

## ToMORROW® suspension for intramammary infusion

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### SECTION 1. IDENTIFICATION

Product name : ToMORROW® suspension for intramammary infusion

Synonyms : ToMORROW® (cephapirin benzathine); Cefa-Dri® (cephapirin benzathine)  
with active ingredient: Cephapirin benzathine

#### Manufacturer or supplier's details

Company name of supplier : Boehringer Ingelheim AH USA

Address : Satellite Blvd Ste 500 3239  
Duluth GA 30096  
USA

Telephone : (678) 638-3000

Prepared by : EHS-Services@Boehringer-Ingelheim.com

Emergency telephone number : Int. Emergency Telephone number: +1 703-527-3887  
US Emergency Telephone number: +1 703-741-5970

#### Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product

Restrictions on use : Safety Data Sheet only for the professional user., For veterinary use only, Refer to the product insert for complete instructions on usage

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### SECTION 2. HAZARDS IDENTIFICATION

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


Respiratory sensitisation : Category 1

Skin sensitisation : Category 1

#### GHS label elements

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- Hazard pictograms : 
- Signal word : Danger
- Hazard statements : H317 May cause an allergic skin reaction.  
H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.
- Precautionary statements : **Prevention:**  
P261 Avoid breathing mist or vapours.  
P272 Contaminated work clothing must not be allowed out of the workplace.  
P280 Wear protective gloves.  
P285 In case of inadequate ventilation wear respiratory protection.
- Response:**  
P302 + P352 IF ON SKIN: Wash with plenty of soap and water.  
P304 + P341 IF INHALED: If breathing is difficult, remove person to fresh air and keep comfortable for breathing.  
P333 + P313 If skin irritation or rash occurs: Get medical advice/attention.  
P342 + P311 If experiencing respiratory symptoms: Call a POISON CENTER/ doctor.  
P363 Wash contaminated clothing before reuse.
- Disposal:**  
P501 Dispose of contents/ container to an approved waste disposal plant.

### Other hazards

This drug is not subject to the labelling requirements under the Globally Harmonized System (GHS)  
The pharmacological effect of the medicament has to be considered (see package leaflet).

## SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

- Substance / Mixture : Mixture
- Chemical nature : Mixture

### Components

Chemical name	CAS-No.	Concentration (% w/w)
Peanut oil	8002-03-7	>= 90 - <= 100
Cephapirin Benzathine	97468-37-6	>= 1 - < 5
dihydroxyaluminium stearate	7047-84-9	>= 1 - < 5

Actual concentration is withheld as a trade secret

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**SECTION 4. FIRST AID MEASURES**

- General advice : In the case of accident or if you feel unwell, seek medical advice immediately.  
(show the package insert where possible).  
First Aid responders should pay attention to self-protection and use the recommended protective clothing  
Remove from exposure, lie down.  
Take off immediately all contaminated clothing.  
Victim to lie down in the recovery position, cover and keep him warm.
- If inhaled : Move to fresh air.
- In case of skin contact : Wash off immediately with plenty of water.
- In case of eye contact : Rinse immediately with plenty of water for at least 15 minutes.  
Keep eye wide open while rinsing.
- If swallowed : Rinse mouth.  
Drink plenty of water.
- Most important symptoms and effects, both acute and delayed : May cause an allergic skin reaction.  
May cause allergy or asthma symptoms or breathing difficulties if inhaled.
- Notes to physician : Observe the summary of product characteristics of proprietary medicinal products  
Treat symptomatically.
- 

**SECTION 5. FIREFIGHTING MEASURES**

- Suitable extinguishing media : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.  
Water  
Dry chemical  
Foam  
Carbon dioxide (CO<sub>2</sub>)
- Unsuitable extinguishing media : None known.
- Specific hazards during fire-fighting : In case of fire and/or explosion do not breathe fumes.
- Hazardous combustion products : Carbon oxides
- Further information : Collect contaminated fire extinguishing water separately. This must not be discharged into drains.  
Fire residues and contaminated fire extinguishing water must be disposed of in accordance with local regulations.
- Special protective equipment : In the event of fire, wear self-contained breathing apparatus.
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for firefighters

Complete suit protecting against chemicals

## SECTION 6. ACCIDENTAL RELEASE MEASURES

- Personal precautions, protective equipment and emergency procedures : Wear personal protective equipment.  
Ensure adequate ventilation.  
High risk of slipping due to leakage/spillage of product.
- Environmental precautions : Do not flush into surface water or sanitary sewer system.
- Methods and materials for containment and cleaning up : Pick up and transfer to properly labelled containers.  
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders).

