SECTION 5. FIREFIGHTING MEASURES

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

Unsuitable extinguishing media : None known.

Specific hazards during fire-fighting : In case of fire and/or explosion do not breathe fumes.

Hazardous combustion products : Carbon oxides

Further information : Collect contaminated fire extinguishing water separately. This must not be discharged into drains.
Fire residues and contaminated fire extinguishing water must be disposed of in accordance with local regulations.

Special protective equipment for firefighters : In the event of fire, wear self-contained breathing apparatus.
Complete suit protecting against chemicals

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures : Wear personal protective equipment.
Ensure adequate ventilation.
High risk of slipping due to leakage/spillage of product.

Environmental precautions : Do not flush into surface water or sanitary sewer system.

Methods and materials for containment and cleaning up : Pick up and transfer to properly labelled containers.
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders).

SECTION 7. HANDLING AND STORAGE

Advice on protection against fire and explosion : No special protective measures against fire required.

Advice on safe handling : Provide sufficient air exchange and/or exhaust in work rooms.

Conditions for safe storage : Refer to the product insert for instructions on storage.

Materials to avoid : Keep away from food, drink and animal feedingstuffs.

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Observe joint storage prohibition.

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

Components	Basis	Category	Values	Remarks
Ivermectin 70288-86-7	BIEL	3A	10 µg/m3	
	BIPC	3		
Abbreviations: BIEL = Boehringer Ingelheim Exposure Limit (internal value) BI-STEL = Boehringer Ingelheim Short-Term Exposure Limit (Excursion limit) BIPC = Boehringer Ingelheim Pregnancy Category BIPC 3: There is evidence in animals and/or humans or the mechanism of actions indicates that the compound has the potential to cause harm to the unborn. Harm to the unborn can occur even if exposure does not exceed the BIEL value.				

Components	Basis	Category	Values	Remarks
Praziquantel 55268-74-1	BIEL	3A	300 µg/m3	
	BIPC	1a		
Abbreviations: BIEL = Boehringer Ingelheim Exposure Limit (internal value) BI-STEL = Boehringer Ingelheim Short-Term Exposure Limit (Excursion limit) BIPC = Boehringer Ingelheim Pregnancy Category BIPC 1a: No risk of harm to the unborn is to be expected, when the exposure does not exceed the BIEL value. Available data in animals and/or humans indicate that the compound does not pose a special risk to the unborn.				

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
titanium dioxide	13463-67-7	TWA (total dust)	15 mg/m3	OSHA Z-1
		TWA (Total dust)	10 mg/m3	OSHA P0
		TWA	10 mg/m3 (Titanium dioxide)	ACGIH

Engineering measures : Local exhaust
Emergency sprinkling nozzle

Personal protective equipment

Respiratory protection : General and local exhaust ventilation is recommended to maintain vapor exposures below recommended limits. Where concentrations are above recommended limits or are unknown, appropriate respiratory protection should be worn.

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Follow OSHA respirator regulations (29 CFR 1910.134) and use NIOSH/MSHA approved respirators. Protection provided by air purifying respirators against exposure to any hazardous chemical is limited. Use a positive pressure air supplied respirator if there is any potential for uncontrolled release, exposure levels are unknown, or any other circumstance where air purifying respirators may not provide adequate protection.

Hand protection Material	:	Nitrile rubber
Remarks	:	The break through time depends amongst other things on the material, the thickness and the type of glove and therefore has to be measured for each case.
Eye protection	:	Safety glasses with side-shields (Not necessary when using full face mask)
Skin and body protection	:	Laboratory: laboratory coat; Factory: disposable Overall.
Protective measures	:	Handle in accordance with good industrial hygiene and safety practice. Do not breathe dust. Avoid contact with skin, eyes and clothing. Only use protective equipment in accordance with national/international regulations. Follow the national regulations about wearing personal protective equipment and the warranty given by the manufacturer for the safe function.
Hygiene measures	:	General industrial hygiene practice. Wash hands and face before breaks and immediately after handling the product. Keep working clothes separately.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	:	paste
Colour	:	orange
Odour	:	amine-like
Odour Threshold	:	No data available
pH	:	No data available
Melting point/range	:	Not applicable
Boiling point/boiling range	:	No data available

