

# Benzylpenicillin / Dihydrostreptomycin Sulphate Formulation

Version Revision Date: SDS Number: Date of last issue: 04.04.2023 2.4 30.09.2023 10811342-00006 Date of first issue: 08.07.2022

#### **SECTION 1. PRODUCT AND COMPANY IDENTIFICATION**

Product name : Benzylpenicillin / Dihydrostreptomycin Sulphate Formulation

Manufacturer or supplier's details

Company name of supplier : MSD

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@msd.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** 

Respiratory sensitization : Category 1

Skin sensitization : Category 1

Reproductive toxicity : Category 2

Specific target organ toxicity

- repeated exposure (Oral)

Category 1 (ear, Kidney, inner ear)

**GHS** label elements

Hazard pictograms

Signal Word : Danger

Hazard Statements : H317 May cause an allergic skin reaction.

H334 May cause allergy or asthma symptoms or breathing diffi-

culties if inhaled.

H361d Suspected of damaging the unborn child.

H372 Causes damage to organs (ear, Kidney, inner ear) through prolonged or repeated exposure if swallowed.

Precautionary Statements : Prevention:

P201 Obtain special instructions before use.

P202 Do not handle until all safety precautions have been read

and understood.

P260 Do not breathe mist or vapors. P264 Wash skin thoroughly after handling.

P270 Do not eat, drink or smoke when using this product.



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P272 Contaminated work clothing should not be allowed out of the workplace.

P280 Wear protective gloves/ protective clothing/ eye protection/

face protection.

P284 Wear respiratory protection.

#### Response:

P302 + P352 IF ON SKIN: Wash with plenty of water. P304 + P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing.

P308 + P313 IF exposed or concerned: Get medical advice/

attention.

P333 + P313 If skin irritation or rash occurs: Get medical advice/

attention.

P342 + P311 If experiencing respiratory symptoms: Call a

POISON CENTER or doctor/ physician.

P362 + P364 Take off contaminated clothing and wash it before

reuse.

#### Storage:

P405 Store locked up.

#### Disposal:

P501 Dispose of contents/ 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)	
Dihydrostreptomycin sulphate	5490-27-7	>= 20 -< 30	
Benzylpenicillin	61-33-6	>= 20 -< 30	
Sodium hydroxymethanesulphinate	149-44-0	>= 0.1 -< 1	

#### **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.



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Get medical attention.

Wash clothing before reuse.

Thoroughly clean shoes before reuse. Flush eyes with water as a precaution.

Get medical attention if irritation develops and persists.

If swallowed, DO NOT induce vomiting.

Get medical attention.

Rinse mouth thoroughly with water. May cause an allergic skin reaction.

Most important symptoms and effects, both acute and

In case of eye contact

delayed

If swallowed

May cause allergy or asthma symptoms or breathing difficul-

ties if inhaled.

Suspected of damaging the unborn child.

Causes damage to organs through prolonged or repeated

exposure if swallowed.

Excessive exposure may aggravate preexisting asthma and other respiratory disorders (e.g. emphysema, bronchitis, reac-

tive airways dysfunction syndrome).

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

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

Notes to physician Treat symptomatically and supportively.

#### **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

Hazardous combustion prod-

Exposure to combustion products may be a hazard to health.

Carbon oxides Metal 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

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).

**Environmental precautions** Avoid release to the environment.

Prevent further leakage or spillage if safe to do so.

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

oil barriers).



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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

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 Advice on safe handling Use only with adequate ventilation.

Do not get on skin or clothing.

Do not breathe mist or vapors.

Do not swallow.

Avoid contact with eyes.

Wash skin thoroughly after handling.

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.

Do not eat, drink or smoke when using this product.

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

environment.

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.

Contaminated work clothing should not be allowed out of the

workplace.

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.

Conditions for safe storage : Keep in properly labeled containers.

Keep tightly closed.



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Store in accordance with the particular national regulations.

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

Strong oxidizing agents

Self-reactive substances and mixtures

Organic peroxides

Explosives 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	
Dihydrostreptomycin sulphate	5490-27-7	TWA	0.4 mg/m3 (OEB 2)		
	Further information: OTO				
		Wipe limit	Not required		
Benzylpenicillin	61-33-6	TWA	600 μg/m3 (OEB 2)	Internal	
	Further information: RSEN, DSEN				
		Wipe limit	100 μg/100 cm2	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.

Laboratory operations do not require special containment.

Personal protective equipment

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

exposure assessment demonstrates exposures outside the

recommended guidelines, use respiratory protection.

Filter type

Particulates type

Hand protection Material

: Chemical-resistant gloves

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.