## SECTION 7. HANDLING AND STORAGE

- Advice on protection against fire and explosion : No special protective measures against fire required.
- Advice on safe handling : Provide sufficient air exchange and/or exhaust in work rooms.
- Conditions for safe storage : Refer to the product insert for instructions on storage.
- Materials to avoid : Keep away from food, drink and animal feedingstuffs.  
Observe joint storage prohibition.

## SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

### Components with workplace control parameters

Components	Basis	Category	Values	Remarks
Cephapirin Benzathine 97468-37-6	BIEL	3A	20 µg/m <sup>3</sup>	
	BIPC	1b		

#### Abbreviations:

BIEL = Boehringer Ingelheim Exposure Limit (internal value)

BI-STEL = Boehringer Ingelheim Short-Term Exposure Limit (Excursion limit)

BIPC = Boehringer Ingelheim Pregnancy Category

BIPC 1b: No risk of harm to the unborn is to be expected, when the exposure does not exceed the BIEL value. There is evidence in animals and/or humans that this material has the potential to cause harm to the unborn at exposure levels exceeding the BIEL value.

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Peanut oil	8002-03-7	TWA (mist - total)	10 mg/m <sup>3</sup>	NIOSH REL
		TWA (mist - respirable)	5 mg/m <sup>3</sup>	NIOSH REL
dihydroxyaluminium stearate	7047-84-9	TWA (Inhal-)	10 mg/m <sup>3</sup>	ACGIH

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		able particulate matter)		
		TWA (Respirable particulate matter)	3 mg/m3	ACGIH
		TWA (Respirable particulate matter)	1 mg/m3 (Aluminium)	ACGIH

**Engineering measures** : Local exhaust  
Emergency sprinkling nozzle

**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** : Nitrile rubber

**Remarks** : The break through time depends amongst other things on the material, the thickness and the type of glove and therefore has to be measured for each case.

**Eye protection** : Safety glasses with side-shields  
(Not necessary when using full face mask)

**Skin and body protection** : Laboratory: laboratory coat; Factory: disposable Overall.

**Protective measures** : Handle in accordance with good industrial hygiene and safety practice.  
Avoid contact with skin, eyes and clothing.  
Only use protective equipment in accordance with national/international regulations. Follow the national regulations about wearing personal protective equipment and the warranty given by the manufacturer for the safe function.

**Hygiene measures** : General industrial hygiene practice.  
Wash hands and face before breaks and immediately after handling the product.  
Keep working clothes separately.

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**SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES**

Appearance	:	suspension
Colour	:	off-white
Odour	:	No data available
pH	:	No data available
Melting point/range	:	No data available
Boiling point/boiling range	:	No data available
Flash point	:	541 °F / 283 °C
Flammability (solid, gas)	:	Not applicable
Self-ignition	:	No data available
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Vapour pressure	:	No data available
Relative vapour density	:	No data available
Relative density	:	No data available
Density	:	No data available
Bulk density	:	Not applicable
Solubility(ies)		
Water solubility	:	No data available
Partition coefficient: n-octanol/water	:	No data available
Auto-ignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity		
Viscosity, dynamic	:	No data available

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Viscosity, kinematic	:	No data available
Explosive properties	:	Not tested
Oxidizing properties	:	No data available
Particle size	:	Not applicable

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**SECTION 10. STABILITY AND REACTIVITY**

Reactivity	:	No dangerous reaction known under conditions of normal use.
Chemical stability	:	No decomposition if stored and applied as directed.
Possibility of hazardous reactions	:	No dangerous reaction known under conditions of normal use.
Conditions to avoid	:	No data available
Incompatible materials	:	No data available
Hazardous decomposition products	:	No data available

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**SECTION 11. TOXICOLOGICAL INFORMATION****Acute toxicity**

Not classified based on available information.

**Components:****Cephapirin Benzathine:**

Acute oral toxicity	:	LD50 (Mouse): 26,088 mg/kg The value is given in analogy to the following substances: Cephapirin sodium
		LD50 (Rat, male): 14,000 mg/kg The value is given in analogy to the following substances: Cephapirin sodium
Acute inhalation toxicity	:	Remarks: No data available
Acute dermal toxicity	:	Remarks: No data available
Acute toxicity (other routes of administration)	:	LD50 (Mouse, male): 4,600 mg/kg Application Route: intravenous The value is given in analogy to the following substances: Cephapirin sodium
		LD50 (Rat, male): 4,580 mg/kg Application Route: intravenous

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The value is given in analogy to the following substances:  
Cephapirin sodium

LD50 (Rabbit): > 3,000 mg/kg  
Application Route: intravenous  
The value is given in analogy to the following substances:  
Cephapirin sodium

**Skin corrosion/irritation**

Not classified based on available information.

