



MATERIAL SAFETY DATA SHEET

Revision date: 21-Jun-2011

Version: 1.0

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

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Material Name: Oxytetracycline Hydrochloride and Hydrocortisone Ointment

Trade Name:	Terra Cortril Topical Ointment
Chemical Family:	Mixture
Intended Use:	Pharmaceutical product used as anti-inflammatory

2. HAZARDS IDENTIFICATION

Appearance: ointment
Signal Word: DANGER

Statement of Hazard: May damage the unborn child.

Additional Hazard Information:

Long Term: Prolonged or repeated contact may cause defatting and drying of the skin.
Known Clinical Effects: May cause effects similar to those seen in clinical use including transient diarrhea, nausea and abdominal pain. Symptoms of chronic exposure to tetracyclines include redness and swelling of the skin, rash, chills, tooth discoloration, yellowing of the skin and eyes, nausea, vomiting, diarrhea, stomach pain, and chest pain. Individuals sensitive to this material or other materials in its chemical class may develop allergic reactions. Wheezing, asthma, low or high blood pressure, dizziness, lung congestion, blood changes (leukocytosis, atypical lymphocytes, toxic granulation of granulocytes and thrombocytopenia purpura), convulsion or shock may also occur.

EU Classification

EU Indication of danger: Toxic to reproduction: Category 1



EU Risk Phrases:

Australian Hazard Classification (NOHSC):

R61 - May cause harm to the unborn child.
Hazardous Substance. Non-Dangerous Goods.

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2. HAZARDS IDENTIFICATION

Note: This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the active substance or its intermediates regardless of the potential risk. The precautionary statements and warnings 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	%
Oxytetracycline hydrochloride	2058-46-0	218-161-2	Repr. Cat.1;R61	3.3
Hydrocortisone	50-23-7	200-020-1	Repr.Cat.3;R63	1
Light Liquid Paraffin	8012-95-1	232-384-2	Not Listed	*

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	%
Paraffin, White Soft	Mixture	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 mentioned in this Section, see Section 16

4. 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.

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.

5. FIRE FIGHTING MEASURES

Extinguishing Media: Use carbon dioxide, dry chemical, or water spray.

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

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

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

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6. ACCIDENTAL RELEASE MEASURES

Health and Safety Precautions:	Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.
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.
Measures for Environmental Protections:	Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.
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

General Handling:	Avoid breathing vapor or mist. Avoid contact with eyes, skin and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash thoroughly after handling. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.
Storage Conditions:	Store as directed by product packaging.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

Oxytetracycline hydrochloride	
Pfizer OEL TWA-8 Hr:	500µg/m ³
Hydrocortisone	
Pfizer OEL TWA-8 Hr:	100 µg/m ³ , Skin
Light Liquid Paraffin	
ACGIH Threshold Limit Value (TWA)	5 mg/m ³ TWA
ACGIH Threshold Limit Value (STEL)	10 mg/m ³ STEL
ACGIH OELs - Notice of Intended Changes	Listed
Australia TWA	5 mg/m ³
Belgium OEL - TWA	Listed
Bulgaria OEL - TWA	Listed
Czech Republic OEL - TWA	Listed
Denmark OEL - TWA	Listed
Finland OEL - TWA	Listed
Greece OEL - TWA	Listed
Ireland OEL - TWAs	Listed
Netherlands OEL - TWA	Listed
OSHA - Final PELs - TWAs:	5 mg/m ³
Poland OEL - TWA	Listed
Portugal OEL - TWA	Listed
Romania OEL - TWA	Listed
Spain OEL - TWA	Listed
Sweden OEL - TWAs	Listed

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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. Keep airborne contamination levels below the exposure limits listed above in this section.

Environmental Exposure Controls: Refer to specific Member State legislation for requirements under Community environmental legislation.

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

Hands: Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.

Eyes: Wear safety glasses or goggles if eye contact is possible.

Skin: Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.

Respiratory protection: If airborne exposures are within or exceed the Occupational Exposure Band (OEB) range, wear an appropriate respirator with a protection factor sufficient to control exposures to the bottom of the OEB range.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State: Suspension Ointment
Molecular Formula: Mixture
Color: No data available.
Molecular Weight: Mixture

Solubility: Insoluble: Water

Polymerization: Will not occur

10. STABILITY AND REACTIVITY

Chemical Stability: Stable under normal conditions of use.
Conditions to Avoid: Fine particles (such as dust and mists) may fuel fires/explosions.
Incompatible Materials: As a precautionary measure, keep away from strong oxidizers

11. TOXICOLOGICAL INFORMATION

General Information: The information included in this section describes the potential hazards of the individual ingredients.

