

**Product Name:**  
**Issued:**

**Comfortis**  
**Feb-18-2009**



## MATERIAL SAFETY DATA SHEET

### 1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

**Manufacturer Name and Address:** Abbott  
Global Pharmaceutical Operations  
200 Abbott Park Rd.  
Abbott Park, Illinois 60064

**Emergency Telephone:** CHEMTREC (USA): 1 - 800 - 424 - 9300

**Product Name:** Comfortis

### 2. COMPOSITION/INFORMATION ON INGREDIENTS

| Ingredients             | Percent | OSHA PEL   | ACGIH TLV  | AIHA WEEL      | Abbott EEL     | Skin Notation |
|-------------------------|---------|------------|------------|----------------|----------------|---------------|
| Spinosad<br>168316-95-8 | 100     | Not Listed | Not Listed | Not Applicable | Not Applicable | None          |

**Notes:**

OSHA PEL: US Occupational Safety and Health Administration-Permissible Exposure Limit.  
ACGIH TLV: American Conference of Governmental Industrial Hygienists - Threshold Limit Value.  
AIHA WEEL: American Industrial Hygiene Association - Workplace Environmental Exposure Level.  
Abbott EEL: Abbott Laboratories Employee Exposure Limit.  
TWA: 8-hour Time Weighted Average.  
STEL: 15-minute Short Term Exposure Limit.  
C: Ceiling Limit.

### 3. HAZARDS IDENTIFICATION

**Emergency Overview:**  
Tablet. tan to brown Solid.  
Odor: roast beef and liver  
May cause eye irritation.

**Routes of Exposure:**

**Oral:** Not determined.  
**Dermal:** Yes  
**Inhalation:** Yes

**Hazard Information:**

**Ingestion Rating:** Not determined.  
**Skin Absorption Rating:** Not determined.  
**Inhalation Rating:** Not determined.  
**Corrosiveness Rating:** Not determined.  
**Skin Contact Rating:** Not determined.  
**Skin Sensitization Rating:** Not determined.  
**Eye Contact Rating:** Possible Irritant.  
**Target Organs:** Not determined.

**Carcinogenicity Rating:**

**Product Name:** Comfortis  
**Issued:** Feb-18-2009

| Ingredients | Percent | OSHA:      | NTP:       | IARC:      | ACGIH:     |
|-------------|---------|------------|------------|------------|------------|
| Spinosad    | 100     | Not Listed | Not Listed | Not Listed | Not Listed |

**NFPA Rating:** Not determined.  
Health: 2

**Signs and Symptoms:** None known from occupational exposure. Available information support the following: eye irritation.

**Medical Conditions Aggravated by Exposure:** None known from occupational exposure.

#### 4. FIRST AID MEASURES

**Eye Contact:** Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

**Skin Contact:** Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

**Inhalation:** Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

**Ingestion:** Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

#### 5. FIRE FIGHTING MEASURES

**Flammability:**

**Lower Explosive Limit:** Not determined.

**Autoignition Temp. (°C):** Not determined.

**Fire-Fighting Information:**

**Suitable Extinguishing Media:** Waterspray, carbon dioxide, dry chemical or foam.

**Special Exposure Hazards:** Wear protective clothing and self-contained breathing apparatus.

#### 6. ACCIDENTAL RELEASE MEASURES

**Methods of Cleaning and Collecting:** Recover product. Place into appropriate container for disposal. Clean area with suitable cleaning materials. Dispose of as directed in Section 13.

**Personal Precautions:** Use personal protective equipment identified in Section 8.

**Environmental Precautions:** Not determined.

#### 7. HANDLING AND STORAGE

**Product Name:** Comfortis  
**Issued:** Feb-18-2009

## 7. HANDLING AND STORAGE

**Handling:** Not determined.

**Storage:** Store at 25 deg. C (77 deg. F) with excursions permitted between 15-30 deg. C (59-85 deg. F).

**Special Precautions:** Not applicable.

## 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

**Engineering Controls:** Use in a well ventilated area.

**Respiratory Protection:** Use approved NIOSH respiratory protection.

**Eyes:** Safety glasses.

**Gloves:** Wear impervious gloves when handling the product formulation.

**Other PPE Data:** Wear appropriate body coverings if contact may occur.

## 9. PHYSICAL AND CHEMICAL PROPERTIES

**Appearance:** Tablet. tan to brown Solid.

**Odor:** Odor: roast beef and liver

**Boiling Pt. @ 760 mm Hg (°C):** Not determined.

**Melting/Freezing Point (°C):** 84 C to 99.5 C (spinosyn A) and 161.5 C to 170 C (spinosyn D)

**Vapor Pressure (mm Hg)** Not determined.

**Bulk Density at 20°C:** 0.512

**Solubility:** water, acetone, acetonitrile, toluene, hexane, dichloromethane, 1-octanol, methanol.

**Specific Gravity:** Not determined.

**pH:** 7.74 ( 10% slurry of spinosad technical in water).

**Viscosity (centipoise):** Not determined.

## 10. STABILITY AND REACTIVITY

**Chemical Stability:** Not determined.

**Self-Heating Tendency:** Not determined.

**Materials to Avoid:** Not determined.

**Hazardous Decomposition Products:** Not determined.

**Hazardous Polymerization:** Not determined.

**Conditions to Avoid:** Not determined.

## 11. TOXICOLOGICAL INFORMATION

**Acute Toxicity - Oral:** Data for component (s) given below.

| Ingredients | Percent | Acute Test | Value | Units | Species |
|-------------|---------|------------|-------|-------|---------|
|-------------|---------|------------|-------|-------|---------|

