

OPSYNVI

Version	Revision Date:	SDS Number:	Date of last issue:
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SECTION 1. IDENTIFICATION

Product name : OPSYNVI
Substance name : OPSYNVI ; macitentan 10 mg / tadalafil 40 mg film-coated tablets
macitentan
tadalafil

Reference number : JNJ-68150420-ZZZ

Manufacturer or supplier's details

Company name of supplier : Janssen Pharmaceuticals, Inc.

Address : 1125 Trenton-Harbourton Rd
Titusville NJ 08560

USA

Telephone : +16097302000

E-mail address of person responsible for the SDS : SDSJanssen@its.jnj.com

Emergency telephone number : **CHEMTREC US: 1-800-424-9300**
CHEMTREC International: +1 703-741-5970

Recommended use of the chemical and restrictions on use

Recommended use : Finished Pharmaceutical Product
This SDS is only intended for occupational use and not for consumer use (see patient packaging insert for consumer use). This SDS is written to provide environmental, health and safety information for personnel that will be handling this finished pharmaceutical product. For health and safety information during manufacturing of this product we refer to the appropriate SDS for each component.
This dosage form is exempt from the requirements of the OSHA Hazard Communication Standard (US OSHA Standard 29 CFR Part 1910.1200).

SECTION 2. HAZARDS IDENTIFICATION

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

Reproductive toxicity : Category 1B

GHS label elements

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Hazard pictograms

:



Signal word

:

Danger

Hazard statements

:

H360D May damage 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.

P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response:

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

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

Chemical nature

:

Solid

Components

Chemical name	CAS-No.	Concentration (% w/w)
Cellulose	9004-34-6	≥ 10 - < 20
TADALAFIL	171596-29-5	≥ 5 - < 10
MACITENTAN	441798-33-0	≥ 1 - < 5
Octadecanoic acid, magnesium salt	557-04-0	≥ 0.1 - < 1
TITANDIOXIDE	13463-67-7	≥ 0.1 - < 1
DODECYL SODIUM SULPHATE	151-21-3	≥ 0.1 - < 1

Actual concentration is withheld as a trade secret

SECTION 4. FIRST AID MEASURES

If inhaled

:

Health injuries are not known or expected under normal use.

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	Consult a physician.
In case of skin contact	: Take off contaminated clothing and shoes immediately. Wash off with soap and water. If symptoms persist, call a physician.
In case of eye contact	: Rinse immediately with plenty of water, also under the eyelids, for at least 5 minutes. Remove contact lenses. If eye irritation persists, consult a specialist.
If swallowed	: If swallowed, rinse mouth with water (only if the person is conscious). Call a physician immediately.
Most important symptoms and effects, both acute and delayed	: Headache flushing anemia muscle pain
Notes to physician	: Treat symptomatically.

SECTION 5. FIREFIGHTING MEASURES

Suitable extinguishing media	: Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Hazardous combustion products	: No information available.
Further information	: No information available.
Special protective equipment for firefighters	: In the event of fire, wear self-contained breathing apparatus.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures	: Evacuate personnel to safe areas. In the event of an accidental release the emergency response team must respond based on a risk assessment and use personal protective equipment as appropriate.
Environmental precautions	: Should not be released into the environment.
Methods and materials for containment and cleaning up	: Large spills: Sweep up or vacuum with HEPA filter or via wet cleaning into suitable containers for disposal. Pick up and arrange without creating dust. Keep in properly labelled containers. Small spills: Moisten a towel, cover the spill, pick up the spill or use HEPA vacuum. Large spills + Small spills: Keep in suitable, closed containers

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for disposal. Treat recovered material as described in the section "Disposal considerations".

SECTION 7. HANDLING AND STORAGE

- Advice on protection against fire and explosion : No data available
- Advice on safe handling : Do not break, crush or spill this Finished Pharmaceutical Product.
To avoid thermal decomposition, do not overheat.
Use personal protective equipment as required.
Avoid inhalation, ingestion and contact with skin and eyes.
- Conditions for safe storage : To maintain product quality, do not store in heat or direct sunlight.
Store in original container.
Keep containers tightly closed in a dry, cool and well-ventilated place.
Keep away from heat and sources of ignition.
Store at room temperature.
- Recommended storage temperature : 59 - 86 °F / 15 - 30 °C

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION**Components with workplace control parameters**

