

SAFETY DATA SHEETS

This SDS packet was issued with item:

078926886

N/A

SAFETY DATA SHEET



Revision date: 06-Jul-2015

Version: 1.0

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

Product Identifier

Material Name: Simbadol

Trade Name: Simbadol
Synonyms: Buprenorphine injection
Chemical Family: Opioid

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

Intended Use: Veterinary product used as Narcotic analgesic
Restrictions on Use: Not for human use

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 and Drug 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: Liquid

Classification of the Substance or Mixture

GHS - Classification

Serious Eye Damage/Eye Irritation: Category 2
Reproductive Toxicity: Category 2
Flammable liquids- Category 3

EU Classification:

EU Indication of danger: Not determined

Label Elements

Signal Word: Warning
Hazard Statements: H226 - Flammable liquid and vapor
H319 - Causes serious eye irritation
H361 - Suspected of damaging fertility or the unborn child

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Precautionary Statements:

- P201 - Obtain special instructions before use
- P202 - Do not handle until all safety precautions have been read and understood
- P210 - Keep away from heat/sparks/open flames/hot surfaces. - No smoking
- P233 - Keep container tightly closed
- P240 - Ground/Bond container and receiving equipment
- P241 - Use explosion-proof electrical/ventilating/lighting/equipment
- P242 - Use only non-sparking tools
- P243 - Take precautionary measures against static discharge
- P280 - Wear protective gloves/protective clothing/eye protection/face protection
- P264 - Wash hands thoroughly after handling
- P370 + P378 - In case of fire: Use dry chemical, CO2, foam or water spray for extinction
- P308 + P313 - IF exposed or concerned: Get medical attention/advice
- P303 + P361 + P353 - IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower
- P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing
- P337 + P313 - If eye irritation persists: Get medical advice/attention
- P403 + P235 - Store in a well-ventilated place. Keep cool
- P405 - Store locked up
- P501 - Dispose of contents/container in accordance with all local and national regulations

Other Hazards

Short Term: Can cause eye irritation . Signs and symptoms might include redness, swelling, blurred vision or pain. May cause slight skin irritation. Vapors may cause drowsiness and dizziness. Breathing high vapor concentrations may cause central nervous system (CNS) depression resulting in dizziness, light-headedness, headache, nausea, and loss of coordination. Continued inhalation may result in unconsciousness and death.

Long Term: may have the potential to produce effects on the developing fetus.

Australian Hazard Classification (NOHSC):

Hazardous Substance. Non-Dangerous Goods.

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	%
Buprenorphine hydrochloride	53152-21-9	258-396-8	Xn;R22 R67 R63	Acute Tox. 3 (H301) Repr. 2 (H361) STOT SE 3 (H336)	<1
Acetic acid	64-19-7	200-580-7	R10 C; R35	Skin Corr.1A (H314) Flam. Liq. 3 (H226)	0.05
Ethyl alcohol (ethanol)	64-17-5	200-578-6	F; R11	Flam. Liq. 2 (H225)	10

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Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	GHS Classification	%
Glucose	50-99-7	200-075-1	Not Listed	Not Listed	1 - 10
Propylparaben	94-13-3	202-307-7	Not Listed	Not Listed	<1
Sodium acetate	127-09-3	204-823-8	Not Listed	Not Listed	<1
Methylparaben	99-76-3	202-785-7	Not Listed	Not Listed	<1
Water	7732-18-5	231-791-2	Not Listed	Not Listed	50 - 90

Additional Information: Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety. In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

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 Exposure: For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.

Medical Conditions Aggravated by Exposure: None known

Indication of the Immediate Medical Attention and Special Treatment Needed

Notes to Physician: None

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: Flammable liquid and vapor. May present a fire hazard under fire conditions. May generate flammable vapors. Vapors are heavier than air and may travel along surfaces to remote ignition sources and flash back.

Advice for Fire-Fighters

During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment and Emergency Procedures

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6. ACCIDENTAL RELEASE MEASURES

Ensure adequate ventilation. Ground and bond containers when transferring material. Personnel must wear appropriate protective equipment (see Section 8). Prevent exposure by any route.

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:

Eliminate possible ignition sources (e.g., heat, sparks, flame, impact, friction, electricity), and follow appropriate grounding procedures. Contain the source of spill if it is safe to do so.

Collect spill with absorbent material. Clean spill area thoroughly. Prevent discharge to drains.

