

SAFETY DATA SHEETS

This SDS packet was issued with item:

078948989

The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).

078948987 078948988 078948990

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



NexGard® Combo, transdermal solution (finished product)

Version	Revision Date:	SDS Number:	Date of last issue: 10.12.2019
1.2	26.05.2020	000000053699	Date of first issue: 28.10.2019

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

1.1 Product identifier

Trade name	:	NexGard® Combo, transdermal solution (finished product)
Synonyms	:	Cat Combo, spot-on solution for cats; PRAZIQUANTEL 8.3% / EPRINOMECTIN 0.4% / ESAFOXOLANER 1.2% TRANSDERMAL SOLUTION with active ingredient: Esafoxolaner, Praziquantel, Eprinomectin

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

Use of the Substance/Mixture	:	Pharmaceutical
Recommended restrictions on use	:	Safety Data Sheet only for the professional user.

1.3 Details of the supplier of the safety data sheet

Company	:	Boehringer Ing. Pharma GmbH & Co.KG Binger Straße 173 55216 Ingelheim Germany
Telephone	:	+498007790900
E-mail address of person responsible for the SDS	:	EHS-Services@Boehringer-Ingelheim.com

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)

Serious eye damage , Category 1	H318: Causes serious eye damage.
Reproductive toxicity , Category 2	H361fd: Suspected of damaging fertility. Suspected of damaging the unborn child.
Effects on or via lactation	H362: May cause harm to breast-fed children.
Short-term (acute) aquatic hazard , Category 1	H400: Very toxic to aquatic life.

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Long-term (chronic) aquatic hazard , Category 1

H410: Very toxic to aquatic life with long lasting effects.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

Hazard pictograms :



Signal word :

Danger

Hazard statements :

H318 Causes serious eye damage.
H361fd Suspected of damaging fertility. Suspected of damaging the unborn child.
H362 May cause harm to breast-fed children.
H410 Very toxic to aquatic life with long lasting effects.

Precautionary statements :

Prevention:

P201 Obtain special instructions before use.
P263 Avoid contact during pregnancy and while nursing.
P273 Avoid release to the environment.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response:

P305 + P351 + P338 + P310 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER/ doctor.
P391 Collect spillage.

Hazardous components which must be listed on the label:

Glycerol formal
Eprinomectin

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.

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).

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Chemical nature : organic

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Components

Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
Glycerol formal	Not Assigned	Eye Irrit. 2; H319 Repr. 2; H361fd	$\geq 20 - < 30$
Praziquantel	55268-74-1 259-559-6	Aquatic Chronic 3; H412	$\geq 2,5 - < 10$
Eprinomectin	123997-26-2	Acute Tox. 3; H301 Repr. 2; H361 Lact.H362 STOT RE 1; H372 Aquatic Acute 1; H400 Aquatic Chronic 1; H410 M-Factor (Acute aquatic toxicity): 1.000 M-Factor (Chronic aquatic toxicity): 1.000	$\geq 0,3 - < 1$

For explanation of abbreviations see section 16.

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 advice 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 : Causes serious eye damage.

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

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-fighting : In case of fire and/or explosion do not breathe fumes.
Can be released in case of fire:
Carbon oxides
Nitrogen oxides (NO_x)

5.3 Advice for firefighters

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

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

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

6.2 Environmental precautions

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

6.3 Methods and material for containment and cleaning up

Methods for cleaning up : Pick up and transfer to properly labelled containers.

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6.4 Reference to other sections

For personal protection see section 8., For disposal considerations see section 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

- Advice on safe handling : Provide sufficient air exchange and/or exhaust in work rooms.
- Advice on protection against fire and explosion : No special protective measures against fire required. The product is not flammable.
- Hygiene measures : General industrial hygiene practice. Wash hands and face before breaks and immediately after handling the product. Keep working clothes separately.

7.2 Conditions for safe storage, including any incompatibilities

- Requirements for storage areas and containers : No special storage conditions required.
- Advice on common storage : Keep away from food, drink and animal feedingstuffs. Observe joint storage prohibition.
- Storage class (TRGS 510) : 10, Combustible liquids not in Storage Class 3

7.3 Specific end use(s)

- Specific use(s) : Consult the technical guidelines for the use of this substance/mixture.

