

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

1.1. Product identifier

Trade name or designation of the mixture	Trifexis
Registration number	-
Synonyms	None.
Item Code	CA4337, CA4339, CA4341, CA4342, CA4344, CA4332, CA4333, CA4334, CA4335, CA4336

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

Identified uses	Veterinary Pharmaceutical
Uses advised against	None known.

1.3. Details of the supplier of the safety data sheet

National Supplier

Company name	Elanco GmbH
Address	Heinz-Lohmann-Str. 4 27472 Cuxhaven Germany

Telephone +49 (0) 4721 747 0

E-mail elanco_sds@elanco.com

1.4 Emergency telephone number CHEMTREC International +1-703-527-3887

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No 1272/2008 as amended

Environmental hazards

Hazardous to the aquatic environment, acute aquatic hazard	Category 1	H400 - Very toxic to aquatic life.
Hazardous to the aquatic environment, long-term aquatic hazard	Category 1	H410 - Very toxic to aquatic life with long lasting effects.

2.2. Label elements

Label according to Regulation (EC) No. 1272/2008 as amended

Contains: Milbemycin A3 5-oxime, Milbemycin A4 5-oxime, Spinosad

Hazard pictograms



Signal word Warning

Hazard statements

H410 Very toxic to aquatic life with long lasting effects.

Precautionary statements

Prevention

P273 Avoid release to the environment.

Response

P391 Collect spillage.

Storage

Not available.

Disposal

P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

Supplemental label information None.

2.3. Other hazards None known.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

General information

Chemical name	%	CAS-No. / EC No.	REACH Registration No.	Index No.	Notes
Spinosad	59	168316-95-8 434-300-1	-	603-209-00-0	
Classification:	Aquatic Acute 1;H400(M=10), Aquatic Chronic 1;H410(M=10)				
Milbemycin A4 5-oxime	0,7	93074-04-5	-	-	
Classification:	Acute Tox. 4;H302, Acute Tox. 4;H332, Aquatic Acute 1;H400(M=10), Aquatic Chronic 1;H410				
Milbemycin A3 5-oxime	0,2	114177-14-9	-	-	
Classification:	Acute Tox. 4;H302, Acute Tox. 4;H332, Aquatic Acute 1;H400(M=10), Aquatic Chronic 1;H410				

Composition comments	Remaining components of this product are non-hazardous and/or are present at concentrations below reportable levels. Spinosad is a mixture of the following components: Spinosyn A (CAS# 131929-63-0) and Spinosyn D (CAS# 131920-60-7). The full text for all H-statements is displayed in section 16.
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SECTION 4: First aid measures

General information Not available.

4.1. Description of first aid measures

Inhalation	If crushed and exposure to content occurs: Move to fresh air. Oxygen or artificial respiration if needed. Consult a physician for specific advice.
Skin contact	Immediately flush skin with plenty of water. Remove contaminated clothing and shoes. Get medical attention if irritation develops and persists. Wash contaminated clothing before reuse.
Eye contact	If crushed and exposure to content occurs: Immediately flush with plenty of water for at least 15 minutes. If easy to do, remove contact lenses. Get medical attention.
Ingestion	Give several glasses of water. Never give anything by mouth to a victim who is unconscious or is having convulsions. Call a physician or poison control centre immediately.

4.2. Most important symptoms and effects, both acute and delayed None known.

4.3. Indication of any immediate medical attention and special treatment needed Not available.

SECTION 5: Firefighting measures

General fire hazards Dust may form explosive mixture with air.

5.1. Extinguishing media

Suitable extinguishing media	Water. Carbon dioxide (CO2). Dry chemical.
Unsuitable extinguishing media	None known.

5.2. Special hazards arising from the substance or mixture Fire or excessive heat may produce hazardous decomposition products.

5.3. Advice for firefighters

Special protective equipment for firefighters	Wear self-contained breathing apparatus and protective clothing.
Special fire fighting procedures	Not available.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

For non-emergency personnel	Wear suitable protective clothing, gloves and eye/face protection. Avoid inhalation of dust. See Section 8 for personal protective equipment.
For emergency responders	Not available.