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. Contain the source of the spill or leak and shut off all electrical equipment if it is safe to do so. Eliminate possible ignition sources (e.g., heat, sparks, flame, impact, friction, electricity), and follow appropriate grounding procedures. Collect spill with a non-combustible absorbent material and transfer to labeled container for disposal. Clean spill area thoroughly. Prevent discharge to drains. Prevent runoff from entering waterways or sewers.

7. HANDLING AND STORAGE

Precautions for Safe Handling

Flammable. Keep away from heat, sparks, flame and all other sources of ignition. Take precautionary measures against static discharges. Ground and bond all bulk transfer equipment. Use only in a well-ventilated area. Restrict access to work area.

Minimize generating airborne mists and vapors. Avoid breathing vapor or mist. Avoid contact with eyes, skin and clothing. Avoid accidental injection. Wash thoroughly after handling. Releases to the environment should be avoided.

Conditions for Safe Storage, Including any Incompatibilities

Storage Conditions:

Keep in a cool, well-ventilated place. Keep container tightly closed when not in use. Keep away from heat, sparks, flame, and other sources of ignition. Protect from light. Store away from direct sunlight.

Storage Temperature:

15-30°C (59-86°F)

Incompatible Materials:

Heat and oxidizers, combustible materials

Specific end use(s):

No data available

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Control Parameters

Refer to available public information for specific member state Occupational Exposure Limits.

Acetic acid

ACGIH Threshold Limit Value (TWA)	10 ppm
ACGIH Threshold Limit Value (STEL)	15 ppm
Australia STEL	15 ppm
	37 mg/m ³
Australia TWA	10 ppm
	25 mg/m ³
Austria OEL - MAKs	10 ppm
	25 mg/m ³
Belgium OEL - TWA	10 ppm
	25 mg/m ³
Bulgaria OEL - TWA	25.0 mg/m ³
Cyprus OEL - TWA	10 ppm
	25 mg/m ³

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Czech Republic OEL - TWA	25 mg/m ³
Denmark OEL - TWA	10 ppm
	25 mg/m ³
Estonia OEL - TWA	10 ppm
	25 mg/m ³
Finland OEL - TWA	5 ppm
	13 mg/m ³
Germany - TRGS 900 - TWAs	10 ppm
	25 mg/m ³
Germany (DFG) - MAK	10 ppm
	25 mg/m ³
Greece OEL - TWA	10 ppm
	25 mg/m ³
Hungary OEL - TWA	25 mg/m ³
Ireland OEL - TWAs	10 ppm
	25 mg/m ³
Latvia OEL - TWA	10 ppm
	25 mg/m ³
Lithuania OEL - TWA	10 ppm
	25 mg/m ³
Luxembourg OEL - TWA	10 ppm
	25 mg/m ³
Malta OEL - TWA	10 ppm
	25 mg/m ³
Vietnam OEL - TWAs	25 mg/m ³
OSHA - Final PELs - TWAs:	10 ppm
	25 mg/m ³
Poland OEL - TWA	15 mg/m ³
Portugal OEL - TWA	10 ppm
Romania OEL - TWA	10 ppm
	25 mg/m ³
Slovakia OEL - TWA	10 ppm
	25 mg/m ³
Slovenia OEL - TWA	10 ppm
	25 mg/m ³
Spain OEL - TWA	10 ppm
	25 mg/m ³
Sweden OEL - TWAs	5 ppm
	13 mg/m ³
Switzerland OEL -TWAs	10 ppm
	25 mg/m ³
Ethyl alcohol (ethanol)	
ACGIH Threshold Limit Value (STEL)	1000 ppm
Australia TWA	1000 ppm
	1880 mg/m ³
Austria OEL - MAKs	1000 ppm
	1900 mg/m ³
Belgium OEL - TWA	1000 ppm
	1907 mg/m ³
Bulgaria OEL - TWA	1000.0 mg/m ³
Czech Republic OEL - TWA	1000 mg/m ³

