according to the OSHA Hazard Communication Standard



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#### **SECTION 1. IDENTIFICATION**

Product name : Cephapirin / Prednisolone Formulation

Other means of identification : Mastiplan (A011329)

Manufacturer or supplier's details

Company name of supplier : Merck & Co., Inc Address : 126 E. Lincoln Avenue

Rahway, New Jersey U.S.A. 07065

Telephone : 908-740-4000 Emergency telephone : 1-908-423-6000

E-mail address : EHSDATASTEWARD@merck.com

Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product Restrictions on use : Not applicable

#### **SECTION 2. HAZARDS IDENTIFICATION**

GHS classification in accordance with the OSHA Hazard Communication Standard (29 CFR 1910.1200)

Respiratory sensitization : Category 1

Reproductive toxicity : Category 2

**GHS** label elements

Hazard pictograms :

Signal Word : Danger

Hazard Statements : H334 May cause allergy or asthma symptoms or breathing diffi-

culties if inhaled.

H361d Suspected of damaging the unborn child.

Precautionary Statements : Prevention:

P201 Obtain special instructions before use.

P202 Do not handle until all safety precautions have been read

and understood.

P261 Avoid breathing mist or vapors.

P280 Wear protective gloves, protective clothing, eye protection

and face protection.

P285 In case of inadequate ventilation wear respiratory protec-

tion.

Response:

P304 + P341 IF INHALED: If breathing is difficult, remove per-

son to fresh air and keep comfortable for breathing.

according to the OSHA Hazard Communication Standard



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> P308 + P313 IF exposed or concerned: Get medical attention. P342 + P311 If experiencing respiratory symptoms: Call a doc-

Storage:

P405 Store locked up.

Disposal:

P501 Dispose of contents and container to an approved waste

disposal plant.

Other hazards

None known.

#### **SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS**

Substance / Mixture Mixture

#### Components

Chemical name	CAS-No.	Concentration (% w/w)
Peanut oil	8002-03-7	>= 70 - < 90
Glyceryl monostearate	123-94-4	>= 5 - < 10
Zeolites	1318-02-1	>= 5 - < 10
Cefapirin	21593-23-7	>= 1 - < 5
prednisolone	50-24-8	>= 0.1 - < 1

Actual concentration is withheld as a trade secret

### **SECTION 4. FIRST AID MEASURES**

General advice In the case of accident or if you feel unwell, seek medical

advice immediately.

When symptoms persist or in all cases of doubt seek medical

advice.

If inhaled If inhaled, remove to fresh air.

> If not breathing, give artificial respiration. If breathing is difficult, give oxygen.

Get medical attention.

In case of skin contact In case of contact, immediately flush skin with soap and plenty

of water.

Remove contaminated clothing and shoes.

Get medical attention. Wash clothing before reuse.

Thoroughly clean shoes before reuse. In case of eye contact Flush eyes with water as a precaution.

Get medical attention if irritation develops and persists.

May cause allergy or asthma symptoms or breathing difficul-

If swallowed If swallowed, DO NOT induce vomiting.

Get medical attention.

Rinse mouth thoroughly with water.

Most important symptoms

and effects, both acute and

delayed

ties if inhaled. Suspected of damaging the unborn child.

Excessive exposure may aggravate preexisting asthma and

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other respiratory disorders (e.g. emphysema, bronchitis, reac-

tive airways dysfunction syndrome).

First Aid responders should pay attention to self-protection, Protection of first-aiders

> and use the recommended personal protective equipment when the potential for exposure exists (see section 8).

Treat symptomatically and supportively. Notes to physician

#### **SECTION 5. FIRE-FIGHTING MEASURES**

Suitable extinguishing media Water spray

> Alcohol-resistant foam Carbon dioxide (CO2)

Dry chemical

Unsuitable extinguishing

media

None known.

Specific hazards during fire

fighting

Exposure to combustion products may be a hazard to health.