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Flash point	: No data available
Evaporation rate	: No data available
Flammability (solid, gas)	: Not applicable
Self-ignition	: No data available
Upper explosion limit / Upper flammability limit	: No data available
Lower explosion limit / Lower flammability limit	: No data available
Vapour pressure	: No data available
Relative vapour density	: No data available
Relative density	: No data available
Density	: No data available
Bulk density	: Not applicable
Solubility(ies) Water solubility	: immiscible
Partition coefficient: n-octanol/water	: No data available
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
Viscosity Viscosity, dynamic	: No data available
Viscosity, kinematic	: No data available
Explosive properties	: Not explosive
Oxidizing properties	: No data available
Particle size	: Not applicable

SECTION 10. STABILITY AND REACTIVITY

Reactivity	: No dangerous reaction known under conditions of normal use.
Chemical stability	: No decomposition if stored and applied as directed.

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Possibility of hazardous reactions : No dangerous reaction known under conditions of normal use.

Conditions to avoid : No data available

Incompatible materials : No data available

Hazardous decomposition products : No data available

SECTION 11. TOXICOLOGICAL INFORMATION

Acute toxicity

Harmful if swallowed.

Product:

Acute oral toxicity : Acute toxicity estimate: 1,407 mg/kg
Method: Calculation method

Acute inhalation toxicity : Acute toxicity estimate: 146.14 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Method: Calculation method

Acute dermal toxicity : Acute toxicity estimate: > 5,000 mg/kg
Method: Calculation method

Components:

Glycerol formal:

Acute oral toxicity : LD50 (Rat): > 3,000 mg/kg

Acute inhalation toxicity : Remarks: No data available

Acute dermal toxicity : Remarks: No data available

praziquantel:

Acute oral toxicity : LD50 (Rat): 2,248 mg/kg
Assessment: The component/mixture is moderately toxic after single ingestion.

LD50 (Mouse): 2,454 mg/kg
Assessment: The component/mixture is moderately toxic after single ingestion.

LD50 (Rabbit): 1,050 mg/kg

Acute inhalation toxicity : Remarks: No data available

Acute dermal toxicity : LD50 (Rabbit): > 2,000 mg/kg

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titanium dioxide:

Acute oral toxicity : LD50 (Rat, female): > 5,000 mg/kg
Method: OECD Test Guideline 425

Acute inhalation toxicity : LC50 (Rat, male): > 6.82 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist

Acute dermal toxicity : LD50 (Rabbit): > 10,000 mg/kg

Ivermectin:

Acute oral toxicity : LD50 (Rat, male): = 42.8 mg/kg
LD50 (Rat, female): = 44.3 mg/kg
LD50 (Mouse, male): = 11.6 mg/kg

Acute inhalation toxicity : LC50 (Rat): 5.11 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist

Acute dermal toxicity : LD50 (Rabbit, male and female): = 406 mg/kg

Skin corrosion/irritation

Not classified based on available information.

Components:

Glycerol formal:

Remarks : Not classified due to data which are conclusive although insufficient for classification.

praziquantel:

Species : Rabbit
Method : OECD Test Guideline 404
Result : No skin irritation

titanium dioxide:

Species : Rabbit
Method : OECD Test Guideline 404
Result : No skin irritation

Ivermectin:

Species : Rabbit
Result : No skin irritation

Serious eye damage/eye irritation

Causes serious eye irritation.

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Components:**Glycerol formal:**

Result : Irritation to eyes, reversing within 21 days

praziquantel:

Species : Rabbit
Result : No eye irritation

titanium dioxide:

Species : Rabbit
Result : No eye irritation
Method : OECD Test Guideline 405

Ivermectin:

Species : Rabbit
Result : Slightly irritating.

Respiratory or skin sensitisation**Skin sensitisation**

May cause an allergic skin reaction.

Respiratory sensitisation

Not classified based on available information.