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Cellulose	9004-34-6	TWA	10 mg/m ³	ACGIH
		TWA (Respirable)	5 mg/m ³	NIOSH REL
		TWA (total)	10 mg/m ³	NIOSH REL
		TWA (total dust)	15 mg/m ³	OSHA Z-1
		TWA (respirable fraction)	5 mg/m ³	OSHA Z-1
		TWA (Total dust)	15 mg/m ³	OSHA P0
		TWA (respirable dust fraction)	5 mg/m ³	OSHA P0
TADALAFIL	171596-29-5	TWA	0.008 mg/m ³	J&J OEL/PBOEL HHC

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		PBOEL-HHC	3 A	J&J OEL/PBOEL HHC
	Further information: J&J has a hazard banding notation: PBOEL HHC. This substance is classified by J&J as being PBOEL HHC 3A.			
MACITENTAN	441798-33-0	TWA	0.0043 mg/m3	J&J OEL/PBOEL HHC
		PBOEL-HHC	3 B	J&J OEL/PBOEL HHC
	Further information: J&J has a hazard banding notation: PBOEL HHC. This substance is classified by J&J as being PBOEL HHC 3B., Notation REPRO: has the potential to have adverse effects on reproduction and fetal development			
Octadecanoic acid, magnesium salt	557-04-0	TWA (Inhalable particulate matter)	10 mg/m3	ACGIH
		TWA (Respirable particulate matter)	3 mg/m3	ACGIH
TITANDIOXIDE	13463-67-7	TWA	2.4 mg/m3	J&J OEL/PBOEL HHC
		TWA	10 mg/m3	ACGIH
DODECYL SODIUM SULPHATE	151-21-3	TWA	0.5 mg/m3	J&J OEL/PBOEL HHC
		PBOEL-HHC	1 B	J&J OEL/PBOEL HHC
	Further information: J&J has a hazard banding notation: PBOEL HHC. This substance is classified by J&J as being PBOEL HHC 1B., Notation DSEN: has the potential to cause delayed allergic skin reaction (sensitization), such as wheals and rashes, Notation RSEN: has the potential to cause delayed allergic reactions (sensitization), such as shortness of breath, asthma and anaphylaxis.			

Engineering measures : All personal protective equipment should be based on a risk assessment. Consult a Environment Health Safety expert if necessary.
If this product is processed not in accordance with the prescribed use, contact the Industrial Hygiene / Environment Health Safety Expert to assess the situation.

Personal protective equipment

Respiratory protection : No personal respiratory protective equipment normally required.

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Hand protection	:	
Remarks	:	Disposable gloves
Eye protection	:	No special precautions required.
Skin and body protection	:	closed work clothing
Protective measures	:	The type of protective equipment must be selected based on the Environmental Health and Safety risk assessment. Consult a Environmental Health and Safety expert if necessary.
Hygiene measures	:	Handle in accordance with good industrial hygiene and safety practice.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	:	Coated, tablet
Colour	:	white, to, off-white
Odour	:	No data available
Odour Threshold	:	No data available
pH	:	No data available
Melting point/ range	:	No data available
Boiling point/boiling range	:	No data available
Flash point	:	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
Solubility(ies)	:	
<u>Water solubility</u>	:	No data available
Partition coefficient: n-	:	No data available

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octanol/water

Auto-ignition temperature : No data available

Decomposition temperature : No data available

Viscosity

Viscosity, dynamic : No data availableViscosity, kinematic : No data available

Explosive properties : No data available

Oxidizing properties : No data available

SECTION 10. STABILITY AND REACTIVITY

Reactivity : None reasonably foreseeable.

Chemical stability : Stable under recommended storage conditions.

Possibility of hazardous reactions : No dangerous reaction known under conditions of normal use.

Conditions to avoid : To avoid thermal decomposition, do not overheat.
Heat, flames and sparks.

Incompatible materials : None known.

Hazardous decomposition products : None known.

SECTION 11. TOXICOLOGICAL INFORMATION**Acute toxicity****Product:**Acute oral toxicity : Acute toxicity estimate: > 5,000 mg/kg
Method: Calculation methodAcute inhalation toxicity : Acute toxicity estimate: 15.87 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Method: Calculation method**Components:****Cellulose:**

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

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

Acute inhalation toxicity : Assessment: The component/mixture is moderately toxic after short term inhalation.

Acute dermal toxicity : LD50 (Rabbit): > 1,000 mg/kg

Acute toxicity (other routes of administration) : (Mouse): 62.5 mg/kg
Application Route: intravenous injection
Symptoms: Tremors, Breathing difficulties, Convulsions

MACITENTAN:

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

DODECYL SODIUM SULPHATE:

Acute oral toxicity : LD50 Oral (Rat): 1,200 mg/kg
Method: OECD Test Guideline 401
Assessment: The component/mixture is moderately toxic after single ingestion.

