

SAFETY DATA SHEET
A&D Zinc oxide Cream

122000013608

Version 1.0

Revision Date 09/30/2015

1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING**Product information**

Product Name: A&D Zinc oxide Cream
SDS Number: 122000013608

Use : Consumer

Company

BAYER HEALTHCARE LLC
Consumer Care
100 Bayer Boulevard PO Box 915
Whippany, NJ 07981-0915
UNITED STATES OF AMERICA
(800) 743-5423

In case of emergency: (800) 331-4536
Chemtec: (800) 424-9300
BAYER INFORMATION PHONE:(800) 331-4536 OR (800) 743-5423

2. HAZARDS IDENTIFICATION**Emergency Overview**

Colour: white **Form:** liquid **Odour:** characteristic.

GHS Classification:

Not a dangerous substance / mixture according to GHS.

GHS Label element:

This material is not subject to the Federal OSHA Hazard Communication Standard 29 CFR 1910.1200.

3. COMPOSITION/INFORMATION ON INGREDIENTS

| Weight percent | Components | CAS-No. |
|-----------------------|-------------------|----------------|
| 3% | Propane-1,2-diol | 57-55-6 |
| 10% | Zinc oxide | 1314-13-2 |

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1%

Paraffin solid

8002-74-2

4. FIRST AID MEASURES

General advice: No hazards which require special first aid measures.

If inhaled: Not an expected entry route.

In case of skin contact: If skin irritation persists, call a physician.

In case of eye contact: Immediately flush eye(s) with plenty of water.

If swallowed: Rinse mouth with water. Consult a physician if necessary.

Contact Number: Use the Bayer Emergency Number in Section 1

5. FIREFIGHTING MEASURES

Suitable extinguishing media: Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.

Unsuitable extinguishing media: High volume water jet

Specific hazards during firefighting: Fire may cause evolution of: Carbon monoxide (CO)
Carbon dioxide (CO₂)

Special protective equipment for firefighters: In the event of fire, wear self-contained breathing apparatus.

Further information: Prevent fire extinguishing water from contaminating surface water or the ground water system.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions: Use personal protective equipment.

Methods for cleaning up: Cover spilled product with liquid-binding material (sand, silica gel, acid binder, universal binder, hybilat). Take up mechanically and fill into labeled, closable containers.

Additional advice: No special precautions required.

Further Accidental Release Notes No special precautions required.

7. HANDLING AND STORAGE

Handling:

Industrial uses: No special handling advice required.

No special protective measures against fire required.

Storage:

Do not use after expiration date.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Zinc oxide (1314-13-2)

US. ACGIH Threshold Limit Values

Time Weighted Average (TWA): 2 mg/m³ (Respirable fraction.)

US. ACGIH Threshold Limit Values

Short Term Exposure Limit (STEL): 10 mg/m³ (Respirable fraction.)

US. NIOSH: Pocket Guide to Chemical Hazards

Recommended exposure limit (REL): 5 mg/m³ (Dust.)

US. NIOSH: Pocket Guide to Chemical Hazards

Recommended exposure limit (REL): 5 mg/m³ (Fume.)

US. NIOSH: Pocket Guide to Chemical Hazards

Ceiling Limit Value and Time Period (if specified): 15 mg/m³ (Dust.)

US. NIOSH: Pocket Guide to Chemical Hazards

Short Term Exposure Limit (STEL): 10 mg/m³ (Fume.)

US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000)

Permissible exposure limit: 15 mg/m³ (Total dust.)

US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000)

Permissible exposure limit: 5 mg/m³ (Fume.)

US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000)

Permissible exposure limit: 5 mg/m³ (Respirable fraction.)

Propane-1,2-diol (57-55-6)

US. OARS. WEELs Workplace Environmental Exposure Level Guide

Time Weighted Average (TWA): 10 mg/m³ (Aerosol.)

Paraffin solid (8002-74-2)

US. ACGIH Threshold Limit Values

Time Weighted Average (TWA): 2 mg/m³ (Fume.)

US. NIOSH: Pocket Guide to Chemical Hazards

Recommended exposure limit (REL): 2 mg/m³ (Fume.)

Respiratory protection:

Recommended Filter type: Organic vapor with prefilter

None required for consumer use of this product.

Hand protection:

Chemically resistant gloves.
None required for consumer use of this product.

Eye protection:

Safety glasses

None required for consumer use of this product.

Hygiene measures:

Cleanliness Guidelines (GMP) for manufacturing of drugs must be observed!