6.2. Environmental precautions	Prevent further leakage or spillage if safe to do so. Prevent spilled material from flowing onto adjacent land or into streams, ponds, or lakes.
6.3. Methods and material for containment and cleaning up	Vacuum material with appropriate dust collection filter in place. If vacuum is not available, lightly mist/wet material and remove by mopping or wet wiping. Be aware of potential for dust explosion when using electrical equipment. Large spills due to traffic accidents, etc., should be reported immediately to CHEMTREC and Elanco Animal Health for assistance.
6.4. Reference to other sections	Refer to Sections 8, 11, 12 and 13 for more information.

SECTION 7: Handling and storage

7.1. Precautions for safe handling	NOT INTENDED FOR HUMAN USE. Avoid contact with eyes, skin, and clothing. Use only with adequate ventilation. Wear personal protective equipment. Wash hands thoroughly after handling.
7.2. Conditions for safe storage, including any incompatibilities	Storage temperature: between 20 and 25 C (68 to 77 F). Excursions permitted from 15 to 30 C (59 to 86 F).
7.3. Specific end use(s)	Not available.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters	
Occupational exposure limits	No exposure limits noted for ingredient(s).
Biological limit values	No biological exposure limits noted for the ingredient(s).
Recommended monitoring procedures	Supplier: TWA 0.3 mg/m ³ (Spinosad) A Lilly exposure guideline has not been established. The above exposure guideline has been established by the supplier.
Derived no effect levels (DNELs)	Not available.
Predicted no effect concentrations (PNECs)	Not available.
8.2. Exposure controls	
Appropriate engineering controls	Laboratory fume hood or local exhaust ventilation.
Individual protection measures, such as personal protective equipment	
General information	Not available.
Eye/face protection	Safety glasses with side-shields conforming to EN 166.
Skin protection	
- Hand protection	Protective gloves complying with EN 374.
- Other	Chemical-resistant gloves and impermeable body covering to minimize skin contact.
Respiratory protection	Respirator selection must be based on known or anticipated exposure levels, the hazards of the product and the safe working limits of the respirator. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).
Thermal hazards	Not available.
Hygiene measures	In a manufacturing setting, wear chemical-resistant gloves and body covering to minimize skin contact. If handled in a ventilated enclosure, as in a laboratory setting, respirator and goggles or face shield may not be required. Safety glasses are always required. Under normal use and handling conditions, wear goggles to protect eyes and wear impermeable gloves and protective equipment to avoid direct contact with skin. Wash thoroughly with soap and water after handling.
Environmental exposure controls	Not available.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance

Physical state	Solid.
Form	Tablet.
Colour	Tan
Odour	Musty
Odour threshold	Not available.
pH	Not available.
Melting point/freezing point	Not available.

Material name: Trifexis

Version #: 05 Revision date: 29-March-2019 Issue date: 28-September-2012 Supersedes date: 03-November-2016

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Initial boiling point and boiling range	Not available.
Flash point	Not available.
Evaporation rate	Not available.
Flammability (solid, gas)	No test data available.
Upper/lower flammability or explosive limits	
Flammability limit - lower (%)	Not available.
Flammability limit - upper (%)	Not available.
Vapour pressure	Not available.
Vapour density	Not available.
Relative density	Not available.
Solubility(ies)	
Solubility (water)	Not available.
Partition coefficient (n-octanol/water)	Not available.
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.
Explosive properties	Not explosive.
Oxidising properties	The substance or mixture is not classified as oxidizing.
9.2. Other information	No relevant additional information available.

SECTION 10: Stability and reactivity

10.1. Reactivity	Not water reactive.
10.2. Chemical stability	Material is stable under normal conditions.
10.3. Possibility of hazardous reactions	Hazardous polymerisation does not occur.
10.4. Conditions to avoid	None known.
10.5. Incompatible materials	Strong oxidising agents.
10.6. Hazardous decomposition products	Fire or excessive heat may produce hazardous decomposition products.

SECTION 11: Toxicological information

General information Not available.

11.1. Information on toxicological effects

Acute toxicity Based on available data, the classification criteria are not met.