Acute inhalation toxicity : Assessment: The component/mixture is moderately toxic after short term inhalation.

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

Skin corrosion/irritation**Components:****Cellulose:**

Species : Rabbit
Remarks : No skin irritation

TADALAFIL:

Result : Skin irritation

DODECYL SODIUM SULPHATE:

Species : Rabbit
Method : OECD Test Guideline 404
Result : Skin irritation

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Serious eye damage/eye irritation**Components:****Cellulose:**

Species	:	Rabbit
Remarks	:	No eye irritation

TADALAFIL:

Species	:	Rabbit
Result	:	Mild eye irritation

DODECYL SODIUM SULPHATE:

Species	:	Rabbit
Result	:	Corrosive to eyes
Method	:	OECD Test Guideline 405

Respiratory or skin sensitisation**Components:****Cellulose:**

Species	:	Guinea pig
Remarks	:	Did not cause sensitisation on laboratory animals.

DODECYL SODIUM SULPHATE:

Result	:	Not a sensitizer
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Germ cell mutagenicity**Components:****TADALAFIL:**

Genotoxicity in vitro	:	Test Type: Ames test Result: negative
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	:	Test Type: A mouse lymphoma test Result: negative
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Germ cell mutagenicity - Assessment	:	Animal testing did not show any mutagenic effects.
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MACITENTAN:

Genotoxicity in vitro	:	Test Type: Ames test Method: Bacterial Reverse Mutation Test Result: negative
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	:	Test Type: A mouse lymphoma test Result: negative
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Test Type: Chromosome aberration test in vitro
Test system: Human lymphocytes
Result: negative

Genotoxicity in vivo : Test Type: Micronucleus test
Species: Rat
Result: negative

Germ cell mutagenicity - Assessment : No evidence of mutagenicity based on in vitro and in vivo studies and expert judgment.

DODECYL SODIUM SULPHATE:

Genotoxicity in vitro : Method: OECD Test Guideline 471
Result: negative

Carcinogenicity**Components:****TADALAFIL:**

Species : Rat
Exposure time : 2 y
Dose : 400 mg/kg body weight
Frequency of Treatment : daily
Result : negative

Carcinogenicity - Assessment : Animal testing did not show any carcinogenic effects.

MACITENTAN:

Carcinogenicity - Assessment : Did not show carcinogenic effects in animal experiments.

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**Components:****TADALAFIL:**

Reproductive toxicity - Assessment : Animal testing did not show any effects on fertility.

Teratogenicity - Assessment : Did not show teratogenic effects in animal experiments.

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Effects on foetal development : Test Type: Embryo-foetal development
Species: Rat
Dose: 25 mg/kg bw/day
Symptoms: Fetotoxicity

Test Type: Embryo-foetal development
Species: Rabbit
Dose: 25 mg/kg bw/day
Symptoms: Fetotoxicity

Reproductive toxicity - Assessment : No information available.

Teratogenicity - Assessment : Clear evidence of adverse effects on development, based on animal experiments.

DODECYL SODIUM SULPHATE:

Effects on fertility : Remarks: negative

STOT - single exposure**Components:****TADALAFIL:**

Assessment : The substance or mixture is classified as specific target organ toxicant, single exposure, category 3 with respiratory tract irritation.

DODECYL SODIUM SULPHATE:

Exposure routes : Inhalation
Assessment : The substance or mixture is classified as specific target organ toxicant, single exposure, category 3 with respiratory tract irritation.

STOT - repeated exposure

No data available

Repeated dose toxicity**Components:****TADALAFIL:**

Species : Mouse
Application Route : Oral
Exposure time : 3 m
Number of exposures : daily
Dose : 800 mg/kg
Symptoms : No adverse effects

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Species : Rat
Application Route : Oral
Exposure time : 6 m
Number of exposures : daily
Dose : 400 mg/kg
Symptoms : No adverse effects

Species : Rat
Application Route : Oral
Exposure time : 3 m
Number of exposures : daily
Dose : 800 mg/kg
Symptoms : No adverse effects

Species : Dog
Application Route : Oral
Exposure time : 12 m
Number of exposures : daily
Dose : 25 mg/kg
Symptoms : Impaired spermatogenesis
Remarks : No human information is available.

