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MATERIAL SAFETY DATA SHEET

Hydrocortisone Acetate Suppositories, 25 mg & 30 mg

Creation Date: 07-10-2003

Revision Date: 04-24-2006

SECTION 1: PRODUCT IDENTIFICATION

Product Name	Hydrocortisone Acetate Suppositories, 25 mg & 30 mg
Common Name/Trade Name	Hydrocortisone Acetate
Manufacturer	Paddock Laboratories, Inc.
Synonyms	Cortisol Acetate Suppositories
Chemical Name	Hydrocortisone Acetate
Chemical Family	Steroid/Anti-Inflammatory
Chemical Formula	C ₂₃ H ₃₂ O ₆

SECTION 2: COMPOSITION AND INGREDIENTS

CHEMICAL NAME	CAS#	%	OSHA PEL	ACGIH TLV	IDLH
Hydrocortisone Acetate	50-03-3	<2	NA	NA	NA
Hydrogenated Vegetable Oil	NA	98.6	NA	NA	NA

SECTION 3: HAZARDS IDENTIFICATION

Potential Acute and Chronic Health Effects	Hazardous in case of skin contact (irritant, permeator), of eye contact (irritant), of ingestion, of inhalation.
Pregnancy Comments	NA

SECTION 4: FIRST AID MEASURES

Skin Exposure	Thoroughly wash with mild soap and water. If irritation persists or develops, seek medical attention.
Eye Exposure	Immediately flush with water for 15 minutes. If irritation persists or develops, seek medical attention.
Inhalation	No adverse effects expected.
Ingestion	Flush out mouth with water. Seek medical attention immediately. Do not induce vomiting.

SECTION 5: FIRE / EXPLOSION HAZARDS & FIREFIGHTING MEASURES

Flammability of the Product	Maybe combustible at high temperatures.
Auto-ignition Temperature	NA
Flash Points	NA
Flammable Limits (in air by volume, %)	Lower: NA Upper: NA
Fire Extinguishing Equipment	Use extinguishing agent suitable for type of surrounding fire. Water Spray: OK Foam: OK Carbon Dioxide: OK Dry Chemical: OK Other: Any "ABC" class
Unusual Fire and Explosion Hazards	This material may produce toxic carbon monoxide and carbon dioxide fumes if heated to decomposition.
Explosion Hazards in presence of Various substances	NA
Firefighting Procedures	Firefighters should wear full protective gear including self contained breathing apparatus.

SECTION 6: SPILL AND LEAK PROCEDURES

Spills	Use appropriate tools to put the spilled solid in a convenient waste disposal container. Finish cleaning by spreading water on the contaminated surface and dispose or according to local and regional authority requirements.
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SECTION 7: HANDLING AND STORAGE

Work and Hygiene Practices	As with all chemicals, avoid getting this product ON YOU or IN YOU. Do not eat, drink or smoke or apply cosmetics while handling the product. Wash hands thoroughly after handling.
Storage and Handling Practices	Store at controlled room temperatures below 30°C (86°F). Keep away from sources of ignition. Wash hands before eating. Avoid contact with eyes, skin and clothing.

SECTION 8: EXPOSURE CONTROLS / PERSONAL PROTECTION

Engineering Controls	Under normal conditions of use, no special controls are required.
<u>Personal Protection</u>	
Respiratory Protection	No special requirements.
Eye Protection	Safety glasses or goggles.
Hand Protection	Gloves.
Body Protection	Lab coat.

SECTION 9: PHYSICAL / CHEMICAL PROPERTIES

Physical state and appearance	White to creamy white suppository.
Molecular Weight	NA
Boiling Point	NA
Vapor Density (AIR=1)	NA
Vapor Pressure (mm Hg)	NA
Melting/Freezing Point	32-35°C

pH	NA
Water Solubility	NA
Specific Gravity (Water =1)	<1
Water Reactivity	No
Volatility	NA
Odor	Practically odorless.

SECTION 10: STABILITY AND REACTIVITY

Stability	This product is stable.
Incompatible Temperature	NA
Incompatible Materials	NA
Conditions of Instability	NA
Hazardous Polymerization	NA
Hazardous Decomposition	May produce toxic carbon monoxide and carbon dioxide fumes if heated to decomposition.
Conditions to Avoid	None known at this time.

SECTION 11: TOXICOLOGICAL INFORMATION

Toxicity (information for Hydrocortisone Acetate)	Intraperitoneal Rat LD ₅₀ : 2300 mg/Kg Subcutaneous Mouse LD ₅₀ : 45 mg/Kg
Suspected Cancer Agent	No

SECTION 12: ECOLOGICAL INFORMATION

Environmental Stability	NA
Ecotoxicity	NA
Products of Biodegradation	The products of degradation are more toxic.
Special Remarks	NA

SECTION 13: WASTE DISPOSAL

Dispose of material according to local, state, federal and environmental disposal regulations or company operating procedures.

SECTION 14: TRANSPORTATION INFORMATION

DOT classification	Not a DOT controlled material.
Identification	NA
DOT Label(s) Required	NA

SECTION 15: REGULATORY INFORMATION

US SARA Reporting Requirements	311/312 Hazard Categories: Immediate Health, 313 Reportable Ingredients: None.
Federal and State Regulations	NA
U.S. TSCA Inventory Status	Hydrocortisone Acetate Suppository is a “drug” as defined by the Federal Food, Drug and Cosmetic Act and is therefore not a chemical substance under TSCA.

SECTION 16: OTHER INFORMATION

DEFINITIONS OF ABBREVIATIONS USED:

ACGIH	American Conference of Governmental Industry Hygienists
CAS	Chemical Abstract Service
IARC	International Agency for Research on Cancer
IDLH	Immediately Dangerous to Life or Health Level
LC₅₀	Medial Lethal Concentration
LD₅₀	Medial Lethal Dose
MSHA	Mine Safety and Health Administration
NA	Not Available
ND	No Data
NE	Not Established
NIOSH	National Institute for Occupational Safety and Health
NTP	National Toxicology Program
OSHA	Occupational Safety and Health Administration
PEL	Permissible Exposure Limit
SARA	Superfund Amendments and Reauthorization Act
STEL	Short Term Exposure Limit
TLV	Threshold Limit Value
TWA	Time Weighted Average

SECTION 17: DISCLAIMER

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