

SAFETY DATA SHEET

Issuing Date 28-May-2015

Revision Date 01-Jun-2015

Revision Number 3



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

Product identifier

Product Name De La Cruz[®] Hydrocortisone Ointment 1%

Other means of identification

Synonyms Pomada De Hidrocortisona 1%

Recommended use of the chemical and restrictions on use

Recommended Use Medicinal products

Uses advised against No information available

Details of the supplier of the safety data sheet

Supplier Name DLC Laboratories, Inc.

Supplier Address 7008 Marcelle St.
Paramount
CA
90723
US

Supplier Phone Number Contact Phone 1-562-602-2184
Fax: 562-602-1931

Supplier Email info@dlclabs.com

Emergency telephone number Emergency: 1-800-858-3889
CHEMTREC: 1-800-424-9300



2. HAZARDS IDENTIFICATION


Classification

This chemical is considered hazardous by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200)

Reproductive Toxicity	Category 1A
Specific target organ toxicity (repeated exposure)	Category 2

GHS Label elements, including precautionary statements

Emergency Overview

Signal word	Danger
Hazard Statements	
May damage fertility or the unborn child	
May cause damage to organs through prolonged or repeated exposure	
	
Appearance	Physical state
White	Ointment
Odor	Odorless

Precautionary Statements - Prevention

Obtain special instructions before use
 Do not handle until all safety precautions have been read and understood
 Use personal protective equipment as required
 Do not breathe dust/fume/gas/mist/vapors/spray

Precautionary Statements - Response

IF exposed or concerned: Get medical advice/attention

Precautionary Statements - Storage

Store locked up

Precautionary Statements - Disposal

Dispose of contents/container to an approved waste disposal plant

Hazards not otherwise classified (HNOC)

Not applicable

Unknown Toxicity

5% of the mixture consists of ingredient(s) of unknown toxicity

Other information

No information available

Interactions with Other Chemicals

No information available.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name	CAS No	Weight-%	Trade Secret
Supplier Trade Secret	Proprietary	3 - 7	*
Supplier Trade Secret	Proprietary	1 - 5	*

*The exact percentage (concentration) of composition has been withheld as a trade secret

4. FIRST AID MEASURES**First aid measures****General Advice**

Show this safety data sheet to the doctor in attendance.

Eye contact

Rinse thoroughly with plenty of water, also under the eyelids. If symptoms persist, call a physician.

Skin contact

Wash with soap and water.

Inhalation

Remove to fresh air.

Ingestion

Rinse mouth immediately and drink plenty of water. Never give anything by mouth to an unconscious person.

Most important symptoms and effects, both acute and delayed

Most Important Symptoms and Effects No information available.

Indication of any immediate medical attention and special treatment needed**Notes to Physician**

Treat symptomatically.

5. FIRE-FIGHTING MEASURES

Suitable Extinguishing Media

Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

Unsuitable extinguishing media

CAUTION: Use of water spray when fighting fire may be inefficient.

Specific hazards arising from the chemical

No information available.

Hazardous Combustion Products

Carbon oxides.

Explosion Data

Sensitivity to Mechanical Impact No.

Sensitivity to Static Discharge No.

Protective equipment and precautions for firefighters

As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures

Personal precautions Avoid contact with eyes. Ensure adequate ventilation. Use personal protective equipment as required. Evacuate personnel to safe areas.

Other Information Refer to protective measures listed in Sections 7 and 8.

Environmental precautions

Environmental precautions Refer to protective measures listed in Sections 7 and 8.

Methods and material for containment and cleaning up

Methods for containment Prevent further leakage or spillage if safe to do so.

Methods for cleaning up Soak up with inert absorbent material. Pick up and transfer to properly labeled containers.

7. HANDLING AND STORAGE

Precautions for safe handling

Handling Handle in accordance with good industrial hygiene and safety practice. Avoid contact with skin, eyes or clothing. Do not eat, drink or smoke when using this product. Take off contaminated clothing and wash before reuse.

Conditions for safe storage, including any incompatibilities

Storage Keep container tightly closed. Store locked up.

