

## **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



# SAFETY DATA SHEET

## 1. Identification

**Product identifier** Comfortis Tablets

**Other means of identification**  
**Item Code** CA4226, CA4228, CA4221, CA4231, CA4230, CA4229, CA4222, CA4227, CA4225, CA4224, CA4223

**Recommended use** Veterinary Pharmaceutical

**Recommended restrictions** None known.

**Manufacturer/Importer/Supplier/Distributor information**  
**Company Name** Elanco Animal Health  
2500 Innovation Way  
Greenfield, IN 46140  
US

**Phone:** 1-877-Elanco1 (1-877-352-6261)

**Emergency Telephone:** Elanco Product Technical Support / Human or Animal Exposure Reporting:  
1-888-545-5973

**Email:** elanco\_sds@elanco.com

**Transportation Emergency Telephone:** CHEMTREC: 1-800-424-9300  
(Outside U.S. 1-703-527-3887)

## 2. Hazard(s) identification

**Physical hazards** Not classified.

**Health hazards** Not classified.

**OSHA defined hazards** Not classified.

**Label elements**

**Hazard symbol** None.

**Signal word** None.

**Hazard statement** The mixture does not meet the criteria for classification.

**Precautionary statement**

**Prevention** Not available.

**Response** Not available.

**Storage** Not available.

**Disposal** Not available.

**Hazard(s) not otherwise classified (HNOC)** None known.

**Supplemental information** None.

## 3. Composition/information on ingredients

### Mixtures

| Chemical name | Common name and synonyms | CAS number  | %       |
|---------------|--------------------------|-------------|---------|
| SPINOSAD      |                          | 168316-95-8 | 57 - 60 |

**Composition comments** Remaining components of this product are non-hazardous and/or are present at concentrations below reportable levels.

## 4. First-aid measures

**Inhalation** If crushed and exposure to content occurs: Move to fresh air. Call a POISON CENTER or doctor/physician.

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

|   |   |
|---|---|
| <b>Eye contact</b>  | If crushed and exposure to content occurs: Immediately flush eye(s) with plenty of water. Get medical attention if irritation develops and persists.  |
| <b>Ingestion</b>  | Call a physician or poison control center immediately. Drink plenty of water. Never give liquid to an unconscious person.   |
| <b>Most important symptoms/effects, acute and delayed</b>                     | None known.   |
| <b>Indication of immediate medical attention and special treatment needed</b> | Treat symptomatically.<br><br>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.  |
| <b>General information</b>  | NOT FOR HUMAN USE!  |
| <b>5. Fire-fighting measures</b>  |   |
| <b>Suitable extinguishing media</b>   | Powder. Water spray. Foam. Carbon dioxide (CO <sub>2</sub> ).   |
| <b>Unsuitable extinguishing media</b>   | None known.   |
| <b>Specific hazards arising from the chemical</b>                             | Fire or excessive heat may produce hazardous decomposition products.  |
| <b>Special protective equipment and precautions for firefighters</b>          | Self-contained breathing apparatus and full protective clothing must be worn in case of fire.   |
| <b>Fire fighting equipment/instructions</b>                                   | Use water spray to cool unopened containers.  |
| <b>General fire hazards</b>   | No unusual fire or explosion hazards noted.   |
| <b>6. Accidental release measures</b>   |   |
| <b>Personal precautions, protective equipment and emergency procedures</b>    | Wear appropriate personal protective equipment.   |
| <b>Methods and materials for containment and cleaning up</b>                  | Wear appropriate protective equipment and clothing during clean-up. Clean up promptly by sweeping or vacuum.  |
| <b>Environmental precautions</b>  | Avoid release to the environment. Avoid discharge into drains, water courses or onto the ground.  |
| <b>7. Handling and storage</b>  |   |
| <b>Precautions for safe handling</b>  | Keep out of reach of children. Observe good industrial hygiene practices.   |
| <b>Conditions for safe storage, including any incompatibilities</b>           | Store at 20 to 25 °C (68 to 77 °F). Excursions permitted from 15 to 30 °C (59 to 86 °F).  |
| <b>8. Exposure controls/personal protection</b>                               |   |
| <b>Occupational exposure limits</b>   | This mixture has no ingredients that have PEL, TLV, or other recommended exposure limit.  |
| <b>Biological limit values</b>  | No biological exposure limits noted for the ingredient(s).  |
| <b>Exposure guidelines</b>  | Supplier: TWA 0.3 mg/m <sup>3</sup> (Spinosad)  |
| <b>Appropriate engineering controls</b>                                       | Good general ventilation (typically 10 air changes per hour) should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level. |
| <b>Individual protection measures, such as personal protective equipment</b>  |   |
| <b>Eye/face protection</b>  | If contact is likely, safety glasses with side shields are recommended.   |
| <b>Skin protection</b>  |   |
| <b>Hand protection</b>  | Chemical resistant gloves.  |
| <b>Other</b>  | Chemical-resistant gloves and impermeable body covering to minimize skin contact.   |
| <b>Respiratory protection</b>   | Use an approved respirator. Select appropriate respirator for physical characteristics of material. Select respirator with appropriate protection factor. Respirator selection must be based on known or anticipated exposure levels, the hazards of the product and the safe working limits of the respirator.   |
| <b>Thermal hazards</b>  | Not available.  |
| <b>General hygiene considerations</b>   | Handle in accordance with good industrial hygiene and safety practice.  |

