according to the Globally Harmonized System



Prednisolone / Chloramphenicol Formulation

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1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Prednisolone / Chloramphenicol Formulation

Manufacturer or supplier's details

Company : MSD

Address : Briahnager - Off Pune Nagar Road

Wagholi - Pune - India 412 207

Telephone : +1-908-740-4000

Emergency telephone number: +1-908-423-6000

E-mail address : EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product Restrictions on use : Not applicable

2. HAZARDS IDENTIFICATION

Manufacture, Storage and Import of Hazardous Chemicals Rules 1989

Classification

Not classified as hazardous according to criteria laid down in Part I of Schedule-1.

GHS Classification

Carcinogenicity : Category 2

Reproductive toxicity : Category 1B

GHS label elements

Hazard pictograms :

Signal word : Danger

Hazard statements : H351 Suspected of causing cancer.

H360 May damage fertility or the unborn child.

Precautionary statements : Prevention:

P203 Obtain, read and follow all safety instructions before use. P280 Wear protective gloves/ protective clothing/ eye protec-

tion/ face protection.

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Response:

P318 IF exposed or concerned, get medical advice.

Storage:

P405 Store locked up.

Disposal:

P501 Dispose of contents/ container to an approved waste

disposal plant.

Other hazards which do not result in classification

Dust contact with the eyes can lead to mechanical irritation.

Contact with dust can cause mechanical irritation or drying of the skin.

May form combustible dust concentrations in air during processing, handling or other means.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Concentration (%
		w/w)
Chloramphenicol	56-75-7	>= 1 - < 5
prednisolone	50-24-8	>= 0.1 - < 0.25
Basic phenylmercury nitrate	8003-05-2	>= 0.0002 - < 0.0025

4. FIRST AID MEASURES

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

vice immediately.

When symptoms persist or in all cases of doubt seek medical

advice.

If inhaled : If inhaled, remove to fresh air.

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 : If in eyes, rinse well with water.

Get medical attention if irritation develops and persists.

If swallowed : If swallowed, DO NOT induce vomiting.

Get medical attention.

Rinse mouth thoroughly with water.

Most important symptoms

Suspected of causing cancer.

and effects, both acute and

May damage fertility or the unborn child.

delayed

Contact with dust can cause mechanical irritation or drying of

the skin.

Dust contact with the eyes can lead to mechanical irritation.

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

and use the recommended personal protective equipment

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when the potential for exposure exists (see section 8).

Notes to physician : Treat symptomatically and supportively.

5. FIREFIGHTING MEASURES

Suitable extinguishing media : Water spray

Alcohol-resistant foam Carbon dioxide (CO2)

Dry chemical None known.

Unsuitable extinguishing

media

Specific hazards during fire-

fighting

Hazardous combustion prod-

ucts

Exposure to combustion products may be a hazard to health.

Carbon 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 firefighters

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

Use personal protective equipment.

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 pro-

tective equipment recommendations (see section 8).

Environmental precautions : Avoid release to the environment.

Prevent further leakage or spillage if safe to do so. 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

Sweep up or vacuum up spillage and collect in suitable con-

tainer for disposal.

Avoid dispersal of dust in the air (i.e., clearing dust surfaces

with compressed air).

Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration. 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 deter-

mine which regulations are applicable.

Sections 13 and 15 of this SDS provide information regarding

certain local or national requirements.

7. HANDLING AND STORAGE

Technical measures : Static electricity may accumulate and ignite suspended dust

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causing an explosion.

Provide adequate precautions, such as electrical grounding

and bonding, or inert atmospheres.

Local/Total ventilation : If sufficient ventilation is unavailable, use with local exhaust

ventilation.

Advice on safe handling : Do not get on skin or clothing.

Do not breathe dust. Do not breathe vapours.

Do not swallow.

Avoid contact with eyes.

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

sessment

Keep container tightly closed.

Minimize dust generation and accumulation. Keep container closed when not in use. Keep away from heat and sources of ignition.

