



# Safety Data Sheet

Issue date 08-Dec-2014

Revision date 08-Dec-2014

Version 2

## 1. Identification Of The Preparation And Of The Company

### Product Identifier

**Product name** Hydrocortisone Acetate Suppository 25 mg

### Other means of Identification

**Product code** 0503

### Recommended use of the chemical and restrictions on use

**Recommended Use** Pharmaceutical product for human use.

### Details of the Supplier of the Safety Data Sheet

#### **Manufacturer Address**

G&W Laboratories, Inc.  
111 Coolidge Street  
South Plainfield, NJ 07080-3895  
Telephone: 800-922-1038

### Emergency Telephone Number

**Emergency telephone** Chemtrec 1-800-424-9300

## 2. Hazards Identification

### Classification

#### **OSHA Regulatory Status**

This chemical is not considered hazardous by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.122)

Not a dangerous substance or mixture according to the Globally Harmonized System (GHS)

### Label Elements

#### **Emergency Overview**

**Appearance** A white, bullet shaped  
suppository

**Physical State** Solid

**Odor** No information available

### Hazards Not Otherwise Classified (HNOC)

#### **Other Information**

No information available

## 3. Composition/Information on Ingredients

Chemical name	CAS No	weight-%
Hydrocortisone Acetate USP	50-03-3	1.39

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

#### 4. First Aid Measures

##### First Aid Measures

<b>General advice</b>	Call 911 or emergency medical service. Do not delay care and transport of a seriously injured person.
<b>Eye contact</b>	Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids. Consult a physician.
<b>Skin contact</b>	Wash skin with soap and water.
<b>Inhalation</b>	Remove to fresh air.
<b>Ingestion</b>	Clean mouth with water and drink afterwards plenty of water.
<b>Self-protection of the first aider</b>	First-Responder: Always use Universal Personal Protective Equipment.

##### Most important symptoms and effects, both acute and delayed

<b>Symptoms</b>	No information available.
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##### Indication of any immediate medical attention and special treatment needed

<b>Note to physicians</b>	Treat symptomatically.
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#### 5. Fire-fighting Measures

##### Suitable extinguishing media

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

<b>Unsuitable extinguishing media</b>	Caution: Use of water spray when fighting fire may be inefficient.
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##### Specific hazards arising from the chemical

No information available.

##### Explosion data

**Sensitivity to mechanical impact** None.

**Sensitivity to static discharge** None.

##### 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

<b>Personal precautions</b>	Ensure adequate ventilation, especially in confined areas.
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##### Environmental precautions

<b>Environmental precautions</b>	See Section 12 for additional Ecological Information.
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##### Methods and material for containment and cleaning up

<b>Methods for containment</b>	Prevent further leakage or spillage if safe to do so.
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<b>Methods for cleaning up</b>	Pick up and transfer to properly labeled containers.
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## 7. Handling and Storage

### Precautions for safe handling

**Advice on safe handling** Handle in accordance with good industrial hygiene and safety practice.

### Conditions for safe storage, including any incompatibilities

**Storage conditions** Keep containers tightly closed in a dry, cool and well-ventilated place.

**Incompatible materials** None known based on information supplied.

## 8. Exposure Controls/Personal Protection

### Control parameters

**Exposure guidelines** This product, as supplied, does not contain any hazardous materials with occupational exposure limits established by the region specific regulatory bodies.

### Appropriate engineering controls

**Engineering controls** Showers  
Eyewash stations  
Ventilation systems.

### Individual protection measures, such as personal protective equipment

**Eye/face protection** No special technical protective measures are necessary.

**Skin and Body protection** No special technical protective measures are necessary.

**Respiratory protection** If exposure limits are exceeded or irritation is experienced, NIOSH/MSHA approved respiratory protection should be worn. Positive-pressure supplied air respirators may be required for high airborne contaminant concentrations. Respiratory protection must be provided in accordance with current local regulations.