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational Exposure Limits

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
Praziquantel	55268-74-1	OEL-8h	0,850 mg/m ³	Sanofi OEL

Contains no substances with occupational exposure limit values.

Components	Basis	Category	Values	Remark
Eprinomectin 123997-26-2	BIEL	3A	10 µg/m ³	
	BIPC	1b		

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Abbreviations:

BIEL = Boehringer Ingelheim Exposure Limit (internal value)
BI-STEL = Boehringer Ingelheim Short-Term Exposure Limit (Excursion limit)
BIPC = Boehringer Ingelheim Pregnancy Category
BIPC 1b: No risk of harm to the unborn is to be expected, when the exposure does not exceed the BIEL value. There is evidence in animals and/or humans that this material has the potential to cause harm to the unborn at exposure levels exceeding the BIEL value.

Components	Basis	Category	Values	Remark
Esafoxolaner 1096103-99-9	BIEL	3A	80 µg/m ³	
	BIPC	1b		
Abbreviations: BIEL = Boehringer Ingelheim Exposure Limit (internal value) BI-STEL = Boehringer Ingelheim Short-Term Exposure Limit (Excursion limit) BIPC = Boehringer Ingelheim Pregnancy Category BIPC 1b: No risk of harm to the unborn is to be expected, when the exposure does not exceed the BIEL value. There is evidence in animals and/or humans that this material has the potential to cause harm to the unborn at exposure levels exceeding the BIEL value.				

8.2 Exposure controls

Engineering measures

Local exhaust
Emergency sprinkling nozzle

Personal protective equipment

Eye protection : Safety glasses with side-shields

Hand protection

Material : Nitrile rubber
Glove thickness : 0,43 mm
Directive : Protective gloves against chemicals and micro-organisms
Protective index : Class 6

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.

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Skin and body protection	: Laboratory: laboratory coat; Factory: disposable Overall.
Respiratory protection	: No personal respiratory protective equipment normally required. 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 national/international regulations. Follow the national regulations about wearing personal protective equipment and the warranty given by the manufacturer for the safe function.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance	: liquid
Colour	: No data available
Odour	: No data available
Odour Threshold	: No data available
pH	: No data available
Melting point/range	: Not applicable
Boiling point/boiling range	: No data available
Flash point	: No data available
Evaporation rate	: No data available
Flammability (solid, gas)	: Not applicable
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

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Relative density : No data available

Bulk density : Not applicable

Solubility(ies)
Water solubility : No data available

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

Explosive properties : Not tested

Oxidizing properties : No data available

9.2 Other information

Self-ignition : No data available

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

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

10.4 Conditions to avoid

Conditions to avoid : Extremes of temperature and direct sunlight.

10.5 Incompatible materials

Materials to avoid : No data available

10.6 Hazardous decomposition products

No data available

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SECTION 11: Toxicological information

11.1 Information on toxicological effects

Acute toxicity

Not classified based on available information.

Product:

Acute oral toxicity	:	LD50 (Rat): > 2.000 mg/kg Method: OECD Test Guideline 423 GLP: yes
Acute dermal toxicity	:	(Rabbit): Method: OECD Test Guideline 404 GLP: yes Assessment: The substance or mixture has no acute dermal toxicity LD50 (Rat): > 2.000 mg/kg Method: OECD Test Guideline 402 GLP: yes

Components:

Glycerol formal:

Acute oral toxicity	:	LD50 (Rat): > 3.000 mg/kg LD50 (Mouse): 8.000 mg/kg
Acute inhalation toxicity	:	Remarks: No data available
Acute dermal toxicity	:	Assessment: Toxic effects cannot be excluded

Praziquantel:

Acute oral toxicity	:	LD50 (Rat): 2.249 mg/kg
Acute inhalation toxicity	:	Remarks: No data available
Acute dermal toxicity	:	Assessment: Toxic effects cannot be excluded

Eprinomectin:

Acute oral toxicity	:	LD50 (Mouse): 70 mg/kg LD50 (Rat): 55 mg/kg
Acute inhalation toxicity	:	Remarks: No data available
Acute dermal toxicity	:	Remarks: No data available

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Skin corrosion/irritation

Not classified based on available information.

Components:

Glycerol formal:

Remarks : May cause skin irritation.

Praziquantel:

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

Eprinomectin:

Result : No skin irritation

Serious eye damage/eye irritation

Causes serious eye damage.

