SAFETY DATA SHEETS

This SDS packet was issued with item:

078582753

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

078582712 078582720 078582738 078582746 078905626 078926168 078926169 078926170 078926171 078926172 078926173

Comfortis Chewable Tablets

Version 2.1 | Revision Date 11/24/2009 | Print Date 03/02/2010

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name	:	Comfortis Chewable Tablets
Substance Number	:	000004278221
Common Name	:	Comfortis Chewable Tablets

Company	:	Elanco Animal Health Division of Eli Lilly and Company Lilly Corporate Center Indianapolis, IN 46285
Telephone	:	1-888-767-5023
Emergency telephone	:	CHEMTREC: 1-800-424-9300 (Outside U.S. 1-703-527-3887)

Item Code	:	CA4223, CA4224, CA4225, CA4227, CA4222, CA4229, CA4230, CA4231

SECTION 2. HAZARDS IDENTIFICATION

Emergency Overview

Lilly Lab Labeling Code
Health: 1
Fire: 1
Reactivity: 0



Primary Hazards: Not hazardous if intact, Liver, Kidney, Bone Marrow

Hazard Summary (Caution): Effects of exposure to contents: May cause liver effects. May cause kidney effects. May cause bone marrow effects.

Emergency Overview

Form	:	tablet
Colour	:	tan to brown
Odour	:	Roast beef and liver

Potential Health Effects

Eyes	:	Effects of exposure to contents: May cause mild or transient irritation.
Aggravated Medical Condition	:	None known.

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Primary Routes of Entry : Skin contact

Additional Information : This product is intended for animal consumption under guidance of a veterinarian. Exposure to small amounts during normal handling is not likely to cause harmful effects. Animal studies have reported the following effects: Liver effects. Kidney effects. Bone marrow changes. (spinosad)

Carcinogenicity

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.

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 identified as a carcinogen or potential carcinogen by OSHA.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name	CAS-No.	Concentration [%]
Spinosad	168316-95-8	57 - 60
Spinosyn A	131929-60-7	
Spinosyn D	131929-63-0	
Excipients	NA	40 - 43

NA = Not applicable, Not assigned, or Not available.

SECTION 4. FIRST AID MEASURES

General advice : Intact capsules or tablets are not considered hazardous under normal handling procedures.

Inhalation : If crushed and exposure to content occurs: Remove to fresh air. Consult a physician after significant exposure.

Skin contact : Wash off with soap and water. Get medical attention if irritation develops and persists.

Eye contact : If crushed and exposure to content occurs: Immediately flush eye(s) with plenty of water. Obtain medical attention.

Ingestion : If conscious, give the victim plenty of water to drink. Never give anything by mouth to an unconscious person. Call a physician immediately.

SECTION 5. FIRE-FIGHTING MEASURES

Flash point : not applicable

Lower explosion limit : no data available

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Upper explosion limit : no data available

Suitable extinguishing media	:	Water Carbon dioxide (CO2) Dry chemical
Unusual Fire and Explosion Hazard.	:	Hazardous decomposition products formed under fire conditions.
Special protective equipment for fire-fighters	:	Wear self-contained breathing apparatus and protective clothing to prevent contact with skin and eyes.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Methods for cleaning up	:	Clean up promptly by sweeping or vacuum. The following are recommended for manufacturing or other situations where exposure to contents may occur. Wear protective equipment, including eye protection, to avoid exposure (see Section 8 for specific handling precautions).

SECTION 7. HANDLING AND STORAGE

Handling

Advice on safe handling	:	NOT FOR HUMAN USE! Keep out of the reach of children.

Storage

Requirements for storage areas and containers	:	Store at 20 to 25 C (68 to 77 F). Excursions permitted from 15 to 30 C (59 to 86 F).

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Exposure guidelines

Components	Exposure Limit Values
Spinosad	**Supplier:** TWA 0.3 mg/m3

The following are recommended for manufacturing or other situations where exposure to contents may occur.