Components	Species	Test Results
Spinosad (CAS 168316-95-8)		
Acute		
Dermal		
LD	Rabbit	> 5000 mg/kg
Inhalation		
LC50	Rat	> 5180 mg/m ³ , 4 hours
Oral		
LD50	Rat	> 2000 mg/kg
Skin corrosion/irritation	Rabbit: No irritation. (Spinosad) Based on available data, the classification criteria are not met.	
Serious eye damage/eye irritation	Rabbit: Slight irritation. (Spinosad) Based on available data, the classification criteria are not met.	
Respiratory sensitisation	Due to lack of data the classification is not possible.	
Skin sensitisation	Guinea pig: Not a skin sensitizer. (Spinosad) Based on available data, the classification criteria are not met.	
Germ cell mutagenicity	Result in genetic toxicity assays (in vitro and in vivo): Negative (Spinosad) Based on available data, the classification criteria are not met.	

Carcinogenicity	Animal testing did not show any carcinogenic effects. (Spinosad) Based on available data, the classification criteria are not met.
Hungary. 26/2000 EüM Ordinance on protection against and preventing risk relating to exposure to carcinogens at work (as amended)	
Not listed.	
Reproductive toxicity	In laboratory animal studies, effects on reproduction have been seen only at doses that produced significant toxicity to the parent animals. (Spinosad) Based on available data, the classification criteria are not met.
Specific target organ toxicity - single exposure	Due to lack of data the classification is not possible.
Specific target organ toxicity - repeated exposure	In animals, has been shown to cause vacuolation of cells in liver, kidney, and bone tissues and changes in blood and serum biochemistry. Dose levels producing these effects were many times higher than any dose levels expected from exposure due to use. (Spinosad) Based on available data, the classification criteria are not met.
Aspiration hazard	No aspiration toxicity classification (spinosad)
Mixture versus substance information	Not available.
Other information	Not available.

SECTION 12: Ecological information

12.1. Toxicity Very toxic to aquatic life with long lasting effects.

Components	Species	Test Results	
Milbemycin A3 5-oxime (CAS 114177-14-9)			
Aquatic			
<i>Acute</i>			
Fish	LC50	Carp (Cyprinus carpio)	0,059 mg/l, 48 hours
Spinosad (CAS 168316-95-8)			
	ErC50	Navicula pelliculosa	0,079 mg/l, 120 h (static)
	NOEC	Navicula pelliculosa	0,036 mg/l
Aquatic			
Algae	NOEC	Duckweed (Lemna minor)	1,4 mg/l
Crustacea	EC50	Daphnia	7,37 mg/l, 48 h
		Water flea (Daphnia magna)	> 1 mg/l, 48 h (static)
	NOEC	Water flea (Daphnia magna)	0,0012 mg/l, 21 days (flow through)
Fish	LC50	Carp (Cyprinus carpio)	4,5 mg/l, 96 h (flow through)
	NOEC	Oncorhynchus mykiss	0,5 mg/l Early life-stage (flow through)

12.2. Persistence and degradability No data is available on the degradability of this product.

12.3. Bioaccumulative potential No data available for this product.

Partition coefficient n-octanol/water (log Kow) Not available.

Bioconcentration factor (BCF)
Spinosad < 500

12.4. Mobility in soil No data available.

12.5. Results of PBT and vPvB assessment No Chemical Safety Assessment has been carried out.

12.6. Other adverse effects Not available.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Disposal methods/information Dispose of contents/container in accordance with local/regional/national/international regulations. Do not allow this material to drain into sewers/water supplies.

SECTION 14: Transport information

General information Effective January 1, 2015 by Special Provision, UN3077 and UN3082 when packaged in inner packages of 5L / 5 KG or less are not subject to the dangerous goods regulations.

ADR

14.1. UN number UN3077

14.2. UN proper shipping name Environmentally hazardous substance, solid, n.o.s. (SPINOSAD, MILBEMYCIN OXIME)

14.3. Transport hazard class(es)

Class 9

Subsidiary risk -

Label(s) 9

Hazard No. (ADR) 90

Tunnel restriction code Not available.

