



SAFETY DATA SHEET

Safety Data Sheet according to Regulation (EC) No. 1907/2006 (REACH)

Issuing Date 07-Dec-2016

Revision Date 23-Aug-2017

Revision Number 2.02

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Product Name	Sudocrem® Antiseptic Healing Cream
Synonyms	Sudocrem® Healing Cream (Australia, New Zealand); Sudocrem® (Canada); Dermocrem® (Puerto Rico)
CAS	Not available
EINECS	No information available
Index No	No information available
Reach Registration Number	No information available

1.2. Relevant identified uses of the substance or mixture and uses advised against

Identified Use	Pharmaceutical
Uses advised against	No information available

1.3. Details of the supplier of the safety data sheet

Manufacturer, Supplier	Teva UK Limited Ridings Point Whistler Drive, Castleford West Yorkshire UK WF10 5HX
-------------------------------	---

For further information, please contact

E-mail Address	https://sudocrem.co.uk/contact
-----------------------	---

1.4. Emergency Telephone Number

Emergency Telephone Number	United States/Canada/Puerto Rico: 1-800/424-9300 (Chemtrec) [24-hrs] International: 01-703-527-3887 (Chemtrec) [24-hours]
-----------------------------------	--

Australia/New Zealand Contact:	Nice Pak Products Pty Ltd 120 Woodlands Drive, Braeside VIC 3195
---------------------------------------	---

Telephone: 1800 506 750(AU) | 0800 555 895 (NZ)

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008
Exempt from requirements - regulated as a medicinal product.

2.2. Label Elements

Exempt from requirements - regulated as a medicinal product

2.3. Other hazards

None known

SECTION 3: Composition/information on ingredients

3.1. Substances

N.A.

3.2. Mixtures

Chemical Name	EC No	REACH Reg. No	CAS-No	Weight %	CLP/GHS classification
Zinc Oxide	EEC No. 215-222-5	01-2119463881-32-0075	1314-13-2	Proprietary	Acute aquatic Tox.1; H400 Chronic aquatic Tox.1; H410
Excipients	-	Not available	-	proprietary	-

Full text of phrases reported in section 16.

SECTION 4: First aid measures

4.1. Description of first aid measures

Eye Contact	Flush eyes with water for at least 15 minutes. Get medical attention if eye irritation develops or persists.
Skin Contact	Wash off immediately with plenty of water. Get medical advice/attention if you feel unwell.
Ingestion	If swallowed, rinse mouth with water (only if the person is conscious). Do NOT induce vomiting. Get medical advice/attention if you feel unwell.
Inhalation	Remove person to fresh air. If signs/symptoms continue, get medical attention.

4.2. Most important symptoms and effects, both acute and delayed

See product insert.

4.3. Indication of immediate medical attention and special treatment needed

Notes to Physician Treat symptomatically.

SECTION 5: Fire-fighting measures

5.1. Extinguishing media

Suitable Extinguishing Media

Water spray. Carbon dioxide (CO₂). Foam. Dry powder. Halons.

Unsuitable extinguishing media

No information available.

5.2. Special hazards arising from the substance or mixture

Thermal decomposition can lead to release of irritating gases and vapors. Combustible material.

5.3. Advice for firefighters

Special protective equipment for firefighters

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

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Use personal protective equipment. Avoid contact with dusts/fumes/mists/vapors. Avoid all unnecessary contact.

6.1.1. For non-emergency personnel

Protective equipment See section 8

Emergency procedures Evacuate the danger area and alert emergency team

6.1.2. For emergency responders

See section 8

6.2. Environmental Precautions

Prevent entry into waterways, sewers, basements or confined areas. Prevent further leakage or spillage if safe to do so. Report according to local regulations.

6.3. Methods and materials for containment and cleaning up

6.3.1. Methods for Containment

No information available.

6.3.2. For cleaning up

Take up mechanically and collect in suitable container for disposal.

6.3.3. Other information

No information available

6.4. Reference to other sections

See Sections 8 & 13 for additional information.

SECTION 7: Handling and storage

7.1. Precautions for Safe Handling

Handling

Avoid contact with skin, eyes and clothing. Handle in accordance with good industrial hygiene and safety practice. Do not breathe vapors/dust. Provide appropriate exhaust ventilation at places where dust is formed.

Hygiene Measures

Handle in accordance with good industrial hygiene and safety practice.

7.2. Conditions for safe storage, including any incompatibilities

Store in accordance with: Product packaging.

7.3. Specific end use(s)

Exposure Scenario

No information available.

Other Guidelines

No information available.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Exposure Limits	Not applicable
Biological occupational exposure limits	No information available.
Derived No Effect Level (DNEL)	No information available.
Predicted No Effect Concentration (PNEC)	No information available.