MACITENTAN:

Species : Dog
NOAEL : 5 mg/kg
Exposure time : 39 w

Species : Rat
NOAEL : 10 mg/kg
Exposure time : 26 w

Aspiration toxicity

No data available

Experience with human exposure

No data available

Toxicology, Metabolism, Distribution

No data available

Neurological effects

No data available

Further information

No data available

Other health hazards

No data available

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SECTION 12. ECOLOGICAL INFORMATION**Ecotoxicity****Components:****Cellulose:**

Toxicity to fish : Remarks: No data available

TADALAFIL:

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

MACITENTAN:

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

DODECYL SODIUM SULPHATE:

Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): 29 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 203

Toxicity to daphnia and other aquatic invertebrates : LC50 (Ceriodaphnia dubia (water flea)): 5.55 mg/l
Exposure time: 48 h
Test Type: flow-through test

Toxicity to algae/aquatic plants : EC50 (Desmodesmus subspicatus (green algae)): > 120 mg/l
Exposure time: 72 h

Toxicity to fish (Chronic toxicity) :

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC: 1 mg/l

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Persistence and degradability**Components:****TADALAFIL:**

Biodegradability : Remarks: No data available

MACITENTAN:

Biodegradability : Remarks: No data available

DODECYL SODIUM SULPHATE:

Biodegradability : Result: Readily biodegradable.

Biochemical Oxygen Demand (BOD) : > 60 %(m)

Dissolved organic carbon (DOC) : > 70 %(m)

Bioaccumulative potential**Components:****TADALAFIL:**

Bioaccumulation : Remarks: No data available

Partition coefficient: n-octanol/water : Remarks: No data available

MACITENTAN:

Bioaccumulation : Remarks: Does not bioaccumulate.

Partition coefficient: n-octanol/water : Pow: 2.9
pH: 7.4**Octadecanoic acid, magnesium salt:**

Partition coefficient: n-octanol/water : Remarks: No data available

TITANDIOXIDE:

Partition coefficient: n-octanol/water : Remarks: No data available

DODECYL SODIUM SULPHATE:

Bioaccumulation : Remarks: No data available

Partition coefficient: n-octanol/water : log Pow: 0.83 (68 °F / 20 °C)

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Mobility in soil**Components:****DODECYL SODIUM SULPHATE:**

Mobility : Remarks: No data available

Distribution among environmental compartments : Remarks: No data available

Other adverse effects**Components:****DODECYL SODIUM SULPHATE:**

Environmental fate and pathways : No data available

Results of PBT and vPvB assessment : Substance is not persistent, bioaccumulative, and toxic (PBT).

Additional ecological information : No data available

SECTION 13. DISPOSAL CONSIDERATIONS**Disposal methods**

Waste from residues : In accordance with National, Federal, State and Local regulations.

Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal.

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.

National Regulations

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49 CFR

Not regulated as a dangerous good

SECTION 15. REGULATORY INFORMATION

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 : 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

Massachusetts Right To Know

Cellulose 9004-34-6

Pennsylvania Right To Know

alpha-D-Glucopyranose, 4-O-beta-D-galactopyranosyl-, hydrate (1:1) 5989-81-1
Cellulose 9004-34-6
TADALAFIL 171596-29-5
Hydroxypropylcellulose 9004-64-2
9063-38-1

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

Cellulose 9004-34-6

Other regulations

Restricted to professional users.

Medicinal products in the finished state, intended for the final user, are not subject to GHS labeling.

This product is not subject to TSCA and TSCA 12(b) Export notification because Food, Drugs and cosmetic products are exempt.

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SECTION 16. OTHER INFORMATION**Full text of other abbreviations**

ACGIH	:	US. ACGIH Threshold Limit Values
ACGIH	:	USA. ACGIH Threshold Limit Values (TLV)
J&J OEL/PBOEL HHC	:	J&J OEL/PBOEL HHC
NIOSH REL	:	USA. NIOSH Recommended Exposure Limits
OSHA P0	:	USA. Table Z-1-A Limits for Air Contaminants (1989 vacated values)
OSHA Z-1	:	USA. Occupational Exposure Limits (OSHA) - Table Z-1 Limits for Air Contaminants
ACGIH / TWA	:	Time weighted average
ACGIH / TWA	:	8-hour, time-weighted average
J&J OEL/PBOEL HHC / TWA	:	Time weighted average
J&J OEL/PBOEL HHC / PBOEL-HHC	:	PBOEL-HHC
NIOSH REL / TWA	:	Time-weighted average concentration for up to a 10-hour workday during a 40-hour workweek
OSHA P0 / TWA	:	8-hour time weighted average
OSHA Z-1 / TWA	:	8-hour time weighted average

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 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

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Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods;
vPvB - Very Persistent and Very Bioaccumulative

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Date and Number Formats

This document uses the following notation for printing dates and numbers:

Date:	Dec 31th, 2012	as	2012/12/31
Numbers:	123456,78	as	123,456.78

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