Other protective measures:

Wear suitable protective equipment.

Please consult label for end-user requirements.

9. PHYSICAL AND CHEMICAL PROPERTIES

| | |
|------------------------------|--|
| Form: | liquid |
| Colour: | white |
| Odour: | characteristic |
| Odour Threshold: | No applicable information is available |
| Melting point: | No applicable information is available |
| Boiling point/boiling range: | No applicable information is available |
| Density: | No applicable information is available |
| Bulk density: | No applicable information is available |
| Vapour pressure: | No applicable information is available |
| Viscosity, dynamic: | No applicable information is available |
| Viscosity, kinematic: | No applicable information is available |
| Flow time: | No applicable information is available |
| Surface tension: | No applicable information is available |
| Miscibility with water: | No applicable information is available |
| Water solubility: | No applicable information is available |
| pH: | No applicable information is available |
| Relative density: | No applicable information is available |
| Partition coefficient: | No applicable information is available |
| Solubility(ies): | No applicable information is available |
| Flash point: | No applicable information is available |
| Flammability (solid, gas): | No applicable information is available |
| Ignition temperature: | No applicable information is available |
| Explosion limits: | No applicable information is available |

10. STABILITY AND REACTIVITY

Conditions to avoid: No data available

Materials to avoid: Oxidizing agents

Hazardous reactions: None known.

Thermal decomposition:

No data available

Hazardous decomposition products:

Carbon monoxide (CO), Carbon dioxide (CO₂)

Oxidizing properties:

No statements available.

Impact sensitivity:

No data available

11. TOXICOLOGICAL INFORMATION

Acute oral toxicity:

Paraffin solid

LD50 Rat: > 5,000 mg/kg

Propane-1,2-diol

LD50 Rat: 22,000 mg/kg

The substance or mixture has no acute oral toxicity

Zinc oxide

LD50 Rat: > 15,000 mg/kg

Method: OECD 401

Acute inhalation toxicity:

Paraffin solid

LC0 Rat: 0.210 mg/l

Propane-1,2-diol

LC50 Rabbit: > 317 mg/l, 2 h

The substance or mixture has no acute inhalation toxicity

Zinc oxide

LC50 Rat: > 5.7 mg/l, 4 h

Acute dermal toxicity:

Paraffin solid

LD50 Rabbit: > 4,000 mg/kg

Propane-1,2-diol

LD50 Rabbit: > 5,000 mg/kg

The substance or mixture has no acute dermal toxicity

Skin irritation:

Paraffin solid

Rabbit

Result: Mild skin irritation

Method: Draize Test

Propane-1,2-diol

Rabbit

Result: No skin irritation

Zinc oxide

Rabbit

Result: No skin irritation

Method: OECD 404

Eye irritation:

Paraffin solid

Rabbit

Result: Mild eye irritation

Method: Draize Test

Propane-1,2-diol

Rabbit

Result: No eye irritation

Zinc oxide

Rabbit

Result: No eye irritation

Method: OECD 405

Sensitisation:

Paraffin solid

Result: Does not cause skin sensitisation.

Propane-1,2-diol

Human experience

Result: Does not cause skin sensitisation.

guinea pig

Result: Does not cause skin sensitisation.

Method: OECD 406

Zinc oxide

Human experience

Result: Does not cause skin sensitisation.

guinea pig

Result: Does not cause skin sensitisation.

Method: Magnusson and Kligmann maximization test

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Subacute, subchronic and prolonged toxicity:

Propane-1,2-diol

NOEL 50,000 mg/kg, Rat Oral, Exposure time 24 month

NOEL 1 mg/l, Rat Inhalation, Exposure time 3 month

Number of exposures: Once daily

Zinc oxide

NOEL 50mg/kg/d

Genotoxicity in vitro:

Propane-1,2-diol

Ames test Bacteria

Dose: yes

Result: negative

Method: OECD 471

Mammalian cells

Result: negative

Method: OECD 476

Zinc oxide

Ames test

Result: negative

Genotoxicity in vivo:

Propane-1,2-diol

Result: negative

Method: OECD 478

Zinc oxide

Result: No indication of mutagenic effects.

Carcinogenicity:

Propane-1,2-diol

Rat:

Exposure time: 2 a

Number of exposures: Once daily

Result: negative

Zinc oxide

Result: Animal testing did not show any carcinogenic effects.

Reproductive toxicity:

Propane-1,2-diol

Application Route: Oral

Rat, female: Test period: 18 d

NOAEL: 1600 mg/kg

Result: Animal testing did not show any effects on fertility.