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

Appearance : suspension



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Color : off-white, white

Odor : No data available

Odor Threshold : No data available

pH : 5.0 - 7.2

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

Relative density : No data available

Density : 1.14 - 1.18 g/cm<sup>3</sup>

Solubility(ies)

Water solubility : No data available

Partition coefficient: n-

octanol/water

: Not applicable

Autoignition temperature : No data available

Decomposition temperature : No data available

Viscosity

Viscosity, kinematic : No data available

Explosive properties : Not explosive

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

Molecular weight : No data available



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Particle size No data available

Particle Size Distribution  $D50 = 15 \mu m$ 

 $D90 = 30 \mu m$ 

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

Not classified as a reactivity hazard. Reactivity 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 hazardous decomposition products are known.

products

#### **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:**

#### Dihydrostreptomycin sulphate:

Acute oral toxicity LD50 (Rat): 9,000 - 25,000 mg/kg

LD50 Oral (Mouse): 30,000 mg/kg

Benzylpenicillin:

Acute oral toxicity LD50 (Rat): 8,000 mg/kg

LD50 (Mouse): > 5,000 mg/kg

Acute toxicity (other routes of :

administration)

LD50 (Mouse): 3,500 mg/kg Application Route: Intraperitoneal

LD50 (Mouse): 329 mg/kg Application Route: Intravenous

#### Sodium hydroxymethanesulphinate:

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

Method: OECD Test Guideline 423

Assessment: The substance or mixture has no acute oral tox-



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

Method: OECD Test Guideline 402

Assessment: The substance or mixture has no acute dermal

toxicity

#### Skin corrosion/irritation

Not classified based on available information.

#### Components:

### Sodium hydroxymethanesulphinate:

Species : Rat

Result : No skin irritation

#### Serious eye damage/eye irritation

Not classified based on available information.

#### **Components:**

#### Sodium hydroxymethanesulphinate:

Species : Rabbit

Result : No eye irritation

Method : OECD Test Guideline 405

#### Respiratory or skin sensitization

#### Skin sensitization

May cause an allergic skin reaction.

#### Respiratory sensitization

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

#### Components:

#### Benzylpenicillin:

Test Type : Local lymph node assay (LLNA)

Routes of exposure : Dermal Species : Mouse

Result : Weak sensitizer

Test Type : Maximization Test

Routes of exposure : Dermal Species : Guinea pig Result : positive

Remarks : Based on data from similar materials

Result : Strong sensitizer

Remarks : Based on human experience.



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#### Sodium hydroxymethanesulphinate:

Test Type **Maximization Test** Routes of exposure Skin contact Species Guinea pig

**OECD Test Guideline 406** Method

Result negative

#### Germ cell mutagenicity

Not classified based on available information.

#### Components:

#### Dihydrostreptomycin sulphate:

Genotoxicity in vitro Test Type: Chromosome aberration test in vitro

Test system: Human lymphocytes

Result: negative

#### Benzylpenicillin:

Germ cell mutagenicity -

Assessment

cell mutagen.

#### Sodium hydroxymethanesulphinate:

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

Method: OECD Test Guideline 471

Result: negative

Test Type: In vitro mammalian cell gene mutation test

Weight of evidence does not support classification as a germ

Method: OECD Test Guideline 476

Result: positive

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

> cytogenetic assay) Species: Mouse

Application Route: Intraperitoneal injection

Method: OECD Test Guideline 474

Result: positive

Germ cell mutagenicity -

Assessment

Positive result(s) from in vivo mammalian somatic cell muta-

genicity tests.

#### Carcinogenicity

Not classified based on available information.

#### **Components:**

#### Dihydrostreptomycin sulphate:

**Species** Rat Application Route Oral Exposure time 2 Years

NOAEL 5 mg/kg body weight

Result negative



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#### Reproductive toxicity

Suspected of damaging the unborn child.

#### Components:

#### Dihydrostreptomycin sulphate:

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

Species: Rabbit

Application Route: Oral

Developmental Toxicity: NOAEL: 5 mg/kg body weight

Test Type: Embryo-fetal development

Species: Guinea pig

Application Route: Intramuscular

General Toxicity Maternal: LOAEL: 100 - 200 mg/kg body

weiaht

Developmental Toxicity: NOAEL: 10 mg/kg body weight Result: Maternal toxicity observed., Embryotoxic effects and

adverse effects on the offspring were detected.

Benzylpenicillin:

Effects on fertility : Test Type: Fertility

Species: Mouse

Result: No effects on fertility.

Test Type: Fertility Species: Rat

Result: No effects on fertility.

Test Type: Fertility Species: Rabbit

Result: No effects on fertility.

Effects on fetal development : Test Type: Development

Species: Mouse

Result: No effects on fetal development.

Test Type: Development

Species: Rat

Result: No effects on fetal development.

Test Type: Development

Species: Rabbit

Result: No effects on fetal development.

Sodium hydroxymethanesulphinate:

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



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Result: negative

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

Species: Rat

Application Route: Ingestion Method: OECD Test Guideline 414

Result: positive

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**

Causes damage to organs (ear, Kidney, inner ear) through prolonged or repeated exposure if swallowed.