8.2. Exposure controls

Engineering Measures	Appropriate Engineering Controls.
Personal protective equipment	
Eye/face protection	Use eye protection appropriate for the task.
Skin protection:	
- Body protection	Use protective clothing appropriate for the task.
- Hand protection	Use appropriate protective gloves.
Respiratory Protection	Use appropriate respiratory protection.
Environmental exposure controls	No information available.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance	
Color	White
Physical State	Semi-Solid
Odor	No information available
Odor Threshold	No information available
pH	No information available
Melting Point/Range	No information available
Boiling Point/Range	No information available
Flash Point	No information available
Evaporation Rate	No information available
Flammability (solid, gas)	No information available
Flammability Limits in Air	
Upper	No information available
Lower	No information available
Vapor Pressure	No information available
Density	1.0301.07 gr/ml
Vapor Density	No information available
Relative Density	No information available
Solubility	No information available
Autoignition Temperature	No information available
Decomposition Temperature	No information available
Viscosity	No information available
Explosive Properties	No information available
Oxidizing Properties	No information available

9.2. Other information

No information available

SECTION 10: Stability and reactivity

10.1. Reactivity

No information available.

10.2. Chemical Stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

None under normal processing.

10.4. Conditions to avoid

Heat, flames and sparks.

10.5. Incompatible materials.

None in particular.

10.6. Hazardous decomposition products

None under normal use.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

acute toxicity	No information available.
skin corrosion/irritation	No information available.
serious eye damage/irritation	No information available.
respiratory or skin sensitization	No information available.
germ cell mutagenicity	No information available.
carcinogenicity	No information available.
reproductive toxicity	No information available.
STOT - single exposure	No information available.
STOT - repeated exposures	No information available.
aspiration hazard	No information available.

Other Information

No information available.

SECTION 12: Ecological information

12.1. Toxicity

Ecotoxicity effects

Chemical Name	Toxicity to Algae	Toxicity to Fish	Microtox	Daphnia Magna (Water Flea)
Zinc Oxide	IC50 (green algae): 0.17 mg/l; 72H	LC50 (rainbow trout): 1.1 mg/l; 96H		LC50 (Daphnia magna) >1000 mg/l;48h

12.2. Persistence and degradability

No information available.

12.3. Bioaccumulative potential

No information available.

12.4. Mobility in soil

No information available.

12.5. Results of PBT and vPvB assessment

No information available.

12.6. Other adverse effects

No information available

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste from Residues/Unused Products

Dispose of in accordance with local regulations.

Contaminated Packaging

Empty containers should be taken for local recycling, recovery or waste disposal.

SECTION 14: Transport information

14.1. UN-No	3077
14.2. Proper Shipping Name	Environmentally hazardous substances, solid, n.o.s. (Zinc Oxide)
14.3. Transport hazard class(es) ADR / RID / ADN (land transport)	9
IMDG (sea transport)	9
IATA / ICAO (air transport)	9
14.4. Packing Group	III
14.5. Environmental hazards Marine Pollutant	Yes
14.6. Special precautions for user Emergency No.	-
ADR/RID-Labels	-
14.7. Technical name	-
Ship type	-
Annex II	-

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

- Regulation 1907/2006/EC (REACH) and successive modifications
- Regulation 1272/2008 (CLP) and successive modifications
- D.Lgs. 81/2008 and successive modifications and Dir. 2009/161/EU
- REGULATION (EU) 2015/830

This safety data sheet complies with the requirements of: GHS

15.2. Chemical Safety Assessment

No information available

SECTION 16: Other information

CLP/GHS - Regulation

Hazard Statements

Full text of H-Statements referred to under sections 2 and 3

H400 - Very toxic to aquatic life

H410 - Very toxic to aquatic life with long lasting effects

Training appropriate for workers is required to ensure protection of human health and environment.

SDS sections updated

Section 1

Source of data

R.T.E.C.S. - REGISTRY OF TOXIC EFFECTS OF CHEMICAL SUBSTANCES

A.C.G.I.H. - AMERICAN CONFERENCE OF INDUSTRIAL HYGIENISTS

H.S.D.B. - HAZARDOUS SUBSTANCES DATA BANK

N.I.O.S.H. - NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH

N.T.P. - NATIONAL TOXICOLOGY PROGRAM

I.A.R.C. - INTERNATIONAL AGENCY FOR RESEARCH ON CANCER

ECHA (European chemicals agency) databases

FDA (Food & Drug administration) database

EMA (European Medicines agency) documents

ChemAdvisor

Chemspider database

Issuing Date

07-Dec-2016

Revision Date

23-Aug-2017

Revision Note

Not applicable

Disclaimer

The information provided on this SDS 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 guide for safe handling, use, processing, storage, transportation, and disposal of the designated material and is not to be considered as 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 material or in any process, unless specified in the text.

End of Safety Data Sheet