Zinc oxide

Result: Animal testing did not show any effects on fertility.

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Teratogenicity:

Propane-1,2-diol

Rat, male: Number of exposures: Once daily

Test period: 15 d

NOAEL: 1600 mg/l

Result: No indication of teratogenic effects.

Zinc oxide

Result: Did not show teratogenic effects in animal experiments.

Carcinogenicity:

No Carcinogenic substances as defined by IARC, NTP and/or OSHA

Experience with human exposure:

Components:

1314-13-2 :

no zinc fever

STOT - single exposure:

No data available

STOT - repeated exposure:

No data available

12. ECOLOGICAL INFORMATION

General advice:

Do not allow to enter surface waters or groundwater. No data is available on the product itself.

Toxicity to fish:

Paraffin solid

Method: DIN 38412

No toxic effects.

Propane-1,2-diol

Acute Fish toxicity: LC50 40,613 mg/l

Test species: Pimephales promelas (fathead minnow) Duration of test: 96 h

Zinc oxide

LC50 1.1 mg/l

Test species: Oncorhynchus mykiss (rainbow trout) Duration of test: 96 h

Toxicity to daphnia and other aquatic invertebrates:

Propane-1,2-diol

LC50 18,340 mg/l

Test species: Ceriodaphnia dubia (water flea) Duration of test: 48 h

Zinc oxide

EC50 > 1,000 mg/l

Test species: Daphnia magna (Water flea) Duration of test: 48 h

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Toxicity to algae:

Propane-1,2-diol

IC50 19,100 mg/l

tested on: Pseudokirchneriella subcapitata (green algae)

Zinc oxide

Growth rate EC50 0.17 mg/l

tested on: Scenedesmus capricornutum (fresh water algae) Duration of test: 72 h

Toxicity to bacteria:

Propane-1,2-diol

NOEC 20,000 mg/l

tested on: Pseudomonas putida

Duration of test: 18 h

Biodegradability:

Paraffin solid

rapidly biodegradable

Method: OECD 301 B

Propane-1,2-diol

87 - 92 %, 28 d rapidly biodegradable

Method: OECD 301 C

Bioaccumulation:

Propane-1,2-diol

Bioconcentration factor (BCF)

0.09

13. DISPOSAL CONSIDERATIONS

If discarded in its purchased form, this product would not be a hazardous waste either by listing or by characteristic. However, under RCRA, it is the responsibility of the product user to determine at the time of disposal, whether a material containing the product or derived from the product should be classified as a hazardous waste. (40 CFR 261.20-24)

Waste disposal should be in accordance with existing federal, state and local environmental control laws.

14. TRANSPORT INFORMATION

Land transport (CFR)

non-regulated

US Sea transport (IMDG)

non-regulated

US Air transport (ICAO / IATA cargo aircraft only)

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non-regulated

US Air transport (ICAO / IATA passenger and cargo aircraft)
non-regulated

International IATA

| | |
|----------------------------------|--|
| UN Number | 3082 |
| Description of the goods | ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. |
| Class | 9 |
| Packaging group | III |
| Dangerous goods labels | 9 |
| Environmentally hazardous | yes |

International IMDG

| | |
|---------------------------------|--|
| UN Number | 3082 |
| Description of the goods | ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. |
| Class | 9 |
| Packaging group | III |
| IMDG-Labels | 9 |
| EmS Number | F-A |
| Marine pollutant | yes |

15. REGULATORY INFORMATION

US. EPA Emergency Planning and Community Right-To-Know Act (EPCRA) SARA Title III Section 302 Extremely Hazardous Substance (40 CFR 355, Appendix A)

Components

None

US. EPA Emergency Planning and Community Right-To-Know Act (EPCRA) SARA Title III Section 313 Toxic Chemicals (40 CFR 372.65) - Supplier Notification Required

Components

None

US. EPA CERCLA Hazardous Substances (40 CFR 302) Components

None

Massachusetts, New Jersey or Pennsylvania Right to Know Substance Lists

| Weight percent | Components | CAS-No. |
|-----------------------|-------------------|----------------|
| 3% | Propane-1,2-diol | 57-55-6 |
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| 1% | Paraffin solid | 8002-74-2 |

California Prop. 65

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To the best of our knowledge, this product does not contain any of the listed chemicals, which the state of California has found to cause cancer, birth defects or other reproductive harm.

OSHA Hazcom Standard Rating

Not subject to OSHA

16. OTHER INFORMATION

Further information

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.