## 9. Physical and chemical properties

|   |  |
|---|--|
| <b>Appearance</b>                                   | Tablet.  |
| <b>Physical state</b>                               | Solid.   |
| <b>Form</b>   | Solid.   |
| <b>Color</b>  | Tan or Brown   |
| <b>Odor</b>   | Roast beef and liver                                     |
| <b>Odor threshold</b>                               | Not available.   |
| <b>pH</b>   | Not available.   |
| <b>Melting point/freezing point</b>                 | Not available.   |
| <b>Initial boiling point and boiling range</b>      | Not available.   |
| <b>Flash point</b>                                  | Not available.   |
| <b>Evaporation rate</b>                             | Not available.   |
| <b>Flammability (solid, gas)</b>                    | No test data available.                                  |
| <b>Upper/lower flammability or explosive limits</b> |  |
| <b>Flammability limit - lower (%)</b>               | Not available.   |
| <b>Flammability limit - upper (%)</b>               | Not available.   |
| <b>Explosive limit - lower (%)</b>                  | Not available.   |
| <b>Explosive limit - upper (%)</b>                  | Not available.   |
| <b>Vapor pressure</b>                               | Not available.   |
| <b>Vapor density</b>                                | Not available.   |
| <b>Relative density</b>                             | Not available.   |
| <b>Solubility(ies)</b>                              |  |
| <b>Solubility (water)</b>                           | Not available.   |
| <b>Partition coefficient (n-octanol/water)</b>      | Not available.   |
| <b>Auto-ignition temperature</b>                    | Not available.   |
| <b>Decomposition temperature</b>                    | Not available.   |
| <b>Viscosity</b>                                    | Not available.   |
| <b>Other information</b>                            |  |
| <b>Explosive properties</b>                         | Not explosive.   |
| <b>Oxidizing properties</b>                         | The substance or mixture is not classified as oxidizing. |

## 10. Stability and reactivity

|   |  |
|---|--|
| <b>Reactivity</b>                         | Not water reactive.  |
| <b>Chemical stability</b>                 | Material is stable under normal conditions.                          |
| <b>Possibility of hazardous reactions</b> | Hazardous polymerization does not occur.                             |
| <b>Conditions to avoid</b>                | Contact with incompatible materials.                                 |
| <b>Incompatible materials</b>             | Strong oxidizing agents.   |
| <b>Hazardous decomposition products</b>   | Fire or excessive heat may produce hazardous decomposition products. |

## 11. Toxicological information

### Information on toxicological effects

#### Acute toxicity

| Components  | Species   | Test Results          |
|---|---|-----------------------|
| SPINOSAD (CAS 168316-95-8)  |   |                       |
| <u>Acute</u>  |   |                       |
| <b>Dermal</b>   |   |                       |
| LD  | Rabbit  | > 5000 mg/kg          |
| <b>Inhalation</b>   |   |                       |
| LC50  | Rat   | > 5180 mg/m3, 4 hours |
| <b>Oral</b>   |   |                       |
| LD50  | Rat   | > 2000 mg/kg          |
| <b>Skin corrosion/irritation</b>                                      | Rabbit: No irritation. (Spinosad)<br>Based on available data, the classification criteria are not met.  |                       |
| <b>Serious eye damage/eye irritation</b>                              | Due to lack of data the classification is not possible.   |                       |
| <b>Respiratory or skin sensitization</b>                              |   |                       |
| <b>Respiratory sensitization</b>                                      | Due to lack of data the classification is not possible.   |                       |
| <b>Skin sensitization</b>   | Guinea pig: Did not cause sensitization on laboratory animals.<br>Based on available data, the classification criteria are not met.   |                       |
| <b>Germ cell mutagenicity</b>   | Result in genetic toxicity assays (in vitro and in vivo): Negative (Spinosad)<br>Based on available data, the classification criteria are not met.  |                       |
| <b>Carcinogenicity</b>  | No effects identified in animal studies. (Spinosad)<br>Based on available data, the classification criteria are not met.  |                       |
| <b>IARC Monographs. Overall Evaluation of Carcinogenicity</b>         |   |                       |
| Not listed.   |   |                       |
| <b>OSHA Specifically Regulated Substances (29 CFR 1910.1001-1052)</b> |   |                       |
| Not regulated.  |   |                       |
| <b>US. National Toxicology Program (NTP) Report on Carcinogens</b>    |   |                       |
| Not listed.   |   |                       |
| <b>Reproductive toxicity</b>  | In laboratory animal studies, effects on reproduction have been seen only at doses that produced significant toxicity to the parent animals. (Spinosad)<br>Based on available data, the classification criteria are not met.  |                       |
| <b>Specific target organ toxicity - single exposure</b>               | Due to lack of data the classification is not possible.   |                       |
| <b>Specific target organ toxicity - repeated exposure</b>             | 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)<br>Based on available data, the classification criteria are not met. |                       |
| <b>Aspiration hazard</b>  | No aspiration toxicity classification   |                       |