Components:**Glycerol formal:**

Remarks : Not classified due to data which are conclusive although insufficient for classification.

praziquantel:

Test Type : modified Buehler test
Species : Guinea pig
Method : OECD Test Guideline 406
Result : Does not cause skin sensitisation.

titanium dioxide:

Test Type : Mouse Local Lymph Node Assay (LLNA)
Species : Mouse
Method : OECD Test Guideline 429
Result : Does not cause skin sensitisation.

Species : Guinea pig
Method : OECD Test Guideline 406
Result : Does not cause skin sensitisation.

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Ivermectin:

Test Type : Buehler test
Species : Guinea pig
Result : May cause sensitisation by skin contact.

Test Type : Mouse Local Lymph Node Assay (LLNA)
Species : Mouse
Result : Does not cause skin sensitisation.

Germ cell mutagenicity

Not classified based on available information.

Components:

Glycerol formal:

Genotoxicity in vitro : Remarks: Not classified due to data which are conclusive although insufficient for classification.

Genotoxicity in vivo : Remarks: Not classified due to data which are conclusive although insufficient for classification.

praziquantel:

Genotoxicity in vitro : Test Type: Ames test
Test system: Salmonella typhimurium
Concentration: 0 - 1000 µg/plate
Metabolic activation: with and without metabolic activation
Result: negative
Remarks: In vitro tests did not show mutagenic effects

Genotoxicity in vivo : Test Type: Micronucleus test
Species: Mouse
Application Route: Oral
Dose: 300, 600 mg/kg/day
Result: negative

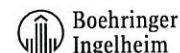
Test Type: Micronucleus test
Species: Rat
Dose: 600 mg/kg/day
Result: negative

titanium dioxide:

Genotoxicity in vitro : Test Type: Ames test
Concentration: 100-200 µg/plate
Metabolic activation: with and without metabolic activation
Method: OECD Test Guideline 471
Result: negative

Test Type: In vitro mammalian cell gene mutation test
Concentration: 31 - 500 µg/L
Metabolic activation: with and without metabolic activation
Method: OECD Test Guideline 476
Result: negative

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Test Type: Chromosome aberration test in vitro
Concentration: 125- 2500 ug/L
Metabolic activation: with and without metabolic activation
Method: OECD Test Guideline 473
Result: negative

Genotoxicity in vivo

: Test Type: Micronucleus test
Species: Mouse (male)
Application Route: Inhalation
Dose: 0,8; 7,2; and 28,5 mg/m3
Method: OECD Test Guideline 474
Result: negative

Test Type: Micronucleus test
Species: Rat (male and female)
Application Route: Oral
Dose: 500; 1.000; and 2.000 mg/kg bw
Method: OECD Test Guideline 474
Result: negative

Ivermectin:

Genotoxicity in vitro

: Test Type: Ames test
Test system: Salmonella typhimurium
Concentration: 2000 µg/plate
Result: negative

Test Type: Mouse lymphoma assay
Concentration: 1000 µg/ml
Result: negative

Test Type: Unscheduled DNA synthesis
Test system: fibroblast cell line
Concentration: 1000 µg/ml
Result: negative

Genotoxicity in vivo

: Test Type: Micronucleus test
Species: Rat
Application Route: Oral
Dose: 20 mg/kg/day
Result: negative

Carcinogenicity

Not classified based on available information.

Components:

Glycerol formal:

Remarks

: Not classified due to data which are conclusive although insufficient for classification.

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praziquantel:

Species : Rat
Exposure time : 104 weeks
Dose : 100 and 250 mg/kg body weight
Remarks : Did not show carcinogenic effects in animal experiments.

Species : Hamster
Exposure time : 80 weeks
Dose : 100 and 250 mg/kg body weight
Remarks : Did not show carcinogenic effects in animal experiments.

Ivermectin:

Species : Mouse
Exposure time : 2 Years
Dose : 10 mg/kg/day
Remarks : Did not show carcinogenic effects in animal experiments.

Species : Rat, male
Application Route : Oral
Exposure time : 2 Years
Dose : 9 mg/kg/day
Remarks : Not classified due to data which are conclusive although insufficient for classification.

Species : Rat, female
Application Route : Oral
Exposure time : 2 Years
Dose : 9 mg/kg/day
Remarks : Did not show carcinogenic effects in animal experiments.