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Denmark OEL - TWA	1000 ppm 1900 mg/m ³
Estonia OEL - TWA	500 ppm 1000 mg/m ³
Finland OEL - TWA	1000 ppm 1900 mg/m ³
France OEL - TWA	1000 ppm 1900 mg/m ³
Germany - TRGS 900 - TWAs	500 ppm 960 mg/m ³
Germany (DFG) - MAK	500 ppm 960 mg/m ³
Greece OEL - TWA	1000 ppm 1900 mg/m ³
Hungary OEL - TWA	1900 mg/m ³
Latvia OEL - TWA	1000 mg/m ³
Lithuania OEL - TWA	500 ppm 1000 mg/m ³
Netherlands OEL - TWA	260 mg/m ³
Vietnam OEL - TWAs	1000 mg/m ³
OSHA - Final PELs - TWAs:	1000 ppm 1900 mg/m ³
Poland OEL - TWA	1900 mg/m ³
Portugal OEL - TWA	1000 ppm
Romania OEL - TWA	1000 ppm 1900 mg/m ³
Slovakia OEL - TWA	500 ppm 960 mg/m ³
Slovenia OEL - TWA	1000 ppm 1900 mg/m ³
Sweden OEL - TWAs	500 ppm 1000 mg/m ³
Switzerland OEL - TWAs	500 ppm 960 mg/m ³

Exposure Controls

Engineering Controls:

Engineering controls should be used as the primary means to control exposures. Use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits.

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.

Eyes:

Safety glasses or goggles

Skin:

Use protective clothing (uniforms, lab coats, disposable coveralls, etc.) in both production and laboratory areas.

Respiratory protection:

Whenever air contamination (mist, vapor or odor) is generated, respiratory protection is recommended as a precaution to minimize exposure. 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.

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9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State:	Liquid preparation	Color:	No data available.
Odor:	No data available.	Odor Threshold:	No data available.
Molecular Formula:	Mixture	Molecular Weight:	Mixture
Solvent Solubility:	No data available		
Water Solubility:	Soluble: Water , Dextrose solutions		
pH:	3.5 - 5.5		
Melting/Freezing Point (°C):	No data available		
Boiling Point (°C):	No data available.		
Partition Coefficient: (Method, pH, Endpoint, Value)			
Buprenorphine hydrochloride	Log P 4.98		
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):	23 - 60C / 73.4 - 140F		
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:	Exposure to light . Exposure to sunlight. Keep away from heat and other sources of ignition, including electrostatic discharge.
Incompatible Materials:	Heat and oxidizers , combustible materials
Hazardous Decomposition Products:	Thermal decomposition products may include carbon monoxide, carbon dioxide and other toxic vapors.

11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects

General Information: Toxicological properties of the formulation have not been investigated. The information in this section describes the potential hazards of the individual ingredients and the formulation.
Routes of exposure: eye contact , skin contact , inhalation

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

Ethyl alcohol (ethanol)

Mouse Oral LD50 3450 mg/kg
Rat Oral LD50 7060mg/kg

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11. TOXICOLOGICAL INFORMATION

Rat Inhalation LC50 10h 20,000ppm

Acetic acid

Rat Oral LD50 3530 mg/kg
Mouse Inhalation LC50 5000ppm

Propylparaben

Mouse Oral LD50 6332 mg/kg
Mouse Sub-tenon injection (eye) LD50 200 mg/kg

Buprenorphine hydrochloride

Mouse Oral LD50 261 mg/kg
Rat Oral LD50 > 600 mg/kg
Mouse / Rat Intravenous LD50 26 / 35 mg/kg
Rat Intraperitoneal LD50 243 mg/kg
Mouse Intraperitoneal LD50 94 mg/kg

Glucose

Rat Oral LD50 25800 mg/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.

Inhalation Acute Toxicity

Based on components, inhalation may cause irritation, headache, drowsiness, dizziness, nausea, vomiting, diarrhea, dehydration, and symptoms of drunkenness. Breathing high vapor concentrations may cause central nervous system (CNS) depression resulting in dizziness, light-headedness, headache, nausea, and loss of coordination. Continued inhalation may result in unconsciousness and death.

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

Ethyl alcohol (ethanol)

Eye Irritation Rabbit Severe
Skin Irritation Rabbit Mild

Irritation / Sensitization Comments: May cause eye irritation.

Skin Irritation / Sensitization May cause mild skin irritation.

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

Propylparaben

3 Week(s) Rat Oral 27.1 g/kg LOAEL Endocrine system
4 Week(s) Rat Oral 347.2 mg/kg LOAEL Male reproductive system

Reproductive & Development Toxicity Comments:

may have the potential to produce effects on the developing fetus.

Carcinogen Status:

Ethanol has been shown to be carcinogenic in long-term studies only when consumed as alcoholic beverage. None of the other components of this mixture are listed as a carcinogen by IARC, NTP or OSHA.