Hazardous combustion prod-

Carbon oxides

Metal oxides Silicon oxides

Specific extinguishing meth-

ods

Use extinguishing measures that are appropriate to local cir-

cumstances and the surrounding environment. Use water spray to cool unopened containers.

Remove undamaged containers from fire area if it is safe to do

SO.

Evacuate area.

Special protective equipment

for fire-fighters

In the event of fire, wear self-contained breathing apparatus.

Use personal protective equipment.

### **SECTION 6. ACCIDENTAL RELEASE MEASURES**

Personal precautions, protec- :

tive equipment and emer-

gency procedures

Use personal protective equipment.

Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

Avoid release to the environment. Environmental precautions

Prevent further leakage or spillage if safe to do so.

Prevent spreading over a wide area (e.g., by containment or

oil barriers).

Retain and dispose of contaminated wash water.

Local authorities should be advised if significant spillages

cannot be contained.

Methods and materials for containment and cleaning up Soak up with inert absorbent material.

For large spills, provide diking or other appropriate

containment to keep material from spreading. If diked material can be pumped, store recovered material in appropriate

container.

Clean up remaining materials from spill with suitable

absorbent.

Local or national regulations may apply to releases and disposal of this material, as well as those materials and items

employed in the cleanup of releases. You will need to

according to the OSHA Hazard Communication Standard



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determine which regulations are applicable.

Sections 13 and 15 of this SDS provide information regarding

certain local or national requirements.

### **SECTION 7. HANDLING AND STORAGE**

Technical measures : See Engineering measures under EXPOSURE

CONTROLS/PERSONAL PROTECTION section.

Local/Total ventilation : Use only with adequate ventilation. Advice on safe handling : Avoid breathing mist or vapors.

Do not swallow.

Avoid contact with eyes.

Avoid prolonged or repeated contact with skin.

Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure

assessment

Keep container tightly closed.

Already sensitized individuals, and those susceptible

to asthma, allergies, chronic or recurrent respiratory disease,

should consult their physician regarding working with

respiratory irritants or sensitizers.

Take care to prevent spills, waste and minimize release to the

environment.

Conditions for safe storage : Keep in properly labeled containers.

Keep tightly closed.

Store in accordance with the particular national regulations.

Materials to avoid : Do not store with the following product types:

Strong oxidizing agents

Gases

### **SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION**

#### Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Peanut oil	8002-03-7	TWA (mist - total)	10 mg/m³	NIOSH REL
		TWA (mist - respirable)	5 mg/m³	NIOSH REL
Glyceryl monostearate	123-94-4	TWA (Inhal- able particu- late matter)	10 mg/m <sup>3</sup>	ACGIH
		TWA (Respirable particulate matter)	3 mg/m³	ACGIH
Zeolites	1318-02-1	TWA (Respirable particulate matter)	1 mg/m³ (Aluminum)	ACGIH

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Cefapirin	21593-23-7	TWA	0.4 mg/m3 (OEB 2)	Internal		
	Further inforr	Further information: RSEN				
prednisolone	50-24-8	TWA	10 μg/m3 (OEB 3)	Internal		
		Wipe limit	100 µg/100 cm <sup>2</sup>	Internal		

**Engineering measures** : Use appropriate engineering controls and manufacturing

technologies to control airborne concentrations (e.g., drip-

less quick connections).

All engineering controls should be implemented by facility design and operated in accordance with GMP principles to

protect products, workers, and the environment.

Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of

the compound to uncontrolled areas (e.g., open-face containment devices).

Minimize open handling.

#### Personal protective equipment

Respiratory protection : General and local exhaust ventilation is recommended to

maintain vapor exposures below recommended limits. Where

concentrations are above recommended limits or are unknown, appropriate respiratory protection should be worn. Follow OSHA respirator regulations (29 CFR 1910.134) and use NIOSH/MSHA approved respirators. Protection provided

by air purifying respirators against exposure to any

hazardous chemical is limited. Use a positive pressure air supplied respirator if there is any potential for uncontrolled release, exposure levels are unknown, or any other

circumstance where air purifying respirators may not provide

adequate protection.