IARC No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

OSHA No component of this product present at levels greater than or equal to 0.1% is on OSHA's list of regulated carcinogens.

NTP No component of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

Reproductive toxicity

Suspected of damaging fertility or the unborn child.
May cause harm to breast-fed children.

Components:

Glycerol formal:

Effects on fertility : Remarks: Not classified due to data which are conclusive although insufficient for classification.

Effects on foetal development : Remarks: Not classified due to data which are conclusive although insufficient for classification.

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Reproductive toxicity - Assessment : Some evidence of adverse effects on sexual function and fertility, and/or on development, based on animal experiments.

praziquantel:

Effects on fertility : Test Type: Fertility/early embryonic development
Species: Rat, male and female
Application Route: Oral
Dose: 30, 100, 300 milligram per kilogram
General Toxicity - Parent: NOEL: 300 mg/kg body weight
Fertility: NOEL: 300 mg/kg body weight
Early Embryonic Development: NOEL: 300 mg/kg body weight
Result: No effects on fertility and early embryonic development were detected.

Effects on foetal development : Test Type: Embryo-foetal development
Species: Rat
Application Route: Oral
Dose: 33, 100, 300 milligram per kilogram
General Toxicity Maternal: NOEL: 300 mg/kg body weight
Embryo-foetal toxicity: NOEL: 300 mg/kg body weight
Symptoms: No effects on embryofoetal and postnatal development

Test Type: Pre-/postnatal development
Species: Rat
Application Route: Oral

Dose: 30, 100, 300 milligram per kilogram
General Toxicity Maternal: NOEL: 300 mg/kg body weight
Teratogenicity: NOEL: 300 mg/kg body weight
Embryo-foetal toxicity: NOEL: 300 mg/kg body weight

Test Type: Embryo-foetal development
Species: Rabbit
Application Route: Oral
Dose: 100, 300 milligram per kilogram
Symptoms: Reduced body weight
Result: No teratogenic effects

Ivermectin:

Effects on fertility : Test Type: Fertility/early embryonic development
Species: Rat
Application Route: Oral
Dose: 0.1, 1, 9 mg/kg/day
General Toxicity - Parent: NOEL: 1 mg/kg body weight
Fertility: NOEL: 1 mg/kg body weight

Effects on foetal development : Test Type: Embryo-foetal development
Species: Mouse
Application Route: Oral
Dose: 0.1; 0.2; 0.4; 0.8 mg/kg/day
General Toxicity Maternal: NOEL: 0.1 mg/kg body weight
Embryo-foetal toxicity: NOEL: 0.2 mg/kg body weight

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Result: Teratogenic effects

Test Type: Embryo-foetal development
Species: Rat
Application Route: Oral
Dose: 1.5; 4; 12 mg/kg/day
General Toxicity Maternal: NOAEL: 4 mg/kg body weight
Embryo-foetal toxicity: NOAEL: 4 mg/kg body weight
Result: Teratogenic effects

Test Type: Embryo-foetal development
Species: Rabbit
Application Route: Oral
Dose: 1.5; 3; 6 mg/kg/day
General Toxicity Maternal: NOEL: 3 mg/kg body weight
Embryo-foetal toxicity: NOEL: 1.5 mg/kg body weight
Result: Teratogenic effects

Reproductive toxicity - Assessment : Some evidence of adverse effects on sexual function and fertility, and/or on development, based on animal experiments. Effects on or via lactation

STOT - single exposure

Not classified based on available information.

Components:

Glycerol formal:

Remarks : Not classified due to data which are conclusive although insufficient for classification.

praziquantel:

Remarks : Not classified due to data which are conclusive although insufficient for classification.

Ivermectin:

Remarks : Not classified due to data which are conclusive although insufficient for classification.

STOT - repeated exposure

Causes damage to organs (Central nervous system) through prolonged or repeated exposure if swallowed.

Components:

Glycerol formal:

Remarks : Not classified due to data which are conclusive although insufficient for classification.

praziquantel:

Remarks : Not classified due to data which are conclusive although insufficient for classification.

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ficient for classification.

