

SAFETY DATA SHEET



Revision date: 26-Nov-2013

Version: 2.0

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1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND THE COMPANY/UNDERTAKING

Product Identifier

Material Name: Dirlotapide Oral Solution

Trade Name: SLENTROL™
Chemical Family: Not determined

Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

Intended Use: Veterinary product

Details of the Supplier of the Safety Data Sheet

Zoetis Inc.
100 Campus Drive, P.O. Box 651
Florham Park, New Jersey 07932 (USA)
Rocky Mountain Poison Control Center Phone: 1-866-531-8896
Product Support/Technical Services Phone: 1-800-366-5288

Zoetis Belgium S.A.
Mercuriusstraat 20
1930 Zaventem
Belgium

Emergency telephone number:
CHEMTREC (24 hours): 1-800-424-9300
Contact E-Mail: VMIPSrecords@zoetis.com

Emergency telephone number:
International CHEMTREC (24 hours): +1-703-527-3887

2. HAZARDS IDENTIFICATION

Appearance: Clear, colorless to yellow liquid

Classification of the Substance or Mixture
Reproductive Toxicity: Category 2

EU Classification:

EU Symbol: Not classified

Label Elements

Signal Word: Warning
Hazard Statements: H361 - Suspected of damaging fertility or the unborn child

Precautionary Statements: P201 - Obtain special instructions before use
P202 - Do not handle until all safety precautions have been read and understood
P280 - Wear protective gloves/protective clothing/eye protection/face protection
P308 + P313 - IF exposed or concerned: Get medical attention/advice
P405 - Store locked up
P501 - Dispose of contents/container in accordance with all local and national regulations



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Other Hazards

Known Clinical Effects:

Based on clinical trials in humans, possible adverse effects following exposure to this compound may include: diarrhea, flatulence, nausea, headache, and abdominal distension. Hazardous Substance. Non-Dangerous Goods.

Australian Hazard Classification (NOHSC):

Note:

This document has been prepared in accordance with standards for workplace safety, which requires the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warning included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	GHS Classification	%
Dirlotapide (CP-742,033)	481658-94-0	Not Listed	Repr.Cat.3;R63	Toxic to Repr. (H361)	0.5

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	GHS Classification	%
Medium Chain Fatty Acid Triglyceride	Unassigned	Not Listed	Not Listed	Not Listed	*

Additional Information:

* Proprietary
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

For the full text of the R phrases and CLP/GHS abbreviations mentioned in this Section, see Section 16

4. FIRST AID MEASURES

Description of First Aid Measures

Eye Contact:

Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.

Skin Contact:

Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.

Ingestion:

Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

Inhalation:

Remove to fresh air and keep patient at rest. Seek medical attention immediately.

Most Important Symptoms and Effects, Both Acute and Delayed

Symptoms and Effects of

No data available

Exposure:

Medical Conditions

None known

Aggravated by Exposure:

Indication of the Immediate Medical Attention and Special Treatment Needed

Notes to Physician:

None

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5. FIRE-FIGHTING MEASURES

Extinguishing Media: Extinguish fires with CO₂, extinguishing powder, foam, or water.

Special Hazards Arising from the Substance or Mixture

Hazardous Combustion Products: Formation of toxic gases is possible during heating or fire.

Fire / Explosion Hazards: Fine particles (such as mists) may fuel fires/explosions.

Advice for Fire-Fighters

Wear approved positive pressure, self-contained breathing apparatus and full protective turn out gear. Dike and collect water used to fight fire.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment and Emergency Procedures

Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

Environmental Precautions

Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

Methods and Material for Containment and Cleaning Up

Measures for Cleaning / Collecting: Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly.

Additional Consideration for Large Spills: Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

7. HANDLING AND STORAGE

Precautions for Safe Handling

Keep away from heat, sparks, and flame. Avoid open handling. Minimize generation of mists. Use local exhaust or perform work under hood/fume cupboard. Avoid inhalation and contact with skin, eyes, and clothing. When handling, use appropriate personal protective equipment (see Section 8).

Conditions for Safe Storage, Including any Incompatibilities

Storage Conditions: Store at room temperature in properly labeled containers. Keep away from heat, sparks and flames.

Specific end use(s): No data available

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Control Parameters

Dirlotapide (CP-742,033)
Zoetis OEL TWA 8-hr

20 ug/m³

Exposure Controls

Engineering Controls: Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes.

Personal Protective Equipment: Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).

Hands: Wear impervious gloves if skin contact is possible.

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Eyes: Safety glasses or goggles
Skin: Use protective clothing (uniforms, lab coats, disposable coveralls, etc.) in both production and laboratory areas.
Respiratory protection: If the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State:	Liquid	Color:	Clear, colorless to yellow
Odor:	No data available.	Odor Threshold:	No data available.
Molecular Formula:	Mixture	Molecular Weight:	Mixture
Solvent Solubility:	No data available		
Water Solubility:	No data available		
pH:	No data available.		
Melting/Freezing Point (°C):	No data available		
Boiling Point (°C):	No data available.		
Partition Coefficient: (Method, pH, Endpoint, Value)			
No data available			
Decomposition Temperature (°C):	No data available.		
Evaporation Rate (Gram/s):	No data available		
Vapor Pressure (kPa):	No data available		
Vapor Density (g/ml):	No data available		
Relative Density:	No data available		
Viscosity:	No data available		
Flammability:			
Autoignition Temperature (Solid) (°C):		No data available	
Flammability (Solids):		No data available	
Flash Point (Liquid) (°C):		No data available	
Upper Explosive Limits (Liquid) (% by Vol.):		No data available	
Lower Explosive Limits (Liquid) (% by Vol.):		No data available	