Hand protection

Material : Chemical-resistant gloves

Remarks : Consider double gloving.

Eye protection : Wear safety glasses with side shields or goggles.

If the work environment or activity involves dusty conditions,

mists or aerosols, wear the appropriate goggles.

Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or

aerosols

Skin and body protection : Work uniform or laboratory coat.

Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets,

disposable suits) to avoid exposed skin surfaces.

Use appropriate degowning techniques to remove potentially

contaminated clothing.

Hygiene measures : If exposure to chemical is likely during typical use, provide

eye flushing systems and safety showers close to the

working place.

When using do not eat, drink or smoke. Wash contaminated clothing before re-use.

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The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

#### **SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES**

Appearance : liquid, oily

Color : No data available

Odor : No data available

Odor Threshold : No data available

pH : No data available

Melting point/freezing point : No data available

Initial boiling point and boiling

range

No data available

Flash point : No data available

Evaporation rate : No data available

Flammability (solid, gas) : Not applicable

Flammability (liquids) : No data available

Upper explosion limit / Upper

flammability limit

No data available

Lower explosion limit / Lower

flammability limit

No data available

Vapor pressure : No data available

Relative vapor density : No data available

Density : No data available

Solubility(ies)

Water solubility : No data available

Partition coefficient: n-

octanol/water

: No data available

Autoignition temperature : No data available

Decomposition temperature : No data available

Viscosity

Viscosity, kinematic : No data available

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Explosive properties : Not explosive

Oxidizing properties : The substance or mixture is not classified as oxidizing.

Molecular weight : No data available

Particle size : No data available

#### **SECTION 10. STABILITY AND REACTIVITY**

Reactivity : Not classified as a reactivity hazard.
Chemical stability : Stable under normal conditions.
Possibility of hazardous reac- : Can react with strong oxidizing agents.

tions

Conditions to avoid : None known. Incompatible materials : Oxidizing agents

Hazardous decomposition : No hazard

products

No hazardous decomposition products are known.

#### **SECTION 11. TOXICOLOGICAL INFORMATION**

#### Information on likely routes of exposure

Inhalation Skin contact Ingestion Eye contact

### **Acute toxicity**

Not classified based on available information.

#### **Components:**

Peanut oil:

Acute oral toxicity : LD50 (Rat): > 2,000 mg/kg

Method: OECD Test Guideline 401

Remarks: Based on data from similar materials

Acute dermal toxicity : LD50 (Rat): > 2,000 mg/kg

Remarks: Based on data from similar materials

Glyceryl monostearate:

Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg

Method: OECD Test Guideline 401

Remarks: Based on data from similar materials

Acute dermal toxicity : LD50 (Rat): > 2,000 mg/kg

Remarks: Based on data from similar materials

#### Zeolites:

according to the OSHA Hazard Communication Standard



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Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg

Method: OECD Test Guideline 401

Acute inhalation toxicity : LC50 (Rat): > 3.35 mg/l

Exposure time: 4 h

Test atmosphere: dust/mist

Acute dermal toxicity : LD50 (Rabbit): > 2,000 mg/kg

Assessment: The substance or mixture has no acute dermal

toxicity

Cefapirin:

Acute oral toxicity : LD50 (Mouse): 26,000 mg/kg

Acute toxicity (other routes of:

administration)

LD50 (Mouse): > 7,600 mg/kg Application Route: Intraperitoneal

LD50 (Rat): 7,800 mg/kg

Application Route: Intraperitoneal

prednisolone:

Acute oral toxicity : LD50 (Mouse): 1,680 mg/kg

LD50 (Rat): > 3,857 mg/kg

Acute inhalation toxicity : Remarks: No data available

Acute dermal toxicity : Remarks: No data available

Acute toxicity (other routes of :

administration)

LD50 (Rat): 147 mg/kg

Application Route: Subcutaneous

LD50 (Mouse): 767 mg/kg

Application Route: Intraperitoneal

### Skin corrosion/irritation

Not classified based on available information.