Ivermectin:

Exposure routes	: Ingestion
Target Organs	: Central nervous system
Assessment	: The substance or mixture is classified as specific target organ toxicant, repeated exposure, category 1.

Repeated dose toxicity

Components:

praziquantel:

Species	: Rat
NOAEL	: 33 mg/kg
Application Route	: Oral
Exposure time	: 4 weeks
Dose	: 33, 100, 300 mg/kg/day
Species	: Rat
Application Route	: Oral
Exposure time	: 4 weeks
Dose	: 33, 100, 300, 1000 mg/kg/day
Symptoms	: No symptoms known or expected.

Species	: Rabbit
NOAEL	: 500 mg/kg
Application Route	: Dermal
Exposure time	: 3 weeks
Dose	: 500 mg/kg/day (5 days per wee)

Ivermectin:

Species	: Mouse
NOAEL	: 10 mg/kg
Application Route	: Dermal
Exposure time	: 13 weeks
Dose	: 1, 3, 10 mg/kg/day
Remarks	: No significant adverse effects were reported

Species	: Rat
NOAEL	: 3 mg/kg
Application Route	: Oral
Exposure time	: 13 weeks
Dose	: 0.1, 0.3, 1.0, 3.0 mg/kg/day

Species	: Dog
NOAEL	: 0.5 mg/kg
Application Route	: Oral
Exposure time	: 13 weeks
Dose	: 0.1, 0.25, 0.5, 1.5 mg/kg/day

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Aspiration toxicity

Not classified based on available information.

Components:

Glycerol formal:

Not classified due to data which are conclusive although insufficient for classification.

praziquantel:

No data available

Ivermectin:

No data available

Further information

Components:

Ivermectin:

Remarks : No data available

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Glycerol formal:

Toxicity to fish : Remarks: No data available

Toxicity to daphnia and other aquatic invertebrates : Remarks: No data available

Toxicity to algae/aquatic plants : Remarks: No data available

Toxicity to fish (Chronic toxicity) : Remarks: No data available

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : Remarks: No data available

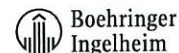
Toxicity to microorganisms : Remarks: No data available

praziquantel:

Toxicity to fish : LC50 (Fish): 13.4 mg/l
Exposure time: 24 h

LC50 (Fish): 55.1 mg/l

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Exposure time: 24 h

LC50 (Fish): 49.7 mg/l
Exposure time: 96 h

LC50 (White amur; Grass carp): 63.4 mg/l
Exposure time: 24 h

LC50 (White amur; Grass carp): 60.6 mg/l
Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 35 mg/l
Exposure time: 48 h

Toxicity to algae/aquatic plants : Remarks: No data available

Toxicity to fish (Chronic toxicity) : Remarks: No data available

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : Remarks: No data available

Toxicity to microorganisms : (activated sludge): > 1,000 mg/l
Exposure time: 3 h
Method: OECD Test Guideline 209

titanium dioxide:

Toxicity to fish : LC50 (Cyprinodon variegatus (sheepshead minnow)): > 10,000 mg/l
Exposure time: 96 h
Test Type: semi-static test
Method: OECD Test Guideline 203

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 daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 0.000013 mg/l
End point: Immobilization
Exposure time: 48 h

Toxicity to algae/aquatic plants : EC50 (Pseudokirchneriella subcapitata (green algae)): > 4 mg/l
End point: Growth rate
Exposure time: 72 h
Method: OECD Test Guideline 201

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Lowest Observed Effect Concentration (Pseudokirchneriella subcapitata (green algae)): 1.25 mg/l
End point: Growth rate
Exposure time: 72 h
Method: OECD Test Guideline 201

NOEC (Pseudokirchneriella subcapitata (green algae)): 0.391 mg/l
End point: Growth rate
Exposure time: 72 h

Toxicity to fish (Chronic toxicity) : Remarks: No data available

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : EC50 (Hyaella azteca (Amphipod)): 0.0017 mg/l
Exposure time: 10 d