Personal protective equipment

Respiratory protection	:	Use an approved respirator.
Eye protection	:	Safety glasses
Skin and body protection	:	Chemical-resistant gloves and impermeable body covering to minimize skin contact. If

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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.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance

Form	: tablet	Colour	: tan to brown
Physical state	: solid	Odour	: Roast beef and liver

Safety data

Flash point	: not applicable	Upper explosion limit	: no data available
Lower explosion limit	: no data available	Water solubility	: no data available

SECTION 10. STABILITY AND REACTIVITY

Materials to avoid	:	Strong oxidizing agents
Hazardous decomposition products	:	Hazardous decomposition products formed under fire conditions.
Thermal decomposition	:	Stable under normal conditions.
Hazardous reactions	:	Hazardous polymerisation does not occur.

SECTION 11. TOXICOLOGICAL INFORMATION

Acute oral toxicity

- Spinosad: LD50 (male rat) 4,444 mg/kg
  LD50 (female rat) > 5,000 mg/kg
  LDLo (dog) > 400 mg/kg

Acute inhalation toxicity

- Spinosad: LC50 (rat) > 5,180 mg/m3 (4 h)

Acute dermal toxicity

- Spinosad: LD50 (rabbit) > 5,000 mg/kg

Skin irritation

- Spinosad: rabbit, No irritation

Eye irritation

- Spinosad: rabbit, slight irritation

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Sensitisation
- Spinosad: guinea pig, Did not cause sensitization on laboratory animals.

Repeated dose toxicity
- Spinosad: 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.

Carcinogenicity
- Spinosad: Animal testing did not show any carcinogenic effects.

Reproductive toxicity
- Spinosad: In laboratory animal studies, effects on reproduction have been seen only at doses that produced significant toxicity to the parent animals.

Mutagenicity
- Spinosad: Result in genetic toxicity assays (in vitro and in vivo): Negative.

SECTION 12. ECOLOGICAL INFORMATION

Toxicity to fish
- Spinosad: LC50 / 96 h / Lepomis macrochirus: 5.94 mg/l
  LC50 / 96 h / Oncorhynchus mykiss: 30 mg/l

Toxicity to algae
- Spinosad: EC50 / Pseudokirchneriella subcapitata: >105.5 ppm
  EC50 / Navicula sp.: 0.107 mg/l

Toxicity to daphnia
- Spinosad: EC50 / 48 h/ Daphnia magna : 92.7 mg/l

SECTION 13. DISPOSAL CONSIDERATIONS

Waste disposal methods : In accordance with local and national regulations.

SECTION 14. TRANSPORT INFORMATION

IMDG	UN Number	:	3077
	Description of the goods	:	Environmentally hazardous substance, solid, n.o.s. (Spinosad)
	Class	:	9
	Packaging group	:	III
	Labels	:	9
	Marine pollutant	:	yes

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Other information : Not dangerous goods in the meaning of DOT.

SECTION 15. REGULATORY INFORMATION

TSCA Status: Not On TSCA Inventory

131929-60-7	Spinosyn A
131929-63-0	Spinosyn D

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

131929-60-7	Spinosyn A
131929-63-0	Spinosyn D
	Excipients
168316-95-8	Spinosad

California Prop. 65
This product does not contain any chemicals known to the State of California to cause cancer, birth, or any other reproductive defects.

US. EPA Emergency Planning and Community Right-To-Know Act (EPCRA) SARA Title III Section 313 Toxic Chemicals (40 CFR 372.65) - Supplier Notification Required
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.

US. EPA Emergency Planning and Community Right-To-Know Act (EPCRA) SARA Title III Section 302 Extremely Hazardous Substance (40 CFR 355, Appendix A)
SARA 302: No chemicals in this material are subject to the reporting requirements of SARA Title III, Section 302.

SECTION 16. OTHER INFORMATION

Further information

As of the date of issuance, we are providing available information relevant to the handling of this material in the workplace. All information contained herein is offered with the good faith belief that it is accurate. THIS MATERIAL SAFETY DATA SHEET SHALL NOT BE DEEMED TO CREATE ANY WARRANTY OF ANY KIND (INCLUDING WARRANTY OF MERCHANT ABILITY OR FITNESS FOR A PARTICULAR PURPOSE). In the event of an adverse incident associated with this material, this safety data sheet is not intended to be a substitute for consultation with appropriately trained personnel. Nor is this safety data sheet intended to be a substitute for product literature which may accompany the finished product.
For additional information contact:
Elanco Companion Animal Health
1-888-545-5973

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