### **Components:**

Peanut oil:

Species : Rabbit

Result : No skin irritation

Remarks : Based on data from similar materials

Glyceryl monostearate:

Species : Rabbit

Result : No skin irritation

Remarks : Based on data from similar materials

Zeolites:

according to the OSHA Hazard Communication Standard



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Species : Rabbit

Method : OECD Test Guideline 404

Result : No skin irritation

prednisolone:

Remarks : No data available

Serious eye damage/eye irritation

Not classified based on available information.

**Components:** 

Peanut oil:

Species : Rabbit

Result : No eye irritation

Remarks : Based on data from similar materials

Glyceryl monostearate:

Species : Rabbit

Result : No eye irritation

Remarks : Based on data from similar materials

Zeolites:

Species : Rabbit

Result : No eye irritation

Method : OECD Test Guideline 405

prednisolone:

Remarks : No data available

Respiratory or skin sensitization

Skin sensitization

Not classified based on available information.

Respiratory sensitization

May cause allergy or asthma symptoms or breathing difficulties if inhaled.

**Components:** 

Glyceryl monostearate:

Test Type : Buehler Test
Routes of exposure : Skin contact
Species : Guinea pig
Result : negative

Remarks : Based on data from similar materials

Zeolites:

Test Type : Buehler Test Routes of exposure : Skin contact

according to the OSHA Hazard Communication Standard



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Species : Guinea pig

Method : OECD Test Guideline 406

Result : negative

Cefapirin:

Assessment : Probability or evidence of high respiratory sensitization rate in

humans

prednisolone:

Remarks : No data available

Germ cell mutagenicity

Not classified based on available information.

Components:

Peanut oil:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)

Result: negative

Glyceryl monostearate:

Genotoxicity in vitro : Test Type: Chromosome aberration test in vitro

Method: OECD Test Guideline 473

Result: negative

Remarks: Based on data from similar materials

Test Type: Bacterial reverse mutation assay (AMES)

Method: OECD Test Guideline 471

Result: negative

Remarks: Based on data from similar materials

Test Type: In vitro mammalian cell gene mutation test

Result: negative

Remarks: Based on data from similar materials

Zeolites:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)

Method: OECD Test Guideline 471

Result: negative

Test Type: Chromosome aberration test in vitro

Method: OECD Test Guideline 473

Result: positive

Test Type: In vitro mammalian cell gene mutation test

Method: OECD Test Guideline 476

Result: negative

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo

cytogenetic assay) Species: Mouse

according to the OSHA Hazard Communication Standard



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Application Route: Ingestion

Method: OECD Test Guideline 474

Result: negative

Cefapirin:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)

Result: negative

prednisolone:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)

Result: negative

Test Type: Mouse Lymphoma

Result: negative

Test Type: sister chromatid exchange assay

Result: negative

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo

cytogenetic assay) Species: Rat

Application Route: Oral

Result: negative

Test Type: sister chromatid exchange assay

Species: Humans Result: negative

#### Carcinogenicity

Not classified based on available information.

#### Components:

#### Zeolites:

Species : Rat
Application Route : Ingestion
Exposure time : 104 weeks
Result : negative

Species : Rat

Application Route : inhalation (dust/mist/fume)

Exposure time : 22 Months Result : negative

prednisolone:

Species : Rat
Application Route : Oral
Exposure time : 18 Months
Result : negative

IARC No ingredient of this product present at levels greater than or equal to 0.1% is

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identified as probable, possible or confirmed human carcinogen by IARC.

**OSHA** No component of this product present at levels greater than or equal to 0.1% is

on OSHA's list of regulated carcinogens.