NOEC (Hyaella azteca (Amphipod)): 0.00021 mg/l
Exposure time: 10 d

Toxicity to microorganisms : Remarks: No data available

Toxicity to soil dwelling organisms : Test Type: artificial soil
EC50 (Eisenia fetida (earthworms)): 5.3 mg/kg
Exposure time: 56 d
Method: OECD Test Guideline 222

Test Type: artificial soil
NOEC (Eisenia fetida (earthworms)): 2.5 mg/kg
Exposure time: 56 d
Method: OECD Test Guideline 222

Persistence and degradability

Components:

Glycerol formal:

Biodegradability : Result: Readily biodegradable.

praziquantel:

Biodegradability : Result: Not readily biodegradable.
Biodegradation: 0 %
Exposure time: 28 d
Method: OECD Test Guideline 301D

titanium dioxide:

Biodegradability : Remarks: The methods for determining biodegradability are not applicable to inorganic substances.

Ivermectin:

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Biodegradability : Result: Persistent substance with a half life of more than 60 days.

Bioaccumulative potential

Components:

Glycerol formal:

Bioaccumulation : Remarks: No data available

Partition coefficient: n-octanol/water : Remarks: No data available

praziquantel:

Bioaccumulation : Remarks: No appreciable bioaccumulation potential is to be expected (log P(o/w) 1-3).

Partition coefficient: n-octanol/water : log Pow: 2.42

titanium dioxide:

Partition coefficient: n-octanol/water : Remarks: No data available

Ivermectin:

Bioaccumulation : Species: Danio rerio (zebra fish)
Bioconcentration factor (BCF): 63 - 111
Remarks: Bioaccumulation is unlikely.

Partition coefficient: n-octanol/water : log Pow: 3.22 (68 °F / 20 °C)

Mobility in soil

Components:

Glycerol formal:

Distribution among environmental compartments : Remarks: No data available

praziquantel:

Distribution among environmental compartments : Remarks: No data available

Ivermectin:

Distribution among environmental compartments : log Koc: 3.6 - 4.4

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Other adverse effects

Product:

Ozone-Depletion Potential : Regulation: 40 CFR Protection of Environment; Part 82 Protection of Stratospheric Ozone - CAA Section 602 Class I Substances
Remarks: This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A + B).

Components:

praziquantel:

Additional ecological information : No data available

Ivermectin:

Results of PBT and vPvB assessment : Persistent and Toxic

Additional ecological information : No data available

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods

Waste from residues : 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

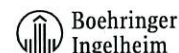
International Regulations

IATA-DGR

UN/ID No. : UN 3082
Proper shipping name : Environmentally hazardous substance, liquid, n.o.s. (Ivermectin)
Class : 9
Packing group : III
Labels : Miscellaneous Dangerous Goods
Packing instruction (cargo aircraft) : 964
Packing instruction (passenger aircraft) : 964
Environmentally hazardous : yes

IMDG-Code

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UN number	:	UN 3082
Proper shipping name	:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Ivermectin)
Class	:	9
Packing group	:	III
Labels	:	9
EmS Code	:	F-A, S-F
Marine pollutant	:	yes

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code
Not applicable for product as supplied.

National Regulations

49 CFR

UN/ID/NA number	:	UN 3082
Proper shipping name	:	Environmentally hazardous substance, liquid, n.o.s. (Ivermectin)
Class	:	9
Packing group	:	III
Labels	:	CLASS 9
ERG Code	:	171
Marine pollutant	:	yes

Special precautions for user

The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

SECTION 15. REGULATORY INFORMATION

CERCLA Reportable Quantity

This material does not contain any components with a CERCLA RQ.

SARA 304 Extremely Hazardous Substances Reportable Quantity

This material does not contain any components with a section 304 EHS RQ.

SARA 302 Extremely Hazardous Substances Threshold Planning Quantity

This material does not contain any components with a section 302 EHS TPQ.

SARA 311/312 Hazards	:	Acute toxicity (any route of exposure) Respiratory or skin sensitisation Reproductive toxicity Specific target organ toxicity (single or repeated exposure) Serious eye damage or eye irritation
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SARA 313	:	This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.
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Clean Air Act

This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A + B).

This product does not contain any hazardous air pollutants (HAP), as defined by the U.S. Clean Air Act Section 112 (40 CFR 61).