## 12. Ecological information

### Ecotoxicity

| Components                    | Species  | Test Results               |  |
|-------------------------------|--|----------------------------|--|
| 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)                  |
| Fish                          | NOEC   | Water flea (Daphnia magna) | 0.0012 mg/l, 21 days (flow thorough)     |
|                               | LC50   | Carp (Cyprinus carpio)     | 4.5 mg/l, 96 h (flow through)            |
|                               | NOEC   | Oncorhynchus mykiss        | 0.5 mg/l Early life-stage (flow through) |
| Persistence and degradability | No data is available on the degradability of this product. |                            |  |
| Bioaccumulative potential     | No data available.   |                            |  |

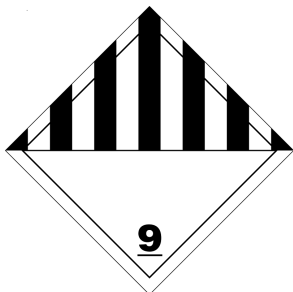
**Bioconcentration factor (BCF)**

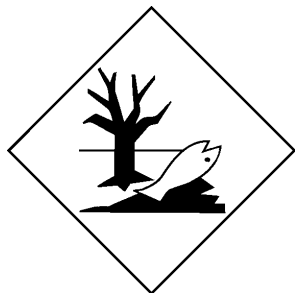
SPINOSAD

&lt; 500

**Mobility in soil** No data available.**Other adverse effects** Not available.**13. Disposal considerations****Disposal instructions** Do not discharge into drains, water courses or onto the ground. Dispose of contents/container in accordance with local/regional/national/international regulations.**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.**DOT**

Not regulated as dangerous goods.

**IATA****UN number** UN3077**UN proper shipping name** Environmentally hazardous substance, solid, n.o.s. mixture (SPINOSAD)**Transport hazard class(es)****Class** 9**Subsidiary risk** -**Packing group** III**Environmental hazards** Yes**ERG Code** 9L**Special precautions for user** Not available.**Other information****Passenger and cargo aircraft** Allowed with restrictions.**Cargo aircraft only** Allowed with restrictions.**IMDG****UN number** UN3077**UN proper shipping name** ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. MIXTURE (SPINOSAD)**Transport hazard class(es)****Class** 9**Subsidiary risk** -**Packing group** III**Environmental hazards****Marine pollutant** Yes**EmS** F-A, S-F**Special precautions for user** Not available.**Transport in bulk according to** Not available.**Annex II of MARPOL 73/78 and the IBC Code****IATA; IMDG**



## 15. Regulatory information

### US federal regulations

This product is not known to be a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.

#### Toxic Substances Control Act (TSCA)

##### TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

#### CERCLA Hazardous Substance List (40 CFR 302.4)

Not listed.

#### SARA 304 Emergency release notification

Not regulated.

#### OSHA Specifically Regulated Substances (29 CFR 1910.1001-1052)

Not regulated.

### Superfund Amendments and Reauthorization Act of 1986 (SARA)

#### SARA 313 (TRI reporting)

Not regulated.

### Other federal regulations

#### Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List

Not regulated.

#### Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)

Not regulated.

### US state regulations

#### California Proposition 65

California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins.

### International Inventories

| Country(s) or region        | Inventory name                                | On inventory (yes/no)* |
|-----------------------------|---|------------------------|
| Canada                      | Domestic Substances List (DSL)                | No                     |
| Canada                      | Non-Domestic Substances List (NDSL)           | No                     |
| United States & Puerto Rico | Toxic Substances Control Act (TSCA) Inventory | No                     |

\*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)

A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

## 16. Other information, including date of preparation or last revision

**Issue date** 08-19-2014

**Revision date** 03-25-2019

**Version #** 03

**List of abbreviations** TWA: Time Weighted Average

**Disclaimer**

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 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:

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