Take precautionary measures against static discharges.

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

environment.

Conditions for safe storage : Keep in properly labelled containers.

Store locked up. 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

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

Components	CAS-No.	Value type (Form of	Control parameters / Permissible	Basis
		exposure)	concentration	
Chloramphenicol	56-75-7	TWA	300 μg/m3 (OEB	
			2)	
prednisolone	50-24-8	TWA	10 μg/m3 (OEB 3)	Internal
		Wipe limit	100 μg/100 cm ²	Internal
Basic phenylmercury nitrate	8003-05-2	TWA	0.1 mg/m3	IN OEL
			(Mercury)	
	Further information: Potential contribution to the overall exposure			
	by the cutaneous route including mucous membranes and eye.			
		TWA	0.1 mg/m3	ACGIH
			(Mercury)	

Engineering measures : A

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 contain-

ment devices).

Minimize open handling.

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Personal protective equipment

Respiratory protection : If adequate local exhaust ventilation is not available or expo-

sure assessment demonstrates exposures outside the rec-

ommended guidelines, use respiratory protection.

Filter type
Hand protection

: Combined particulates and organic vapour type

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.

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.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : cream

Colour : No data available

Odour : No data available

Odour 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 : Not applicable

Evaporation rate : Not applicable

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May form combustible dust concentrations in air during pro-Flammability (solid, gas)

cessing, handling or other means.

Flammability (liquids) Not applicable

Upper explosion limit / Upper

flammability limit

No data available

Lower explosion limit / Lower

flammability limit

No data available

Not applicable Vapour pressure

Relative vapour density Not applicable

Relative density No data available

Density No data available

Solubility(ies)

Water solubility No data available

Partition coefficient: n-

octanol/water

Not applicable

No data available Auto-ignition temperature

No data available Decomposition temperature

Viscosity

Viscosity, kinematic Not applicable

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

10. STABILITY AND REACTIVITY

Not classified as a reactivity hazard. Reactivity Chemical stability Stable under normal conditions.

Possibility of hazardous reac-

tions

May form combustible dust concentrations in air during pro-

cessing, handling or other means. Can react with strong oxidizing agents.

Conditions to avoid Heat, flames and sparks.

Avoid dust formation.

Incompatible materials

Oxidizing agents Hazardous decomposition

products

No hazardous decomposition products are known.

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11. TOXICOLOGICAL INFORMATION

Information on likely routes of:

exposure

Inhalation Skin contact

Ingestion Eye contact

Acute toxicity

Not classified based on available information.

Product:

Acute oral toxicity : Acute toxicity estimate: > 5,000 mg/kg

Method: Calculation method

Components:

Chloramphenicol:

Acute oral toxicity : LD50 Oral (Rat): 2,500 mg/kg

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

Basic phenylmercury nitrate:

Acute oral toxicity : LD50 (Mouse): > 50 - 300 mg/kg

Remarks: Based on data from similar materials

Acute inhalation toxicity : Assessment: Corrosive to the respiratory tract.

Skin corrosion/irritation

Not classified based on available information.

Components:

prednisolone:

Remarks : No data available

Basic phenylmercury nitrate:

Result : Corrosive after 4 hours or less of exposure Remarks : Based on data from similar materials

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Serious eye damage/eye irritation

Not classified based on available information.

Components:

Chloramphenicol:

Remarks Mild eye irritation

prednisolone:

Remarks No data available

Basic phenylmercury nitrate:

Irreversible effects on the eye Result Remarks Based on skin corrosivity.

Respiratory or skin sensitisation

Skin sensitisation

Not classified based on available information.

Respiratory sensitisation

Not classified based on available information.

Components:

prednisolone:

Remarks No data available

Germ cell mutagenicity

Not classified based on available information.