#### **Components:**

#### Dihydrostreptomycin sulphate:

Assessment : Causes damage to organs through prolonged or repeated

exposure.

#### Repeated dose toxicity

#### **Components:**

#### Dihydrostreptomycin sulphate:

Species : Guinea pig
LOAEL : 40 mg/kg
Application Route : Oral
Exposure time : 90 d
Target Organs : ear

Symptoms : hearing loss

Species : Cat
LOAEL : 100 mg/kg
Application Route : Oral
Exposure time : 60 d
Target Organs : ear

Symptoms : ataxia, hearing loss, Reduced body weight

Species : Cat
LOAEL : 300 mg/kg
Application Route : Oral
Exposure time : 21 d
Target Organs : ear

Symptoms : ataxia, hearing loss, Reduced body weight

#### Sodium hydroxymethanesulphinate:

Species : Rat



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NOAEL : 600 mg/kg
Application Route : Ingestion
Exposure time : 13 Weeks

Method : OECD Test Guideline 408

Aspiration toxicity

Not classified based on available information.

**Experience with human exposure** 

**Components:** 

Dihydrostreptomycin sulphate:

General Information : Symptoms: Erythema, hearing loss, Nausea, Rash, Vomiting,

Headache, hypotension

Benzylpenicillin:

Inhalation : Symptoms: Allergic reactions, Abdominal pain, bron-

chospasm, skin rash

**SECTION 12. ECOLOGICAL INFORMATION** 

**Ecotoxicity** 

**Components:** 

Benzylpenicillin:

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): > 100 mg/l

Exposure time: 96 hrs

Method: OECD Test Guideline 203

Toxicity to daphnia and other :

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): 3.6 mg/l

Exposure time: 48 hrs

Method: OECD Test Guideline 202

Toxicity to algae/aquatic

plants

EC50 (Raphidocelis subcapitata (freshwater green alga)): >

100 mg/l

Exposure time: 72 hrs

Method: OECD Test Guideline 201

NOEC (Raphidocelis subcapitata (freshwater green alga)): 50

ma/l

Exposure time: 72 hrs

Method: OECD Test Guideline 201

EC50 (blue-green algae): 0.74 mg/l

Exposure time: 72 hrs

Method: OECD Test Guideline 201

NOEC (blue-green algae): 0.14 mg/l

Exposure time: 72 hrs

Method: OECD Test Guideline 201



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Toxicity to microorganisms : EC50: > 500 mg/l

Exposure time: 3 h

Test Type: Respiration inhibition Method: OECD Test Guideline 209

NOEC: 5 mg/l Exposure time: 3 h

Test Type: Respiration inhibition Method: OECD Test Guideline 209

Sodium hydroxymethanesulphinate:

Toxicity to fish : LC50 (Leuciscus idus (Golden orfe)): > 10,000 mg/l

Exposure time: 96 h

Toxicity to daphnia and other :

aquatic invertebrates

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

Exposure time: 48 h

Method: OECD Test Guideline 202

Toxicity to algae/aquatic

plants

ErC50 (Desmodesmus subspicatus (green algae)): 370 mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

NOEC (Desmodesmus subspicatus (green algae)): 10 mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

Toxicity to fish (Chronic tox-

icity)

NOEC (Danio rerio (zebra fish)): 13.5 mg/l

Exposure time: 35 d

Method: OECD Test Guideline 210

Toxicity to daphnia and other : aquatic invertebrates (Chron-

ic toxicity)

EC10 (Daphnia magna (Water flea)): 8 mg/l

Exposure time: 21 d

Method: OECD Test Guideline 211

Toxicity to microorganisms : NOEC: 10 mg/l

Exposure time: 4 h

Persistence and degradability

**Components:** 

Benzylpenicillin:

Biodegradability : Result: Readily biodegradable.

Biodegradation: 70.10 % Exposure time: 28 d

Method: OECD Test Guideline 301B

Sodium hydroxymethanesulphinate:

Biodegradability : Result: Readily biodegradable.

Biodegradation: 77 % Exposure time: 28 d

Method: OECD Test Guideline 301B



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#### **Bioaccumulative potential**

#### **Components:**

#### Sodium hydroxymethanesulphinate:

Partition coefficient: n-

:  $\log Pow: < 0.3$ 

octanol/water

### Mobility in soil

No data available

#### Other adverse effects

No data available

#### **SECTION 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

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**

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**

#### NOM-002-SCT

Not regulated as a dangerous good

### Special precautions for user

Not applicable

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

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

Federal Law for the control of chemical precursors, essential chemical products and machinery for

Not applicable



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producing capsules, tablets and pills.

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

AICS : not determined

DSL : not determined

IECSC : not determined

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

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#### Full text of other abbreviations

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, Bioaccumulative 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

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/



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MX / Z8