Product:

Species : Rabbit
Method : OECD Test Guideline 405
Result : Risk of serious damage to eyes.
GLP : yes

Components:

Glycerol formal:

Result : Irritating to eyes.

Praziquantel:

Remarks : No data available

Eprinomectin:

Species : Rabbit
Result : No eye irritation

Respiratory or skin sensitisation

Skin sensitisation

Not classified based on available information.

Respiratory sensitisation

Not classified based on available information.

Components:

Glycerol formal:

Remarks : No data available

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Praziquantel:

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

Remarks	: No data available
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Eprinomectin:

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

Germ cell mutagenicity

Not classified based on available information.

Components:

Glycerol formal:

Genotoxicity in vitro	: Remarks: No data available
Genotoxicity in vivo	: Test Type: Micronucleus test Result: negative

Praziquantel:

Genotoxicity in vitro	: Remarks: No data available
Genotoxicity in vivo	: Remarks: No data available

Eprinomectin:

Genotoxicity in vitro	: Test Type: Ames test Test system: S. typhimurium and E. coli Result: negative Test Type: In vitro mammalian cell gene mutation test Test system: V79 cells (Chinese hamster) Result: negative Test Type: Chromosome aberration test in vitro Test system: Chinese hamster ovary cells Result: negative
Genotoxicity in vivo	: Test Type: Micronucleus test Species: Mouse Result: negative

Carcinogenicity

Not classified based on available information.

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Components:

Glycerol formal:

Remarks : No data available

Praziquantel:

Remarks : No data available

Carcinogenicity - Assessment : Did not show carcinogenic effects in animal experiments.

Eprinomectin:

Remarks : The chemical structure does not suggest such an effect.

Reproductive toxicity

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

Components:

Glycerol formal:

Effects on fertility : Remarks: No data available

Effects on foetal development : Remarks: No data available

Reproductive toxicity - Assessment : Some evidence of adverse effects on development, based on animal experiments.

Some evidence of adverse effects on sexual function and fertility, based on animal experiments.

Praziquantel:

Effects on fertility : Remarks: No data available

Effects on foetal development : Remarks: No data available

Reproductive toxicity - Assessment : Animal testing did not show any effects on fertility.

Eprinomectin:

Effects on fertility : Remarks: No data available

Effects on foetal development : Test Type: Two-generation study
Species: Rat
Application Route: Ingestion
Dose: 0, 1, 2,5-3, 6 mg/kg /day
General Toxicity Maternal: NOEL: 1 mg/kg body weight

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Developmental Toxicity: NOEL: 1 mg/kg body weight
Remarks: Did not show teratogenic effects in animal experiments

Test Type: Embryo-foetal development
Species: Rabbit
Application Route: Oral
Dose: 0,5 to 8 mg/kg/day
General Toxicity Maternal: NOEL: 0,5 mg/kg body weight
Embryo-foetal toxicity: NOAEL: 0,5 mg/kg body weight
Remarks: Did not show teratogenic effects in animal experiments

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 : No data available

Praziquantel:

Remarks : No data available

Eprinomectin:

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

STOT - repeated exposure

Not classified based on available information.

Components:

Glycerol formal:

Remarks : No data available

Praziquantel:

Remarks : No data available

Eprinomectin:

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

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Repeated dose toxicity

Components:

Eprinomectin:

Species	:	Rabbit
NOEL	:	1,5 mg/kg
Application Route	:	Oral
Exposure time	:	28-day
Dose	:	1,5 - 25 mg/kg/day

Species	:	Rat
NOEL	:	5 mg/kg
Application Route	:	Oral
Dose	:	1 - 30 mg/kg/day

Species	:	Rat
NOEL	:	10 mg/kg
Application Route	:	Oral
Exposure time	:	28-day
Dose	:	0,5 - 60 mg/kg/day

Aspiration toxicity

Not classified based on available information.