NTP No ingredient of this product present at levels greater than or equal to 0.1% is

identified as a known or anticipated carcinogen by NTP.

#### Reproductive toxicity

Suspected of damaging the unborn child.

#### Components:

### Glyceryl monostearate:

Effects on fertility : Test Type: Combined repeated dose toxicity study with the

reproduction/developmental toxicity screening test

Species: Rat

Application Route: Ingestion Method: OECD Test Guideline 422

Result: negative

Remarks: Based on data from similar materials

Effects on fetal development : Test Type: Combined repeated dose toxicity study with the

reproduction/developmental toxicity screening test

Species: Rat

Application Route: Ingestion Method: OECD Test Guideline 422

Result: negative

Remarks: Based on data from similar materials

Zeolites:

Effects on fetal development : Test Type: Embryo-fetal development

Species: Rat

Application Route: Ingestion

Result: negative

Cefapirin:

Effects on fertility : Test Type: Fertility/early embryonic development

Species: Rat

Application Route: Intraperitoneal injection Fertility: LOAEL: > 500 mg/kg body weight

Result: No effects on fertility.

Effects on fetal development : Test Type: Embryo-fetal development

Species: Rat

Application Route: Intraperitoneal injection

Developmental Toxicity: LOAEL: > 200 mg/kg body weight

prednisolone:

Effects on fertility : Test Type: Fertility/early embryonic development

Species: Rat

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Application Route: Subcutaneous Fertility: NOAEL: 1 mg/kg body weight

Result: No effects on fertility.

Effects on fetal development : Test Type: Embryo-fetal development

Species: Mouse Application Route: Oral

Developmental Toxicity: LOAEL: 0.5 mg/kg body weight Result: Malformations were observed., Cleft palate

Test Type: Embryo-fetal development

Species: Rat

**Application Route: Oral** 

Developmental Toxicity: LOAEL: 30 mg/kg body weight

Result: decreased blood formation

Species: Rat

Application Route: Subcutaneous

Developmental Toxicity: NOAEL: 25 mg/kg body weight

Result: No effects on fetal development.

Reproductive toxicity - As-

sessment

Some evidence of adverse effects on development, based on

animal experiments.

#### STOT-single exposure

Not classified based on available information.

### STOT-repeated exposure

Not classified based on available information.

#### Components:

Zeolites:

Assessment : No significant health effects observed in animals at concentra-

tions of 0.2 mg/l/6h/d or less.

prednisolone:

Target Organs : Bone marrow, Adrenal gland, Liver

Assessment : Causes damage to organs through prolonged or repeated

exposure.

### Repeated dose toxicity

### **Components:**

## Glyceryl monostearate:

Species : Rat

NOAEL : >= 12,500 mg/kg

Application Route : Ingestion Exposure time : 84 Days

Remarks : Based on data from similar materials

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Zeolites:

Species : Rat

NOAEL : 250 - 300 mg/kg

Application Route : Ingestion Exposure time : 90 Days

Species : Monkey LOAEL : 0.001 mg/l

Application Route : inhalation (dust/mist/fume)

Exposure time : 24 Months

Cefapirin:

Species : Rat

LOAEL : >= 200 mg/kg
Application Route : Intraperitoneal

Target Organs : Blood Remarks : anemia

Species : Dog
LOAEL : 20 mg/kg
Application Route : Oral
Exposure time : 4 Months

Target Organs : Gastrointestinal tract

Species : Dog

LOAEL : 100 mg/kg
Application Route : Intramuscular
Exposure time : 10 Months

Target Organs : Blood, Gastrointestinal tract

Remarks : anemia

prednisolone:

Species : Rat
LOAEL : 0.6 mg/kg
Application Route : Oral
Exposure time : 63 Days
Target Organs : Bone marrow

Species : Dog
LOAEL : 2.5 mg/kg
Application Route : Oral
Exposure time : 6 Weeks
Target Organs : Adrenal gland

Species : Rabbit
LOAEL : 1 mg/kg
Application Route : Oral
Exposure time : 24 Weeks
Target Organs : Liver

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**Aspiration toxicity** 

Not classified based on available information.