This product does not contain any chemicals listed under the U.S. Clean Air Act Section 112(r) for Accidental Release Prevention (40 CFR 68.130, Subpart F).

This product does not contain any chemicals listed under the U.S. Clean Air Act Section 111 SOCM Intermediate or Final VOC's (40 CFR 60.489).

Clean Water Act

This product does not contain any Hazardous Substances listed under the U.S. CleanWater Act, Section 311, Table 116.4A.

This product does not contain any Hazardous Chemicals listed under the U.S. CleanWater Act, Section 311, Table 117.3.

This product does not contain any toxic pollutants listed under the U.S. Clean Water Act Section 307

This product does not contain any priority pollutants related to the U.S. Clean Water Act

US State Regulations

Massachusetts Right To Know

titanium dioxide	13463-67-7
tert-butyl-4-methoxyphenol	25013-16-5

Pennsylvania Right To Know

Glycerol formal	Not Assigned
praziquantel	55268-74-1
Klucel EXF Pharm	9004-64-2
Castor oil, hydrogenated	8001-78-3
titanium dioxide	13463-67-7

Maine Chemicals of High Concern

tert-butyl-4-methoxyphenol	25013-16-5
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Vermont Chemicals of High Concern

tert-butyl-4-methoxyphenol	25013-16-5
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Washington Chemicals of High Concern

tert-butyl-4-methoxyphenol	25013-16-5
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California Prop. 65

WARNING: This product can expose you to chemicals including tert-butyl-4-methoxyphenol, which is/are known to the State of California to cause cancer. For more information go to www.P65Warnings.ca.gov.

California Permissible Exposure Limits for Chemical Contaminants

titanium dioxide	13463-67-7
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The components of this product are reported in the following inventories:

TCSI	: Not in compliance with the inventory
TSCA	: Product contains substance(s) not listed on TSCA inventory.
AIIC	: Not in compliance with the inventory

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

praziquantel

Klucel EXF Pharm

Glycerol formal

ENCS : Not in compliance with the inventory

ISHL : Not in compliance with the inventory

KECI : Not in compliance with the inventory

PICCS : Not in compliance with the inventory

IECSC : Not in compliance with the inventory

NZIoC : Not in compliance with the inventory

TECI : Not in compliance with the inventory

TSCA list

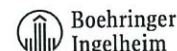
No substances are subject to a Significant New Use Rule.

No substances are subject to TSCA 12(b) export notification requirements.

SECTION 16. OTHER INFORMATION

Further information

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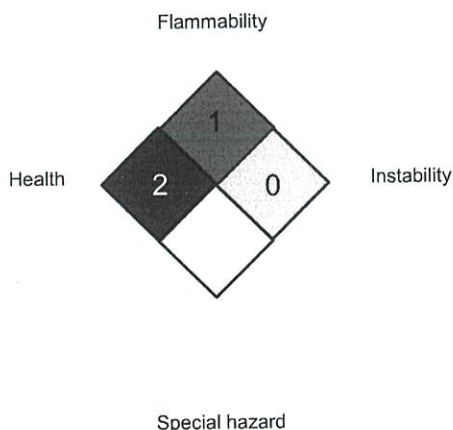
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NFPA 704:



HMIS® IV:

HEALTH	*	4
FLAMMABILITY		1
PHYSICAL HAZARD		0

HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "*" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.

Full text of other abbreviations

ACGIH	:	USA. ACGIH Threshold Limit Values (TLV)
OSHA P0	:	USA. Table Z-1-A Limits for Air Contaminants (1989 vacated values)
OSHA Z-1	:	USA. Occupational Exposure Limits (OSHA) - Table Z-1 Limits for Air Contaminants
ACGIH / TWA	:	8-hour, time-weighted average
OSHA P0 / TWA	:	8-hour time weighted average
OSHA Z-1 / TWA	:	8-hour time weighted average

AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; 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; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; HMIS - Hazardous Materials Identification System; 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 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; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumu-

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lative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; 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

Sources of key data used to compile the Safety Data Sheet : The specifications are based on own tests and/or literature data.

Revision Date : 04/07/2022

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.

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