**General hygiene considerations** Handle in accordance with good industrial hygiene and safety practice.

## 9. Physical and Chemical Properties

### Information on basic physical and chemical properties

<b>Physical State</b>	Solid	<b>Odor</b>	No information available
<b>Appearance</b>	A white, bullet shaped suppository	<b>Odor Threshold</b>	No information available
<b>Color</b>	White		
<b><u>Property</u></b>	<b><u>Values</u></b>	<b><u>Remarks • Method</u></b>	
<b>pH</b>	No information available		
<b>Melting point/freezing point</b>	No information available		
<b>Boiling point / boiling range</b>	No information available		
<b>Flash point</b>	No information available		
<b>Evaporation Rate</b>	No information available		
<b>Flammability (solid, gas)</b>	No information available		
<b>Flammability limit in air</b>			
<b>Upper flammability limit:</b>	No information available		
<b>Lower flammability limit:</b>	No information available		
<b>Vapor pressure</b>	No information available		
<b>Vapor density</b>	No information available		
<b>Specific gravity</b>	No information available		
<b>Water solubility</b>	No information available		
<b>Solubility in other solvents</b>	No information available		

Partition coefficient	No information available
Autoignition temperature	No information available
Decomposition temperature	No information available
Kinematic viscosity	No information available
Dynamic viscosity	No information available
Explosive properties	No information available
Oxidizing properties	No information available

**Other Information**

Softening point	No information available
Molecular weight	No information available
VOC content (%)	No information available
Density	No information available
Bulk density	No information available

**10. Stability and Reactivity****Reactivity**

This product is stable under normal conditions.

**Chemical stability**

Stable under recommended storage conditions.

**Possibility of hazardous reactions**

None under normal processing.

**Conditions to avoid**

Avoid heat, light, and contact with incompatible chemicals.

**Incompatible materials**

None known based on information supplied.

**Hazardous Decomposition Products**

None known based on information supplied.

**11. Toxicological Information****Information on likely routes of exposure**

<b>Product Information</b>	Product does not present an acute toxicity hazard based on known or supplied information. Suppository for rectal use only.
<b>Inhalation</b>	Not an expected route of exposure.
<b>Eye contact</b>	Not an expected route of exposure.
<b>Skin contact</b>	No known hazard in contact with skin.
<b>Ingestion</b>	Not an expected route of exposure.

**Information on toxicological effects**

<b>Symptoms</b>	No information available.
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**Delayed and immediate effects as well as chronic effects from short and long-term exposure**

<b>Sensitization</b>	No information available.
<b>Germ Cell Mutagenicity</b>	No information available.
<b>Carcinogenicity</b>	No information available.
<b>Reproductive Toxicity</b>	No information available.

STOT - single exposure	No information available.
STOT - repeated exposure	No information available.
Aspiration Hazard	No information available.

**Numerical measures of toxicity - Product Information****12. Ecological Information****Ecotoxicity**

No information available

**Persistence and degradability**

No information available.

**Bioaccumulation**

No information available.

**Other adverse effects**

No information available

**13. Disposal Considerations****Waste treatment methods**

**Disposal of wastes** Disposal should be in accordance with applicable regional, national and local laws and regulations.

**Contaminated packaging** Do not reuse container.

**14. Transport Information**

**DOT** Not regulated

**TDG** Not regulated

**ICAO (air)** Not regulated

**IATA** Not regulated

**IMDG** Not regulated

**15. Regulatory information****International Inventories**

TSCA	Does not comply
DSL/NDL	Does not comply
EINECS/ELINCS	Does not comply
ENCS	Does not comply
IECSC	Does not comply
KECL	Does not comply
PICCS	Does not comply
AICS	Does not comply

**Legend:**

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory

DSL/NDL - Canadian Domestic Substances List/Non-Domestic Substances List

EINECS/ELINCS - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances

ENCS - Japan Existing and New Chemical Substances

IECSC - China Inventory of Existing Chemical Substances

KECL - Korean Existing and Evaluated Chemical Substances

PICCS - Philippines Inventory of Chemicals and Chemical Substances

AICS - Australian Inventory of Chemical Substances

**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	No
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****U.S. EPA Label information**

EPA Pesticide registration number Not applicable

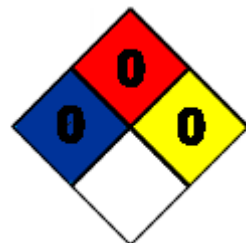
**16. Other information****NFPA**

Health Hazards 0

Flammability 0

Instability 0

Physical and chemical properties -

**HMIS**

Health Hazards 0

Flammability 0

Physical Hazards 0

Personal Protection X

0	Health
0	Flammability
0	Reactivity
X	Personal Protection

Prepared by G&W Laboratories, Inc.  
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Revision note

New OSHA/GHS format.

**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**