**Experience with human exposure** 

**Components:** 

Cefapirin:

Ingestion : Symptoms: Nausea, Vomiting, Abdominal pain, Diarrhea,

vaginitis, colitis, anorexia, Rash, anaphylaxis

prednisolone:

Ingestion : Symptoms: sodium retention, Headache, Vertigo, fluid reten-

tion, subcutaneous bleeding, striae, skin atrophy, menstrual

irregularities

**SECTION 12. ECOLOGICAL INFORMATION** 

**Ecotoxicity** 

Components:

Peanut oil:

Toxicity to fish : LC50 (Danio rerio (zebra fish)): > 10,000 mg/l

Exposure time: 96 h

Remarks: Based on data from similar materials

Toxicity to daphnia and other :

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): > 100 mg/l

Exposure time: 48 h

Remarks: Based on data from similar materials

Glyceryl monostearate:

Toxicity to fish : LL50 (Leuciscus idus (Golden orfe)): > 100 mg/l

Exposure time: 48 h

Remarks: Based on data from similar materials

Toxicity to daphnia and other :

aquatic invertebrates

EL50 (Daphnia magna (Water flea)): > 32 mg/l

Exposure time: 47 h

Method: Directive 67/548/EEC, Annex V, C.2. Remarks: No toxicity at the limit of solubility.

Based on data from similar materials

Toxicity to algae/aquatic

plants

EL50 (Pseudokirchneriella subcapitata (green algae)): > 100

mg/l

Exposure time: 72 h

Test substance: Water Accommodated Fraction

Method: OECD Test Guideline 201

Remarks: No toxicity at the limit of solubility.

NOELR (Pseudokirchneriella subcapitata (green algae)): > 1

mg/l

Exposure time: 72 h

Test substance: Water Accommodated Fraction

Method: OECD Test Guideline 201

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Remarks: No toxicity at the limit of solubility.

Toxicity to daphnia and other

aquatic invertebrates (Chron-

ic toxicity)

NOEC (Daphnia magna (Water flea)): > 0.22 mg/l

Exposure time: 21 d

Method: OECD Test Guideline 211

Remarks: No toxicity at the limit of solubility.

Based on data from similar materials

EC10 (Pseudomonas putida): > 1 mg/l Toxicity to microorganisms

Exposure time: 18 h

Remarks: Based on data from similar materials

Zeolites:

LL50 (Pimephales promelas (fathead minnow)): > 100 mg/l Toxicity to fish

Exposure time: 96 h

Toxicity to daphnia and other :

aquatic invertebrates

EL50 (Daphnia magna (Water flea)): > 100 mg/l

Exposure time: 48 h Method: ISO 6341

Toxicity to algae/aquatic

plants

EL50 (Desmodesmus subspicatus (green algae)): > 100 mg/l

Exposure time: 72 h

Test substance: Water Accommodated Fraction

Method: OECD Test Guideline 201

NOELR (Desmodesmus subspicatus (green algae)): > 1 mg/l

Exposure time: 72 h

Test substance: Water Accommodated Fraction

Method: OECD Test Guideline 201

Toxicity to fish (Chronic tox-

icity)

NOELR (Pimephales promelas (fathead minnow)): > 1 mg/l

Exposure time: 30 d

Toxicity to daphnia and other :

aquatic invertebrates (Chron-

ic toxicity)

NOELR (Daphnia magna (Water flea)): > 1 mg/l

Exposure time: 21 d

Method: OECD Test Guideline 211

Toxicity to microorganisms EC50 (Pseudomonas putida): > 100 mg/l

> Exposure time: 16 h Method: DIN 38 412 Part 8

prednisolone:

Toxicity to daphnia and other :