14.4. Packing group III

14.5. Environmental hazards Yes

14.6. Special precautions for user Not available.

RID

14.1. UN number UN3077

14.2. UN proper shipping name Environmentally hazardous substance, solid, n.o.s. (SPINOSAD, MILBEMYCIN OXIME)

14.3. Transport hazard class(es)

Class 9

Subsidiary risk -

Label(s) 9

14.4. Packing group III

14.5. Environmental hazards Yes

14.6. Special precautions for user Not available.

ADN

14.1. UN number UN3077

14.2. UN proper shipping name Environmentally Hazardous Solid, N.o.s. (Spinoad, Milbemycin Oxime)

14.3. Transport hazard class(es)

Class 9

Subsidiary risk -

Label(s) 9

14.4. Packing group III

14.5. Environmental hazards Yes

14.6. Special precautions for user Not available.

IATA

14.1. UN number UN3077

14.2. UN proper shipping name Environmentally hazardous substance, solid, n.o.s. (Spinoad, Milbemycin Oxime)

14.3. Transport hazard class(es)

Class 9

Subsidiary risk -

14.4. Packing group III

14.5. Environmental hazards Yes

ERG Code 9L

14.6. Special precautions for user Not available.

Other information

Passenger and cargo aircraft Allowed with restrictions.

Cargo aircraft only Allowed with restrictions.

IMDG

14.1. UN number UN3077

14.2. UN proper shipping name ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (SPINOSAD, MILBEMYCIN OXIME)

14.3. Transport hazard class(es)

Class 9

Subsidiary risk -

14.4. Packing group III

14.5. Environmental hazards

Marine pollutant Yes

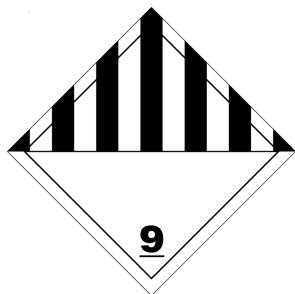
EmS F-A, S-F

14.6. Special precautions for user Not available.

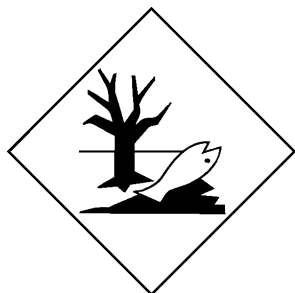
14.7. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not available.

ADN; ADR; IATA; IMDG; RID



Marine pollutant



SECTION 15: Regulatory information

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

EU regulations

Regulation (EC) No. 1005/2009 on substances that deplete the ozone layer, Annex I and II, as amended

Not listed.

Regulation (EC) No. 850/2004 On persistent organic pollutants, Annex I as amended

Not listed.

Regulation (EU) No. 649/2012 concerning the export and import of dangerous chemicals, Annex I, Part 1 as amended

Not listed.

Regulation (EU) No. 649/2012 concerning the export and import of dangerous chemicals, Annex I, Part 2 as amended

Not listed.

Regulation (EU) No. 649/2012 concerning the export and import of dangerous chemicals, Annex I, Part 3 as amended

Not listed.

Regulation (EU) No. 649/2012 concerning the export and import of dangerous chemicals, Annex V as amended

Not listed.

Regulation (EC) No. 1907/2006, REACH Article 59(10) Candidate List as currently published by ECHA

Not listed.

Authorisations

Regulation (EC) No. 1907/2006, REACH Annex XIV Substances subject to authorization, as amended

Not listed.

Restrictions on use

Regulation (EC) No. 1907/2006, REACH Annex XVII Substances subject to restriction on marketing and use as amended

Not listed.

Other EU regulations

Directive 2012/18/EU on major accident hazards involving dangerous substances, as amended

Spinosad (CAS 168316-95-8)

Other regulations

The product is classified and labelled in accordance with Regulation (EC) 1272/2008 (CLP Regulation) as amended and respective national laws implementing EC directives.

National regulations

Not available.

15.2. Chemical safety assessment

Chemical Safety Assessment is not required for this substance.

SECTION 16: Other information

List of abbreviations

TWA: Time Weighted Average

References	Not available.
Information on evaluation method leading to the classification of mixture	Not available.
Full text of any H-statements not written out in full under Sections 2 to 15	H302 Harmful if swallowed. H332 Harmful if inhaled. H400 Very toxic to aquatic life. H410 Very toxic to aquatic life with long lasting effects.
Revision information	Product and Company Identification: Product and Company Identification SECTION 2: Hazards identification: Supplemental label information SECTION 4: First aid measures: 4,2. Most important symptoms and effects, both acute and delayed Physical & Chemical Properties: Multiple Properties SECTION 9: Physical and chemical properties: Explosive properties SECTION 11: Toxicological information: Corrosivity SECTION 12: Ecological information: 12,5. Results of PBT and vPvB assessment SECTION 16: Other information: Disclaimer SECTION 16: Other information: List of abbreviations
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