Components:

Chloramphenicol:

Genotoxicity in vitro Test Type: DNA damage and repair, unscheduled DNA syn-

thesis in mammalian cells (in vitro)

Test system: human diploid fibroblasts

Result: positive

Test Type: DNA damage and repair, unscheduled DNA syn-

thesis in mammalian cells (in vitro) Test system: rat hepatocytes

Result: positive

Test Type: Bacterial reverse mutation assay (AMES)

Result: negative

Test Type: Chromosome aberration test in vitro

Test system: mammalian cells

Result: positive

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Genotoxicity in vivo : Test Type: Chromosomal aberration

Species: Mouse

Cell type: Bone marrow

Result: positive

Test Type: Micronucleus test

Species: Mouse

Cell type: Bone marrow

Result: negative

Test Type: Micronucleus test

Species: Rat

Cell type: Bone marrow

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

Suspected of causing cancer.

Components:

Chloramphenicol:

Remarks : IARC: (International Agency for Research on Cancer)

Carcinogenicity - Assess-

ment

Limited evidence of carcinogenicity in animal studies

prednisolone:

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

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Reproductive toxicity

May damage fertility or the unborn child.

Components:

Chloramphenicol:

Effects on foetal develop-

ment

Species: Monkey, female

Result: No significant adverse effects were reported

Species: Mouse

Developmental Toxicity: LOAEL: 500 mg/kg body weight Result: Embryo-foetal toxicity, Fetal growth retardation

Species: Rat

Developmental Toxicity: LOAEL: 500 - 2,000 mg/kg body

weight

Result: Embryo-foetal toxicity, Fetal growth retardation, Tera-

togenic effects

Species: Rabbit

Developmental Toxicity: LOAEL: 1,000 mg/kg body weight Result: Embryo-foetal toxicity, Fetal growth retardation

Reproductive toxicity - As-

sessment

Clear evidence of adverse effects on sexual function and fertil-

ity, and/or on development, based on animal experiments

prednisolone:

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

Species: Rat

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

Result: No effects on fertility

Effects on foetal develop-

ment

Test Type: Embryo-foetal development

Species: Mouse

Application Route: Oral

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

Test Type: Embryo-foetal 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 foetal development

Reproductive toxicity - As-

sessment

Some evidence of adverse effects on development, based on

animal experiments.

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Basic phenylmercury nitrate:

Effects on foetal develop-

ment

Test Type: Embryo-foetal development

Species: Mouse

Application Route: Intraperitoneal injection

Result: positive

Remarks: Based on data from similar materials

Reproductive toxicity - As-

sessment

Clear evidence of adverse effects on development, based on

animal experiments.

STOT - single exposure

Not classified based on available information.

Components:

Chloramphenicol:

Exposure routes : Oral

Target Organs : Blood, Bone marrow

STOT - repeated exposure

Not classified based on available information.

Components:

Chloramphenicol:

Exposure routes : Oral, Inhalation

Target Organs : Blood, Bone marrow, Liver

prednisolone:

Target Organs : Bone marrow, Adrenal gland, Liver

Assessment : Causes damage to organs through prolonged or repeated

exposure.

Basic phenylmercury nitrate:

Exposure routes : Oral Target Organs : Kidney

Assessment : Shown to produce significant health effects in animals at con-

centrations of 10 mg/kg bw or less.

Repeated dose toxicity

Components:

Chloramphenicol:

Species : Dog

Target Organs : Blood, Bone marrow

Symptoms : decrease in appetite, Reduced body weight

prednisolone:

Species : Rat : 0.6 mg/kg

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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

Basic phenylmercury nitrate:

Species : Rat

NOAEL : < 1.25 mg/kg
Application Route : Ingestion
Exposure time : 2 yr

Remarks : Based on data from similar materials

Aspiration toxicity

Not classified based on available information.