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): > 85 mg/l

Exposure time: 48 h

Toxicity to algae/aquatic

plants

mg/l

Exposure time: 72 h

EC50 (Pseudokirchneriella subcapitata (green algae)): > 160

NOEC (Pseudokirchneriella subcapitata (green algae)): 160

mg/l

Exposure time: 72 h

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Toxicity to daphnia and other :

aquatic invertebrates (Chron-

ic toxicity)

NOEC (Ceriodaphnia dubia (water flea)): 0.23 mg/l

Exposure time: 7 d

Persistence and degradability

**Components:** 

Glyceryl monostearate:

Biodegradability Result: Readily biodegradable.

Remarks: Based on data from similar materials

Bioaccumulative potential

**Components:** 

Glyceryl monostearate:

Partition coefficient: n-

octanol/water

: log Pow: 6.1

Zeolites:

Bioaccumulation Species: Oysters

Bioconcentration factor (BCF): 0.34 - 1.44

Partition coefficient: n-

octanol/water

Remarks: No data available

prednisolone:

Partition coefficient: n-

octanol/water

log Pow: 1.46

Mobility in soil

No data available

Other adverse effects

No data available

### **SECTION 13. DISPOSAL CONSIDERATIONS**

**Disposal methods** 

Waste from residues Dispose of in accordance with local regulations.

Do not dispose of waste into sewer.

Empty containers should be taken to an approved waste Contaminated packaging

handling site for recycling or disposal.

If not otherwise specified: Dispose of as unused product.

### **SECTION 14. TRANSPORT INFORMATION**

#### International Regulations

**UNRTDG** 

Not regulated as a dangerous good

**IATA-DGR** 

according to the OSHA Hazard Communication Standard



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Not regulated as a dangerous good

**IMDG-Code** 

Not regulated as a dangerous good

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

**Domestic regulation** 

**49 CFR** 

Not regulated as a dangerous good

Special precautions for user

Not applicable

#### **SECTION 15. REGULATORY INFORMATION**

#### **CERCLA Reportable Quantity**

This material does not contain any components with a CERCLA RQ.

### SARA 304 Extremely Hazardous Substances Reportable Quantity

This material does not contain any components with a section 304 EHS RQ.

### SARA 302 Extremely Hazardous Substances Threshold Planning Quantity

This material does not contain any components with a section 302 EHS TPQ.

SARA 311/312 Hazards : Respiratory or skin sensitization

Reproductive toxicity

SARA 313 : This material does not contain any chemical components with

known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

#### **US State Regulations**

### Pennsylvania Right To Know

 Peanut oil
 8002-03-7

 Glyceryl monostearate
 123-94-4

 Zeolites
 1318-02-1

 Cefapirin
 21593-23-7

#### California Permissible Exposure Limits for Chemical Contaminants

Peanut oil 8002-03-7 Glyceryl monostearate 123-94-4

#### The ingredients of this product are reported in the following inventories:

AICS : not determined

DSL : not determined

IECSC : not determined

according to the OSHA Hazard Communication Standard



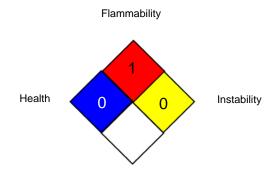
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#### **SECTION 16. OTHER INFORMATION**

#### **Further information**

#### NFPA 704:



Special hazard

#### HMIS® IV:



HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "\*" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.

#### Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)
NIOSH REL : USA. NIOSH Recommended Exposure Limits

ACGIH / TWA : 8-hour, time-weighted average

NIOSH REL / TWA : Time-weighted average concentration for up to a 10-hour

workday during a 40-hour workweek

AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; HMIS - Hazardous Materials Identification System; IARC -International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office

according to the OSHA Hazard Communication Standard



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of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

Sources of key data used to compile the Material Safety

**Data Sheet** 

Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agen-

cy, http://echa.europa.eu/

Revision Date : 12/04/2023

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 is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.

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