Components:

Glycerol formal:

No data available

Praziquantel:

No data available

Eprinomectin:

No data available

Further information

Components:

Praziquantel:

Remarks	:	May be harmful by inhalation, ingestion, skin absorption.
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Eprinomectin:

Remarks	:	Neurotoxic effect.
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SECTION 12: Ecological information

12.1 Toxicity

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 microorganisms	:	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

Ecotoxicology Assessment

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

Praziquantel:

Toxicity to fish	:	LC50 (Fish): 13,4 mg/l Exposure time: 24 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 microorganisms	:	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

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Ecotoxicology Assessment

Acute aquatic toxicity : Toxic effects cannot be excluded

Chronic aquatic toxicity : Toxic effects cannot be excluded

Eprinomectin:

Toxicity to fish : LC50 (Lepomis macrochirus (Bluegill sunfish)): 0,37 mg/l
Method: OECD Test Guideline 203

LC50 (Oncorhynchus mykiss (rainbow trout)): 1,2 mg/l
Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 0,00045 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 202
The value is given in analogy to the following substances:
Avermectin A1a, 4''-(acetylamino)-5-O-demethyl-4''-deoxy-, (4''R)-

Toxicity to algae/aquatic plants : EC50 (Pseudokirchneriella subcapitata (algae)): 3,4 mg/l
Method: OECD Test Guideline 201

M-Factor (Acute aquatic toxicity) : 1.000

Toxicity to microorganisms :
Remarks: No data available

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

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC: 0,000028 mg/l
End point: reproduction rate
Species: Daphnia magna (Water flea)
Method: OECD Test Guideline 211

M-Factor (Chronic aquatic toxicity) : 1.000

Toxicity to soil dwelling organisms : NOEC: 19 mg/kg
Species: Eisenia fetida (earthworms)
Method: OECD Test Guideline 222

Sediment toxicity : NOEC: 0,00034 mg/l
Species: Chironomus riparius (Midge larvae)
Method: OECD Test Guideline 218

12.2 Persistence and degradability

Components:

Glycerol formal:

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Biodegradability : Result: Readily biodegradable.

Praziquantel:

Biodegradability : Result: Not readily biodegradable.

Eprinomectin:

Biodegradability : Inoculum: Soil
Result: Persistent substance with a half life of more than 60 days.
Method: OECD Test Guideline 307

Inoculum: Sediment
Result: Persistent substance with a half life of more than 60 days.
Method: OECD Test Guideline 308

12.3 Bioaccumulative potential

Components:

Glycerol formal:

Bioaccumulation : Remarks: No bioaccumulation is to be expected ($\log P(o/w) < 1$).

Partition coefficient: n-octanol/water : $\log Pow: -0,99$

Praziquantel:

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

Partition coefficient: n-octanol/water : $\log Pow: 2,42$

Eprinomectin:

Bioaccumulation : Remarks: An appreciable bioaccumulation potential is to be expected ($\log P(o/w) > 3$).

Species: Fish
Method: OECD Test Guideline 305
Remarks: Does not bioaccumulate.

Partition coefficient: n-octanol/water : $Pow: 5,4$

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12.4 Mobility in soil

Components:

Praziquantel:

Distribution among environmental compartments : Remarks: No data available

Eprinomectin:

Distribution among environmental compartments	:	Medium: Soil
		Koc: 1000
		Kd: 15,7
		Method: Adsorption/Desorption
		Medium: Soil
		Koc: 9208
		Kd: 133,5
		Method: Adsorption/Desorption

12.5 Results of PBT and vPvB assessment

Product:

Assessment : 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..

Components:

Eprinomectin:

Assessment	:	Persistent and Toxic.
	:	This substance/mixture contains components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB)..

12.6 Other adverse effects

Components:

Glycerol formal:

Additional ecological information : No data available

Praziquantel:

Additional ecological information : No data available

Eprinomectin:

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Additional ecological information : No data available

SECTION 13: Disposal considerations

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

ADR	: UN 3082
RID	: UN 3082
IMDG	: UN 3082
IATA	: UN 3082

14.2 UN proper shipping name

ADR	: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Eprinomectin)
RID	: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Eprinomectin)
IMDG	: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Eprinomectin)
IATA	: Environmentally hazardous substance, liquid, n.o.s. (Eprinomectin)

14.3 Transport hazard class(es)

ADR	: 9
RID	: 9
IMDG	: 9
IATA	: 9

14.4 Packing group

ADR	
Packing group	: III
Classification Code	: M6

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Hazard Identification Number : 90
Labels : 9
Tunnel restriction code : (-)

RID

Packing group : III
Classification Code : M6
Hazard Identification Number : 90
Labels : 9

