

SAFETY DATA SHEETS

This SDS packet was issued with item:

078582746

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 078582753 078905626 078926168 078926169 078926170 078926171 078926172

078926173

Comfortis Chewable Tablets

Version 1.2

Revision Date 10/07/2007

Print Date 10/07/2007

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

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

Company : Lilly Companion Animal Health
2001 West Main St
Greenfield, IN 46140

Telephone : 1-888-767-5023
Emergency telephone number : CHEMTREC: 1-800-424-9300 (Outside U.S. 1-703-527-3887)

Item Code : CA4223, CA4224, CA4225, CA4227, CA4222

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.

Primary Routes of Entry : Skin contact

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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 Upper explosion limit : no data available

Lower explosion limit : no data available

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- Suitable extinguishing media : Water Carbon dioxide (CO₂). Dry chemical. Halons.
- 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 room temperature. 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/m ³

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 handled in a ventilated enclosure, as in a laboratory setting, respirator and goggles or

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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) > 7,500 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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Sensitization

- 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.

Toxicity to reproduction

- 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**Ecotoxicity effects****Toxicity to fish**

- Spinosad LC50 / 96 h / Bluegill sunfish: 5.94 mg/l
LC50 / 96 h / Oncorhynchus mykiss (rainbow trout): 30 mg/l

Toxicity to algae

- Spinosad EC50 / Selenastrum capricornutum: >105.5 ppm
EC50 / Navicula sp.: 0.107 mg/l

Toxicity to daphnia

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

Elimination information (persistence and degradability)**SECTION 13. DISPOSAL CONSIDERATIONS**

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

SECTION 14. TRANSPORT INFORMATION

Other information : Not dangerous goods in the meaning of DOT, IMO/IMDG, ICAO/IATA



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SECTION 15. REGULATORY INFORMATION

TSCA Status: Not On TSCA Inventory

131929-60-7 Spinosyn A

131929-63-0 Spinosyn D

California Prop. 65

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

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:

Lilly Companion Animal Health

1-888-545-5973