**Components:****Cephapirin Benzathine:**

Remarks : No data available

**Serious eye damage/eye irritation**

Not classified based on available information.

**Components:****Cephapirin Benzathine:**

Remarks : No data available

**Respiratory or skin sensitisation****Skin sensitisation**

May cause an allergic skin reaction.

**Respiratory sensitisation**

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

**Components:****Cephapirin Benzathine:**

Assessment : May cause sensitisation by skin contact.

Assessment : May cause sensitisation by inhalation.

**Germ cell mutagenicity**

Not classified based on available information.

**Components:****Cephapirin Benzathine:**

Genotoxicity in vitro : Test Type: Ames test  
Result: negative  
The value is given in analogy to the following substances:  
Cephapirin sodium

Test Type: Mouse lymphoma assay  
Result: negative  
The value is given in analogy to the following substances:



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Cephapirin sodium

Genotoxicity in vivo : Test Type: Micronucleus test  
Species: Mouse  
Application Route: Oral  
Result: negative  
The value is given in analogy to the following substances:  
Cephapirin sodium

**Carcinogenicity**

Not classified based on available information.

**Components:****Cephapirin Benzathine:**

Remarks : No data available

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

Not classified based on available information.

**Components:****Cephapirin Benzathine:**

Effects on fertility : Test Type: Fertility  
Species: Rat, male and female  
Dose: 200, 500 mg/kg/day  
Symptoms: No effects on fertility  
The value is given in analogy to the following substances:  
Cephapirin sodium

Effects on foetal development : Test Type: Embryo-foetal development  
Species: Mouse  
Dose: 200, 500 mg/kg/day  
Symptoms: No effects on embryofoetal and postnatal development  
The value is given in analogy to the following substances:  
Cephapirin sodium

Test Type: Embryo-foetal development  
Species: Rat  
Dose: 200, 500 mg/kg/day  
Symptoms: No effects on embryofoetal and postnatal development  
The value is given in analogy to the following substances:

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Cephapirin sodium

**STOT - single exposure**

Not classified based on available information.

**Components:****Cephapirin Benzathine:**

Remarks : Not classified due to data which are conclusive although insufficient for classification.

**STOT - repeated exposure**

Not classified based on available information.

**Components:****Cephapirin Benzathine:**

Remarks : Not classified due to data which are conclusive although insufficient for classification.

**Repeated dose toxicity****Components:****Cephapirin Benzathine:**

Species	: Rat
Application Route	: intraperitoneal
Exposure time	: 26 weeks
Dose	: $\geq$ 200 mg/kg
Symptoms	: anemia

The value is given in analogy to the following substances: Cephapirin sodium

Species	: Rat
Application Route	: Oral
Exposure time	: 13 weeks
Dose	: 23 mg/kg/day
Symptoms	: No adverse effects

The value is given in analogy to the following substances: Cephapirin sodium

**Aspiration toxicity**

Not classified based on available information.

**Components:****Cephapirin Benzathine:**

No data available

**Further information****Components:****Cephapirin Benzathine:**

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Remarks : No data available

**SECTION 12. ECOLOGICAL INFORMATION****Ecotoxicity****Components:****Cephapirin Benzathine:**

Toxicity to fish : Remarks: No data available

Toxicity to daphnia and other aquatic invertebrates : Remarks: No data available

Toxicity to algae/aquatic plants : Remarks: No data available

Toxicity to fish (Chronic toxicity) : Remarks: No data available

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : Remarks: No data available

Toxicity to microorganisms : Remarks: No data available

**Ecotoxicology Assessment**

Acute aquatic toxicity : Toxic effects cannot be excluded

Chronic aquatic toxicity : Toxic effects cannot be excluded

**Persistence and degradability****Components:****Peanut oil:**

Biodegradability : Result: Readily biodegradable.

**Cephapirin Benzathine:**

Biodegradability : Result: No data available

**dihydroxyaluminium stearate:**

Biodegradability : Remarks: No data available

**Bioaccumulative potential****Components:****Peanut oil:**

Partition coefficient: n- : Remarks: No data available

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octanol/water

**Cephapirin Benzathine:**

Bioaccumulation : Remarks: No data available

Partition coefficient: n-  
octanol/water : Remarks: No data available**dihydroxyaluminium stearate:**Partition coefficient: n-  
octanol/water : Remarks: No data available**Mobility in soil****Components:****Cephapirin Benzathine:**Distribution among environ-  
mental compartments : Remarks: No data available**Other adverse effects****Product:**Ozone-Depletion Potential : Regulation: 40 CFR Protection of Environment; Part 82 Pro-  
tection of Stratospheric Ozone - CAA Section 602 Class I  
Substances  
Remarks: This product neither contains, nor was manufac-  
tured with a Class I or Class II ODS as defined by the U.S.  
Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A + B).**Components:****Cephapirin Benzathine:**Additional ecological infor-  
mation : No data available

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**SECTION 13. DISPOSAL CONSIDERATIONS****Disposal methods**

Waste from residues : Dispose of in accordance with local regulations.