IMDG

Packing group : III
Labels : 9
EmS Code : F-A, S-F

IATA (Cargo)

Packing instruction (cargo aircraft) : 964
Packing instruction (LQ) : Y964
Packing group : III
Labels : Miscellaneous

IATA (Passenger)

Packing instruction (passenger aircraft) : 964
Packing instruction (LQ) : Y964
Packing group : III
Labels : Miscellaneous

14.5 Environmental hazards

ADR

Environmentally hazardous : yes

RID

Environmentally hazardous : yes

IMDG

Marine pollutant : yes

IATA (Passenger)

Environmentally hazardous : yes

IATA (Cargo)

Environmentally hazardous : yes

14.6 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.

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

Not applicable for product as supplied.

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SECTION 15: Regulatory information

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

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles (Annex XVII)	:	Conditions of restriction for the following entries should be considered: Number on list 3
REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59).	:	Not applicable
REACH - List of substances subject to authorisation (Annex XIV)	:	Not applicable
Regulation (EC) No 1005/2009 on substances that deplete the ozone layer	:	Not applicable
Regulation (EU) 2019/1021 on persistent organic pollutants (recast)	:	Not applicable
Regulation (EC) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals	:	Eprinomectin

Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances.
Not applicable

E1 ENVIRONMENTAL HAZARDS

Water contaminating class (Germany)	:	WGK 3 highly hazardous to water Classification according to AwSV, Annex 1 (5.2)
TA Luft List (Germany)	:	Total dust: Not applicable Inorganic substances in powdered form: Not applicable Inorganic substances in vapour or gaseous form: Not applicable Organic Substances: portion Class 1: 0,08 % Carcinogenic substances: Not applicable Mutagenic: Not applicable Toxic to reproduction: Not applicable

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Volatile organic compounds : Directive 2010/75/EU of 24 November 2010 on industrial emissions (integrated pollution prevention and control)
Not applicable

Other regulations:

Take note of Law on the protection of mothers at work, in education and in studies (Maternity Protection Act - MuSchG).

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

REACH	: Not in compliance with the inventory
DSL	: This product contains the following components that are not on the Canadian DSL nor NDSL. Esafoxolaner Eprinomectin Praziquantel 1,4:3,6-dianhydro-2,5-di-O-methyl-D-glucitol Glycerol formal
AICS	: Not in compliance with the inventory
NZIoC	: Not in compliance with the inventory
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
TCSI	: Not in compliance with the inventory
TSCA	: Substance(s) not listed on TSCA inventory

15.2 Chemical safety assessment

A Chemical Safety Assessment is not required for this substance when it is used in the specified applications.

SECTION 16: Other information

Full text of H-Statements

H301	: Toxic if swallowed.
H319	: Causes serious eye irritation.
H361	: Suspected of damaging fertility or the unborn child.

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H361fd	:	Suspected of damaging fertility. Suspected of damaging the unborn child.
H362	:	May cause harm to breast-fed children.
H372	:	Causes damage to organs through prolonged or repeated exposure if swallowed.
H400	:	Very toxic to aquatic life.
H410	:	Very toxic to aquatic life with long lasting effects.
H412	:	Harmful to aquatic life with long lasting effects.

Full text of other abbreviations

Acute Tox.	:	Acute toxicity
Aquatic Acute	:	Short-term (acute) aquatic hazard
Aquatic Chronic	:	Long-term (chronic) aquatic hazard
Eye Irrit.	:	Eye irritation
Lact.	:	Effects on or via lactation
Repr.	:	Reproductive toxicity
STOT RE	:	Specific target organ toxicity - repeated exposure
Sanofi OEL	:	Sanofi
Sanofi OEL / OEL-8h	:	Occupational exposure limit value (8h)

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 to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of Very High Concern; TCSI - Taiwan Chemical Substance Inventory; TRGS - Technical Rule for Hazardous Substances; TSCA - Toxic Substances Control Act (United States); UN - United Nations; vPvB - Very Persistent and Very Bioaccumulative

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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 mixture:

Eye Dam. 1	H318
Repr. 2	H361fd
Lact.	H362
Aquatic Acute 1	H400
Aquatic Chronic 1	H410

Classification procedure:

Based on product data or assessment
Calculation method
Calculation method
Calculation method
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.

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