Incompatible Products None known based on information supplied.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters

Exposure Guidelines

Chemical Name	ACGIH TLV	OSHA PEL	NIOSH IDLH
Supplier Trade Secret	STEL = 10 mg/m ³ TWA: 5 mg/m ³	TWA: 5 mg/m ³ (vacated) TWA: 5 mg/m ³	IDLH: 2500 mg/m ³ TWA: 5 mg/m ³ STEL: 10 mg/m ³

ACGIH TLV: American Conference of Governmental Industrial Hygienists - Threshold Limit Value OSHA PEL: Occupational Safety and Health Administration - Permissible Exposure Limits NIOSH IDLH Immediately Dangerous to Life or Health

Other Exposure Guidelines See section 15 for national exposure control parameters Vacated limits revoked by the Court of Appeals decision in AFL-CIO v. OSHA, 965 F.2d 962 (11th Cir., 1992)

Appropriate engineering controls

Engineering Measures Showers
Eyewash stations
Ventilation systems

Individual protection measures, such as personal protective equipment

Eye/face protection No special protective equipment required.

Skin and body protection Wear protective gloves and protective clothing.

Respiratory protection No protective equipment is needed under normal use conditions. If exposure limits are exceeded or irritation is experienced, ventilation and evacuation may be required.

Hygiene Measures Handle in accordance with good industrial hygiene and safety practice. Do not eat, drink or smoke when using this product. Wash hands before breaks and immediately after handling the product.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical and Chemical Properties

Physical state	Ointment	Odor	Odorless
Appearance & Color	White	Odor Threshold	No information available

<u>Property</u>	<u>Values</u>	<u>Remarks</u>	<u>Method</u>
pH	3	None known	
Melting / freezing point	No data available	None known	
Boiling point / boiling range	No data available	None known	
Flash Point	No data available	None known	
Evaporation Rate	No data available	None known	
Flammability (solid, gas)	No data available	None known	
Flammability Limit in Air			
Upper flammability limit	No data available		
Lower flammability limit	No data available		
Vapor pressure	No data available	None known	
Vapor density	No data available	None known	
Specific Gravity	.98	None known	
Water Solubility	Insoluble in water	None known	
Solubility in other solvents	No data available	None known	
Partition coefficient: n-octanol/water	No data available	None known	
Autoignition temperature	No data available	None known	
Decomposition temperature	No data available	None known	
Kinematic viscosity	No data available	None known	
Dynamic viscosity	No data available	None known	
Explosive properties	No data available		
Oxidizing properties	No data available		

Other Information

Softening Point	No data available
VOC Content (%)	No data available
Particle Size	No data available
Particle Size Distribution	

10. STABILITY AND REACTIVITY**Reactivity**

No data available.

Chemical stability

Stable under recommended storage conditions.

Possibility of Hazardous Reactions

None under normal processing.

Hazardous Polymerization

Hazardous polymerization does not occur.

Conditions to avoid

None known based on information supplied.

Incompatible materials

None known based on information supplied.

Hazardous Decomposition Products

Carbon oxides.

11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure**Product Information**

Inhalation	Specific test data for the substance or mixture is not available.
Eye contact	Specific test data for the substance or mixture is not available.
Skin contact	Specific test data for the substance or mixture is not available.
Ingestion	Specific test data for the substance or mixture is not available.

Component Information

Chemical Name	Oral LD50	Dermal LD50	Inhalation LC50
Supplier Trade Secret	-	-	= 2062 ppm (Rat) 4 h
Supplier Trade Secret	= 5000 mg/kg (Rat)	-	-

Information on toxicological effects

Symptoms No information available.

Delayed and immediate effects as well as chronic effects from short and long-term exposure

Sensitization No information available.

Mutagenic Effects No information available.

Carcinogenicity The table below indicates whether each agency has listed any ingredient as a carcinogen.