Ethyl alcohol (ethanol)

IARC:

Group 1 (Carcinogenic to Humans)

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11. TOXICOLOGICAL INFORMATION

Product Level Toxicity Data

Acute Toxicity Estimate (ATE),
oral >10,000 mg/kg
Acute Toxicity Estimate (ATE),
inhalation (vapor) >10 mg/l

12. ECOLOGICAL INFORMATION

Environmental Overview: Environmental properties of the formulation have not been investigated. The following information is available for the individual ingredients. Releases to the environment should be avoided.

Toxicity:

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

Ethyl alcohol (ethanol)

Oncorhynchus mykiss (Rainbow Trout) LC50/96h 12,900-15,300 mg/L

Acetic acid

Pimephales promelas (Fathead Minnow) LC-50 1 Hours > 315 mg/L

Pimephales promelas (Fathead Minnow) LC-50 24 Hours 122 mg/L

Mysidopsis bahia (Mysid Shrimp) LC-50 48 Hours 100-300 mg/L

Persistence and Degradability: No data available

Bio-accumulative Potential:

Buprenorphine hydrochloride Log P 4.98

Mobility in Soil: No data available

13. DISPOSAL CONSIDERATIONS

Waste Treatment Methods:

Waste of this product may qualify as a RCRA Hazardous Waste. Status should be confirmed by testing for RCRA hazardous characteristics (i.e. corrosivity, toxicity, reactivity, or ignitability). 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.

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Aqueous products containing alcohol at 24 percent or less are not subject to the requirements of the EU ADR, IATA, or IMDG. They are similarly exempt from US DOT requirements provided that they contain no less than 50 percent water.

DOT Not regulated for transportation

U.S. DOT Reportable Quantity (RQ), 49 CFR 172.101 Appendix A:

Acetic acid

CERCLA/SARA Hazardous Substances and their Reportable Quantities:	5000 lb 2270 kg
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15. REGULATORY INFORMATION

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

Canada - WHMIS: Classifications

WHMIS hazard class:

Class D, Division 2, Subdivision A
Class D, Division 2, Subdivision B
Class B, Division 2

This product has been classified in accordance with the hazard criteria of the CPR and the SDS contains all of the information required by the CPR.



Buprenorphine hydrochloride

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Australia (AICS):	Present
EU EINECS/ELINCS List	258-396-8

Acetic acid

CERCLA/SARA 313 Emission reporting	Not Listed
CERCLA/SARA Hazardous Substances and their Reportable Quantities:	5000 lb 2270 kg
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 2 Schedule 5 Schedule 6
EU EINECS/ELINCS List	200-580-7

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15. REGULATORY INFORMATION

Glucose

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
REACH - Annex IV - Exemptions from the obligations of Register:	Present
EU EINECS/ELINCS List	200-075-1

Propylparaben

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	202-307-7

Sodium acetate

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	204-823-8

Methylparaben

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	202-785-7

Ethyl alcohol (ethanol)

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	carcinogen initial date 4/29/11 in alcoholic beverages developmental toxicity initial date 10/1/87 in alcoholic beverages
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	200-578-6

Water

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
REACH - Annex IV - Exemptions from the obligations of Register:	Present
EU EINECS/ELINCS List	231-791-2

16. OTHER INFORMATION

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

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Flammable liquids-Cat.2; H225 - Highly flammable liquid and vapor
Flammable liquids-Cat.3; H226 - Flammable liquid and vapor
Skin corrosion/irritation-Cat.1A; H314 - Causes severe skin burns and eye damage
Acute toxicity, oral-Cat.3; H301 - Toxic if swallowed
Reproductive toxicity-Cat.2; H361 - Suspected of damaging fertility or the unborn child
Specific target organ toxicity, single exposure; Narcotic effects-Cat.3; H336 - May cause drowsiness and dizziness

F - Highly flammable
C - Corrosive
Xn - Harmful

R35 - Causes severe burns.
R11 - Highly flammable.
R10 - Flammable.
R22 - Harmful if swallowed.
R67 - Vapors may cause drowsiness and dizziness.
R63 - Possible risk of harm to the unborn child.

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

Reasons for Revision: New data sheet.

Prepared by: Toxicology and Hazard Communication
Zoetis Global Risk Management

Zoetis Inc. believes that the information contained in this 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