10. STABILITY AND REACTIVITY

Reactivity:	No data available
Chemical Stability:	Stable under normal conditions of use.
Possibility of Hazardous Reactions	
Oxidizing Properties:	No data available
Conditions to Avoid:	Fine particles (such as mists) may fuel fires/explosions. As a precautionary measure, keep away from heat sources and electrostatic discharge.
Incompatible Materials:	As a precautionary measure, keep away from strong oxidizers
Hazardous Decomposition Products:	No data available

11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects

General Information: Toxicological properties of the formulation have not been investigated. The information included in this section describes the potential hazards of the individual ingredients.

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11. TOXICOLOGICAL INFORMATION

Acute Toxicity: (Species, Route, End Point, Dose)

Dirlotapide (CP-742,033)

Rat Oral LD 50 > 200 mg/kg

Rat Dermal LD 50 > 2000mg/kg

Dog Oral Maximum Asymptomatic Dose 25mg/kg

Acute Toxicity Comments: A greater than symbol (>) indicates that the toxicity endpoint being tested was not achievable at the highest dose used in the test.

Irritation / Sensitization: (Study Type, Species, Severity)

Dirlotapide (CP-742,033)

Eye Irritation Rabbit Minimal

Skin Irritation Rabbit Negative

Skin Sensitization - LLNA Mouse Negative

Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)

Dirlotapide (CP-742,033)

3 Month(s) Dog Oral 0.25 mg/kg/day NOEL Liver, Gastrointestinal System

3 Month(s) Rat Oral 1 mg/kg/day NOEL Liver, Gastrointestinal system

2 Week(s) Rat Oral 5 mg/kg/day NOEL Liver, Gastrointestinal system

6 Month(s) Rat Oral 1 mg/kg/day NOEL Liver

9 Month(s) Dog Oral 0.25 mg/kg/day NOEL Liver

Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))

Dirlotapide (CP-742,033)

Embryo / Fetal Development Rat Oral 10 mg/kg/day NOEL Maternal toxicity

Embryo / Fetal Development Rat Oral 1 mg/kg/day NOEL Developmental toxicity

Fertility & Embryonic Development (Male/Female) Rat Oral 1 (F), 200 (M) mg/kg/day NOEL Fertility, Early embryonic development

Embryo / Fetal Development Rabbit Oral 5.0 mg/kg/day NOEL Maternal Toxicity, Fetotoxicity

Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

Dirlotapide (CP-742,033)

Bacterial Mutagenicity (Ames) *Salmonella*, *E. coli* Negative

Chromosome Aberration Human Lymphocytes Negative

In Vivo Micronucleus Rat Negative

Carcinogen Status: None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

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12. ECOLOGICAL INFORMATION

Environmental Overview: Environmental properties of the formulation have not been thoroughly investigated.

Toxicity:

Aquatic Toxicity: (Species, Method, End Point, Duration, Result)

Dirlotapide (CP-742,033)

Tisbe battagliai (Marine Copepod) ISO LC-50 48 Hours > 0.42 mg/L

Skeletonema costatum (Marine Diatom) OPPTS EC-50 96 Hours > 0.57 mg/L

Cyprinodon variegatus (Sheepshead Minnow) OPPTS LC-50 96 Hours > 0.30 mg/L

Aquatic Toxicity Comments: A greater than symbol (>) indicates that aquatic toxicity was not observed at the maximum dose tested.

Bacterial Inhibition: (Inoculum, Method, End Point, Result)

Dirlotapide (CP-742,033)

Activated sludge OECD EC-50 > 100 mg/L

Persistence and Degradability: No data available

Bio-accumulative Potential: No data available

Mobility in Soil: No data available

13. DISPOSAL CONSIDERATIONS

Waste Treatment Methods:

Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

14. TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

15. REGULATORY INFORMATION

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

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15. REGULATORY INFORMATION

Canada - WHMIS: Classifications

WHMIS hazard class:

Class D, Division 2, Subdivision A



Medium Chain Fatty Acid Triglyceride

CERCLA/SARA 313 Emission reporting

Not Listed

California Proposition 65

Not Listed

EU EINECS/ELINCS List

Not Listed

Dirlotapide (CP-742,033)

CERCLA/SARA 313 Emission reporting

Not Listed

California Proposition 65

Not Listed

Standard for the Uniform Scheduling

Schedule 4

for Drugs and Poisons:

EU EINECS/ELINCS List

Not Listed

16. OTHER INFORMATION

Text of R phrases and GHS Classification abbreviations mentioned in Section 3

H361 - Suspected of damaging fertility or the unborn child

R63 - Possible risk of harm to the unborn child.

Data Sources:

The data contained in this MSDS may have been gathered from confidential internal sources, raw material suppliers, or from the published literature.

Reasons for Revision:

Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking. Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 5 - Fire Fighting Measures. Updated Section 7 - Handling and Storage. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 11 - Toxicology Information. Updated Section 15 - Regulatory Information.

Prepared by:

Toxicology and Hazard Communication
Zoetis Global Risk Management

Zoetis Inc. believes that the information contained in this Material Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time.

End of Safety Data Sheet