Contaminated packaging : Packs that cannot be cleaned should be disposed of in the  
same manner as the contents.  
Uncontaminated packaging can be recycled.

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**SECTION 14. TRANSPORT INFORMATION****International Regulations**

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**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.

**National Regulations****49 CFR**

Not regulated as a dangerous good

**Special precautions for user**

Not applicable

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**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 sensitisation**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.**Clean Air Act**

This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A + B).

This product does not contain any hazardous air pollutants (HAP), as defined by the U.S. Clean Air Act Section 112 (40 CFR 61).

This product does not contain any chemicals listed under the U.S. Clean Air Act Section 112(r) for Accidental Release Prevention (40 CFR 68.130, Subpart F).

This product does not contain any chemicals listed under the U.S. Clean Air Act Section 111 SOCM I Intermediate or Final VOC's (40 CFR 60.489).

**Clean Water Act**

This product does not contain any Hazardous Substances listed under the U.S. CleanWater Act, Section 311, Table 116.4A.

This product does not contain any Hazardous Chemicals listed under the U.S. CleanWater Act, Section 311, Table 117.3.

This product does not contain any toxic pollutants listed under the U.S. Clean Water Act Section 307

This product does not contain any priority pollutants related to the U.S. Clean Water Act

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### US State Regulations

#### Massachusetts Right To Know

No components are subject to the Massachusetts Right to Know Act.

#### Pennsylvania Right To Know

Peanut oil	8002-03-7
Cephapirin Benzathine	97468-37-6
dihydroxyaluminium stearate	7047-84-9

#### Maine Chemicals of High Concern

Product does not contain any listed chemicals

#### Vermont Chemicals of High Concern

Product does not contain any listed chemicals

#### Washington Chemicals of High Concern

Product does not contain any listed chemicals

#### California Permissible Exposure Limits for Chemical Contaminants

Peanut oil	8002-03-7
dihydroxyaluminium stearate	7047-84-9

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

TCSI	:	Not in compliance with the inventory
TSCA	:	Product contains substance(s) not listed on TSCA inventory.
AIIC	:	Not in compliance with the inventory
DSL	:	This product contains the following components that are not on the Canadian DSL nor NDSL.  Cephapirin Benzathine
ENCS	:	Not in compliance with the inventory
ISHL	:	Not in compliance with the inventory
KECI	:	Not in compliance with the inventory
PICCS	:	Not in compliance with the inventory
IECSC	:	Not in compliance with the inventory
NZIoC	:	Not in compliance with the inventory
TECI	:	Not in compliance with the inventory

#### TSCA list

No substances are subject to a Significant New Use Rule.

No substances are subject to TSCA 12(b) export notification requirements.

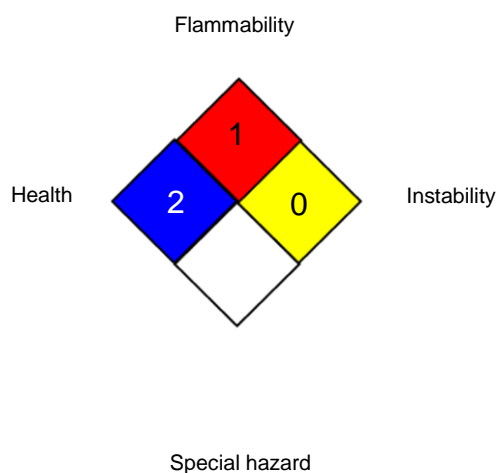
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## SECTION 16. OTHER INFORMATION

### Further information

#### NFPA 704:



#### HMIS® IV:

HEALTH	*	2
FLAMMABILITY		1
PHYSICAL HAZARD		0

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); EC<sub>x</sub> - Concentration associated with x% response; EHS - Extremely Hazardous Substance; EL<sub>x</sub> - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErC<sub>x</sub> - 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; IC<sub>50</sub> - 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; LC<sub>50</sub> - Lethal Concentration to 50 % of a test population; LD<sub>50</sub> - 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;

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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 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 Safety Data Sheet : The specifications are based on own tests and/or literature data.

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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.

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