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

Oxytetracycline hydrochloride

Mouse Oral LD50 6696 mg/kg
Mouse SC LD50 600 mg/kg
Rat SC LD50 800 mg/kg
Mouse IV LD50 100 mg/kg
Rat IV LD50 302 mg/kg

Hydrocortisone

Rat Oral LD 50 5000 mg/kg

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11. TOXICOLOGICAL INFORMATION

Mouse	Oral	LD 50	5000 mg/kg
Rat	Subcutaneous	LD 50	449 mg/kg
Rat	Intraperitoneal	LD 50	150 mg/kg

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

Light Liquid Paraffin

Eye Irritation	Rabbit	Moderate
Skin Irritation	Rabbit	Mild

Hydrocortisone

Eye Irritation	Rabbit	Minimal
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Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)

Oxytetracycline hydrochloride

13 Week(s)	Mouse	Oral	3821 mg/kg/day	NOAEL	None identified
13 Week(s)	Rat	Oral	3352 mg/kg/day	NOAEL	Liver
12 Month(s)	Dog	Oral	125 mg/kg/day	NOAEL	Male reproductive system
24 Month(s)	Dog	Oral	250 mg/kg/day	NOAEL	None identified
14 Day(s)	Rat	Oral	108 g/kg	LOEL	Brain

Hydrocortisone

7 Day(s)	Mouse	Oral	140 mg/kg/day	LOAEL	Thymus
4 Day(s)	Mouse	Subcutaneous	100 mg/kg/day	LOAEL	Liver
2 Week(s)	Mouse	Subcutaneous	560 mg/kg/day	LOAEL	Liver, Bone Marrow
85 Day(s)	Rat	Subcutaneous	175 mg/kg/day	LOAEL	Adrenal gland

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

Oxytetracycline hydrochloride

2 Generation Reproductive Toxicity	Rat	Oral	18 mg/kg/day	NOAEL	No effects at maximum dose
Embryo / Fetal Development	Rat	Oral	1500 mg/kg/day	NOAEL	Maternal Toxicity
Embryo / Fetal Development	Mouse	Oral	2100 mg/kg/day	NOAEL	Embryotoxicity

Hydrocortisone

Embryo / Fetal Development	Mouse	Oral	10 mg/kg/day	LOAEL	Teratogenic
Reproductive & Fertility	Rat	Oral	210 mg/kg/day	LOAEL	Maternal Toxicity

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

Oxytetracycline hydrochloride

Bacterial Mutagenicity (Ames)	<i>Salmonella</i>	Negative
<i>In Vitro</i> Chromosome Aberration	Chinese Hamster Ovary (CHO) cells	Negative
Sister Chromatid Exchange	Chinese Hamster Ovary (CHO) cells	Negative
Micronucleus	Mouse	Negative
Mammalian Cell Mutagenicity	Mouse Lymphoma	Positive with activation

Hydrocortisone

Bacterial Mutagenicity (Ames)	<i>Salmonella</i>	Negative
Unscheduled DNA Synthesis	Rat	Negative

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11. TOXICOLOGICAL INFORMATION

Carcinogenicity: (Duration, Species, Route, Dose, End Point, Effect(s))

Oxytetracycline hydrochloride

24 Month(s)	Rat	Oral, in feed	150 mg/kg/day	NOEL	Not carcinogenic
103 Week(s)	Mouse	Oral, in feed	1372 mg/kg/day	NOEL	Not carcinogenic

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

Light Liquid Paraffin

IARC: Group 3

12. ECOLOGICAL INFORMATION

Environmental Overview: Environmental properties have not been thoroughly investigated. Releases to the environment should be avoided. See Aquatic toxicity data of the active ingredient, below:

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

Oxytetracycline hydrochloride

<i>Oncorhynchus mykiss</i> (Rainbow Trout)	ASTM EPA	LC50	96 Hours	> 116 mg/L
<i>Daphnia magna</i> (Water Flea)	ASTM EPA	EC50	48 Hours	> 102 mg/L
<i>Lepomis macrochirus</i> (Bluegill Sunfish)	ASTM EPA	LC50	96 Hours	> 94.9 mg/L
<i>Selenastrum capricornutum</i> (Green Alga)	ISO	EC50	72 Hours	4.18 mg/L

Aquatic Toxicity Comments: A greater than (>) symbol indicates that acute ecotoxicity was not observed at the maximum solubility. Since the substance is insoluble in aqueous solutions above this concentration, an acute ecotoxicity value (i.e. LC/EC50) is not achievable.

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

EU Indication of danger: Toxic to reproduction: Category 1

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15. REGULATORY INFORMATION

EU Risk Phrases:

R61 - May cause harm to the unborn child.

OSHA Label:

DANGER

May damage the unborn child.

Canada - WHMIS: Classifications

WHMIS hazard class:

Class D, Division 2, Subdivision A



Oxytetracycline hydrochloride

California Proposition 65

Inventory - United States TSCA - Sect. 8(b)

Australia (AICS):

EU EINECS/ELINCS List

developmental toxicity, initial date 10/1/91 (internal use)

Listed

Listed

218-161-2

Hydrocortisone

Inventory - United States TSCA - Sect. 8(b)

Australia (AICS):

Standard for the Uniform Scheduling
for Drugs and Poisons:

EU EINECS/ELINCS List

Listed

Listed

Schedule 2

Schedule 3

Schedule 4

200-020-1

Light Liquid Paraffin

Inventory - United States TSCA - Sect. 8(b)

Australia (AICS):

EU EINECS/ELINCS List

Listed

Listed

232-384-2

16. OTHER INFORMATION

Text of R phrases mentioned in Section 3

R61 - May cause harm to the unborn child.

R63 - Possible risk of harm to the unborn child.

Data Sources:

Publicly available toxicity information. Pfizer proprietary drug development information.

Prepared by:

Product Stewardship Hazard Communications
Pfizer Global Environment, Health, and Safety Operations

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Pfizer 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