Chemical Name	ACGIH	IARC	NTP	OSHA
Supplier Trade Secret	A4	Group 3		

ACGIH (American Conference of Governmental Industrial Hygienists)

A4 - Not Classifiable as a Human Carcinogen

IARC (International Agency for Research on Cancer)

Group 3 - Not Classifiable as to Carcinogenicity in Humans

Reproductive toxicity Contains a known or suspected reproductive toxin.

STOT - single exposure No information available.

STOT - repeated exposure Causes damage to organs through prolonged or repeated exposure. Based on classification criteria from the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200), this product has been determined to cause systemic target organ toxicity from chronic or repeated exposure. (STOT RE).

Chronic Toxicity No known effect based on information supplied. Contains a known or suspected carcinogen. Contains a known or suspected reproductive toxin. Possible risk of irreversible effects. Avoid repeated exposure. Prolonged exposure may cause chronic effects.

Target Organ Effects

Reproductive System. Eyes. Respiratory system. Skin. Lungs.

Aspiration Hazard

No information available.

Numerical measures of toxicity Product Information

The following values are calculated based on chapter 3.1 of the GHS document

Not applicable

12. ECOLOGICAL INFORMATION

Ecotoxicity

The environmental impact of this product has not been fully investigated.

Persistence and Degradability

No information available.

Bioaccumulation

No information available

Other adverse effects

No information available.

13. DISPOSAL CONSIDERATIONS

Waste treatment methods

Disposal methods

This material, as supplied, is not a hazardous waste according to Federal regulations (40 CFR 261). This material could become a hazardous waste if it is mixed with or otherwise comes in contact with a hazardous waste, if chemical additions are made to this material, or if the material is processed or otherwise altered. Consult 40 CFR 261 to determine whether the altered material is a hazardous waste. Consult the appropriate state, regional, or local regulations for additional requirements.

Contaminated Packaging

Dispose of contents/containers in accordance with local regulations.

California Hazardous Waste Codes 311

14. TRANSPORT INFORMATION

DOT

Proper Shipping Name
Hazard Class

NOT REGULATED
NON REGULATED
N/A

TDG

Not regulated

MEX

Not regulated



<u>ICAO</u>	Not regulated
<u>IATA</u>	Not regulated
Proper Shipping Name	NON REGULATED
Hazard Class	N/A
<u>IMDG/IMO</u>	Not regulated
Hazard Class	N/A
<u>RID</u>	Not regulated
<u>ADR</u>	Not regulated
<u>ADN</u>	Not regulated

15. REGULATORY INFORMATION

International Inventories

TSCA	Complies
DSL	All components are listed either on the DSL or NDSL.

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory
 DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List

US Federal Regulations

SARA 313

Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product does not contain any chemicals which are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372

SARA 311/312 Hazard Categories

Acute Health Hazard	No
Chronic Health Hazard	Yes
Fire Hazard	No
Sudden release of pressure hazard	No
Reactive Hazard	No

CWA (Clean Water Act)

This product does not contain any substances regulated as pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42)

CERCLA

This material, as supplied, does not contain any substances regulated as hazardous substances under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302) or the Superfund Amendments and Reauthorization Act (SARA) (40 CFR 355). There may be specific reporting requirements at the local, regional, or state level pertaining to releases of this material

US State Regulations

California Proposition 65

This product does not contain any Proposition 65 chemicals.

U.S. State Right-to-Know Regulations

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International Regulations**Mexico****National occupational exposure limits**

Component	Carcinogen Status	Exposure Limits
Supplier Trade Secret (3 - 7)		Mexico: TWA= 5 mg/m ³ Mexico: STEL= 10 mg/m ³

*Mexico - Occupational Exposure Limits - Carcinogens***Canada****WHMIS Hazard Class**

Not determined

16. OTHER INFORMATION

NFPA	Health Hazards 1	Flammability 0	Instability 0	Physical and Chemical Hazards -
HMIS	Health Hazards 1*	Flammability 0	Physical Hazard 0	Personal Protection X

Chronic Hazard Star Legend * = Chronic Health Hazard**Prepared By**

Product Stewardship
23 British American Blvd.
Latham, NY 12110
1-800-572-6501

Disclaimer

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text

End of Safety Data Sheet