**Product Name:** Comfortis  
**Issued:** Feb-18-2009

| Ingredients | Percent | Acute Test | Value | Units | Species     |
|-------------|---------|------------|-------|-------|-------------|
| Spinosad    | 100     | LD50 >     | 7,500 | mg/kg | Male Rats   |
|             |         |            | 5,000 | mg/kg | Female Rats |
|             |         |            | 400   | mg/kg | Dogs        |

**Acute Toxicity - Dermal:** Data for component (s) given below.

| Ingredients | Percent | Acute Test | Value | Units | Species |
|-------------|---------|------------|-------|-------|---------|
| Spinosad    | 100     | LD50 >     | 5,000 | mg/kg | Rabbits |

**Acute Toxicity - Inhalation:** Data for component (s) given below.

| Ingredients | Percent | Test    | Value | Units                      | Species |
|-------------|---------|---------|-------|----------------------------|---------|
| Spinosad    | 100     | LC 50 > | 5,000 | mg/m <sup>3</sup> , 4 hour | Rats    |

**Notes to Toxicologist:** 4 hour study.

**Corrosivity:** Not determined.

**Dermal Irritation:** Did not produce skin irritation in rabbits.

**Eye Irritation:** May be an eye irritant. Produced mild eye irritation in rabbits.

**Sensitization:** Negative in guinea pig sensitization studies.

**Target Organ Effects:** May cause phospholipidosis in multiple organs.

**Reproductive Effects:** In animals adverse reproductive effects include: reduced fetal growth, maternal toxicity, vaginal bleeding, mortality

**Carcinogenicity:** None expected from normal clinical use of this product.

**Mutagenicity:** Negative in mutagenicity assays.

**Notes:**

1. ALD: Approximate lethal dosage
2. LC50: Concentration in air that produces 50% mortality
3. LD50: Oral or dermal dosage that produces 50% mortality

## 12. ECOLOGICAL INFORMATION

**Aquatic Toxicity:** Not determined.

| Ingredients | Percent | LC 50 (mg/l) | Species       | Duration |
|-------------|---------|--------------|---------------|----------|
| Spinosad    | 100     | 5.94         | Bluegill      | 96 Hours |
|             |         | 30           | Rainbow Trout |          |

| Ingredients | Percent | Eb50/ErC50 (mg/l) | Species       | Duration |
|-------------|---------|-------------------|---------------|----------|
| Spinosad    | 100     | 92.7              | Daphnia magna | 48 Hours |

**Biodegradation:** Not determined.

**General Notes:** Do not allow undiluted material or large quantities to reach groundwater, bodies of water or sewer system.

**Product Name:** Comfortis  
**Issued:** Feb-18-2009

**Notes:**

1. EC50: Concentration in water that produces 50% mortality in *Daphnia* sp.
2. LC50: Concentration in water that produces 50% mortality in fish.
3. EbC50/ErC50: Concentration in water that produces 50% inhibition of growth and in algae.

### 13. DISPOSAL CONSIDERATIONS

**Waste Disposal Methods:** Disposal should be made in accordance with federal, state and local regulations.

### 14. TRANSPORT INFORMATION

**DOT/ADR:**  
**Status:** Not Regulated.

**ICAO/IATA:**  
**Status:** Not Regulated.

**IMDG:**  
**Status:** Not Regulated.

**TDG (Canada):**  
**Status:** Not Regulated.

### 15. REGULATORY INFORMATION

**SARA 313 Information**

| Ingredients | Percent | SARA 313 Chemical: | CERCLA RQ/SARA EHS RQ (lbs): | SARA EHS TPQ (lbs): |
|-------------|---------|--------------------|------------------------------|---------------------|
| Spinosad    | 100     | No                 | Not Applicable               | Not applicable      |

**SARA 311/312 Hazard Categories:**

**Immediate Health:** Not determined.  
**Delayed Health:** Not determined.  
**Fire:** Not determined.  
**Sudden Pressure:** Not determined.  
**Reactivity:** Not determined.

**TSCA Inventory Status:** Not determined.

**CERCLA Status:** Not determined.

**RCRA Status:** Not determined.

**Proposition 65 Status:** Does not contain chemicals known to the state of California to cause cancer or reproductive harm.

**EC HAZARD CLASSIFICATION:**

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**Category of Danger:** None.

**Indication of danger:** None.

**GHS CLASSIFICATION:** Class 4 - Minimum Hazard.

**CANADIAN REGULATIONS:**

**Canadian Inventory:** Not determined.  
**Canadian NDSL:** Not determined.  
**WHMIS Hazard Class:** Not determined.

**Notes:**

1. SARA = Superfund Amendments and the Reauthorization Act.
2. CERCLA = Comprehensive Environmental Response, Compensation and Liability Act.
3. FIFRA = Federal Insecticide, Fungicide and Rodenticide Act.
4. TSCA = Toxic Substances Control Act.
5. EC = European Community.
6. WHMIS = Canadian Workplace Hazardous Materials Information System.
7. UN GHS = United Nations Globally Harmonized System for Hazard Identification.

## 16. OTHER INFORMATION

**Document Authored By:** Global Occupational Toxicology (D-03QW)

**Disclaimer:**

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