Experience with human exposure

Components:

Chloramphenicol:

General Information : Target Organs: Blood

Target Organs: Bone marrow

Symptoms: aplastic anemia, confusion, Diarrhoea, Fever,

Headache, Nausea, Vomiting

prednisolone:

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

tion, subcutaneous bleeding, striae, skin atrophy, menstrual

irregularities

12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

prednisolone:

Toxicity to daphnia and other : EC50 (Daphnia magna (Water flea)): > 85 mg/l

aquatic invertebrates Exposure time: 48 h

Toxicity to algae/aquatic : NOEC (Pseudokirchneriella subcapitata (green algae)): 160

plants mg/l

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Exposure time: 72 h

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

Exposure time: 72 h

Toxicity to daphnia and other : aquatic invertebrates (Chron-

NOEC: 0.23 mg/l Exposure time: 7 d

ic toxicity)

Species: Ceriodaphnia dubia (water flea)

Basic phenylmercury nitrate:

Toxicity to fish EC50 (Oncorhynchus mykiss (rainbow trout)): > 0.001 - 0.01

Exposure time: 96 h

Remarks: Based on data from similar materials

Toxicity to daphnia and other :

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): > 0.001 - 0.01 mg/l

Exposure time: 48 h

Remarks: Based on data from similar materials

Toxicity to algae/aquatic

plants

ErC50 (Pseudokirchneriella subcapitata (green algae)): >

0.01 - 0.1 mg/l Exposure time: 96 h

Remarks: Based on data from similar materials

EC10 (Pseudokirchneriella subcapitata (green algae)): > 0.01

- 0.1 mg/l

Exposure time: 72 h

Remarks: Based on data from similar materials

M-Factor (Acute aquatic tox-

icity)

100

NOEC (Bacteria): > 0.001 - 0.01 mg/l Toxicity to microorganisms

Exposure time: 18 h

Remarks: Based on data from similar materials

Toxicity to fish (Chronic tox-

icity)

NOEC: > 0.0001 - 0.001 mg/l

Exposure time: 32 d

Species: Pimephales promelas (fathead minnow) Remarks: Based on data from similar materials

Toxicity to daphnia and other : aquatic invertebrates (Chron-

ic toxicity)

NOEC: > 0.001 - 0.01 mg/l

Exposure time: 35 d

Species: Mysidopsis bahia (opossum shrimp) Remarks: Based on data from similar materials

M-Factor (Chronic aquatic

toxicity)

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Persistence and degradability

Components:

Basic phenylmercury nitrate:

Biodegradability : Result: Readily biodegradable.

Remarks: Based on data from similar materials

Bioaccumulative potential

Components:

prednisolone:

Partition coefficient: n-

octanol/water

log Pow: 1.46

Basic phenylmercury nitrate:

Partition coefficient: n-

octanol/water

log Pow: 1.27

Mobility in soil

No data available

Other adverse effects

No data available

13. DISPOSAL CONSIDERATIONS

Disposal methods

Waste from residues : Do not dispose of waste into sewer.

Dispose of in accordance with local regulations.

Contaminated packaging : Empty containers should be taken to an approved waste han-

dling site for recycling or disposal.

If not otherwise specified: Dispose of as unused product.

14. TRANSPORT INFORMATION

International Regulations

UNRTDG

Not regulated as a dangerous good

IATA-DGR

Not regulated as a dangerous good

IMDG-Code

Not regulated as a dangerous good

Transport in bulk according to IMO instruments

Not applicable for product as supplied.

Special precautions for user

Not applicable

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15. REGULATORY INFORMATION

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

The components of this product are reported in the following inventories:

AICS : not determined

DSL : not determined

IECSC : not determined

16. OTHER INFORMATION

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Further information

Sources of key data used to

compile the 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/

Date format : dd.mm.yyyy

Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)

IN OEL : India. Permissible levels of certain chemical substances in

work environment.

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

IN OEL / TWA : Time-Weighted Average Concentration (TWA) (8 hrs.)

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR -Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation: DSL - Domestic Substances List (Canada): ECx - Concentration associated with x% response; 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; 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; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumu-

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lative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; 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; WHMIS - Workplace Hazardous Materials Information System

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.

IN / EN