SECTION 1. IDENTIFICATION

Product name	:	ERLEADA
Substance name	:	ERLEADA 240 mg FC tablet apalutamide

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 Pharmacotherapeutic group: Endocrine therapy 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)

Skin sensitisation	:	Category 1
Reproductive toxicity	:	Category 1B
Specific target organ toxicity - repeated exposure	:	Category 2 (male reproductive organs, Endocrine system, Central nervous system)
Short-term (acute) aquatic	:	Category 3

hazard

Long-term (chronic) aquatic hazard : Category 2

GHS label elements

Hazard pictograms :

Signal word : Danger

Hazard statements :
H317 May cause an allergic skin reaction.
H360 May damage fertility or the unborn child.
H373 May cause damage to organs (male reproductive organs, Endocrine system, Central nervous system) through prolonged or repeated exposure.
H402 Harmful to aquatic life.
H411 Toxic to aquatic life with long lasting effects.

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 dust.
P272 Contaminated work clothing must not be allowed out of the workplace.
P273 Avoid release to the environment.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response:

P302 + P352 IF ON SKIN: Wash with plenty of soap and water.
P308 + P313 IF exposed or concerned: Get medical advice/ attention.
P333 + P313 If skin irritation or rash occurs: Get medical advice/ attention.
P363 Wash contaminated clothing before reuse.
P391 Collect spillage.

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)
microcrystalline cellulose	9004-34-6	>= 30 - < 50
APALUTAMIDE	956104-40-8	>= 20 - < 30
DIOXOSILANE	7631-86-9	>= 1 - < 5
titandioxide	13463-67-7	>= 0.1 - < 1
Octadecanoic acid, magnesium salt	557-04-0	>= 0.1 - < 1

Actual concentration is withheld as a trade secret

SECTION 4. FIRST AID MEASURES

If inhaled : If breathed in, move person into fresh air.
Consult a physician.

In case of skin contact : Take off contaminated clothing and shoes immediately.
Wash off with plenty of 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 : Consult the patient packaging insert for more information about this Finished Pharmaceutical Product.
fractures
Fatigue
weight decrease
Diarrhoea
Rash
hypertension
hot flushes
decrease in appetite
Nausea
joint pain
Increased blood pressure

Notes to physician : Treat symptomatically.
Consult the patient packaging insert for more information about this Finished Pharmaceutical Product.

SECTION 5. FIREFIGHTING MEASURES

Suitable extinguishing media : Use extinguishing measures that are appropriate to local

circumstances and the surrounding environment.

Unsuitable extinguishing media	:	Water spray jet
Specific hazards during firefighting	:	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	:	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. Avoid dust formation. Avoid breathing dust. Evacuate personnel to safe areas.
Environmental precautions	:	Should not be released into the environment. Do not flush into surface water or sanitary sewer system.
Methods and materials for containment and cleaning up	:	Large spills: Sweep up (intact) or vacuum with HEPA filter (broken or crushed) 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 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. Keep away from heat and sources of ignition. 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.
Recommended storage	:	59 - 86 °F / 15 - 30 °C

temperature

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
microcrystalline cellulose	9004-34-6	TWA	10 mg/m3	ACGIH
		TWA (Respirable)	5 mg/m3	NIOSH REL
		TWA (total)	10 mg/m3	NIOSH REL
		TWA (total dust)	15 mg/m3	OSHA Z-1
		TWA (respirable fraction)	5 mg/m3	OSHA Z-1
		TWA (Total dust)	15 mg/m3	OSHA P0
		TWA (respirable dust fraction)	5 mg/m3	OSHA P0
APALUTAMIDE	956104-40-8	TWA	0.018 mg/m3	J&J OEL/PBOEL HHC
		STV	0.100 mg/100cm²	J&J OEL/PBOEL HHC
		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., Notation DSEN: has the potential to cause delayed allergic skin reaction (sensitization), such as wheals and rashes, Notation REPRO: has the potential to have adverse effects on reproduction and fetal development, Notation SKIN: has the potential for absorption via the skin.			
DIOXOSILANE	7631-86-9	TWA	10 mg/m3	ACGIH
		STEL	0 ppm	ACGIH
		TWA (Dust)	20 Million particles per cubic foot (Silica)	OSHA Z-3
		TWA (Dust)	80 mg/m3 / %SiO2 (Silica)	OSHA Z-3
		TWA	6 mg/m3 (Silica)	NIOSH REL
		TWA	0.05 mg/m3	NIOSH REL

		(Respirable dust)	(Silica)	
		PEL (respirable)	0.05 mg/m3	OSHA CARC
titandioxide	13463-67-7	TWA	2.4 mg/m3	J&J OEL/PBOEL HHC
		TWA	10 mg/m3	ACGIH
Octadecanoic acid, magnesium salt	557-04-0	TWA (Inhalable particulate matter)	10 mg/m3	ACGIH
		TWA (Respirable particulate matter)	3 mg/m3	ACGIH

Engineering measures : All personal protective equipment should be based on a risk assessment. Consult a Environment Health Safety expert if necessary.
Engineering controls should be used as the primary means to control possible exposures. Use process enclosures, local exhaust ventilation or other engineering controls to keep exposure levels below recommended exposure limits.
If this product is processed not in accordance with the prescribed use, contact the Industrial Hygiene / Environment Health Safety Expert to assess the situation.
Validated Industrial Hygiene Analytical methods are developed to monitor and quantify inhalable exposure to the Active Pharmaceutical Ingredient. For more information contact Bureau Veritas Laboratories - Lake Zurich (BV_LZLab@bureauveritas.com) or the Laboratory of Occupational and Environmental Hygiene (lamh.be).

Personal protective equipment

Respiratory protection : No personal respiratory protective equipment normally required.

Hand protection
- Material : Nitrile rubber
- Remarks : Take note of the information given by the producer concerning permeability and break through times, and of special workplace conditions (mechanical strain, duration of contact).
Impervious gloves

Eye protection : No special precautions required.

Skin and body protection : closed work clothing

Protective measures : The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.

Hygiene measures	:	Handle in accordance with good industrial hygiene and safety practice.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	:	Coated, tablet
Colour	:	grey
Flash point	:	Not applicable
Density	:	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. Exposure to moisture Exposure to light.
Incompatible materials	:	None known.
Hazardous decomposition products	:	None known.

SECTION 11. TOXICOLOGICAL INFORMATION

Acute toxicity

Product:

Acute oral toxicity	:	Acute toxicity estimate: 2,500 mg/kg Method: Calculation method

Components:

APALUTAMIDE:

Acute oral toxicity	:	LD50 (Rat, male): > 1,000 mg/kg Method: Acute oral toxicity GLP: no LD50 (Rat, female): > 250 mg/kg

Method: Acute oral toxicity
GLP: no
Assessment: The component/mixture is moderately toxic after single ingestion.

LD50 (Dog, female): > 20 mg/kg
Method: Acute oral toxicity
GLP: no

Acute inhalation toxicity : Remarks: No data available

Acute dermal toxicity : Remarks: May be harmful if absorbed through skin.

Acute toxicity (other routes of administration) : Remarks: No data available

Skin corrosion/irritation

Components:

APALUTAMIDE:

Remarks : No data available

Serious eye damage/eye irritation

Components:

APALUTAMIDE:

Result : negative
Method : In vitro BCOP (Bovine Corneal Opacity and Permeability) assay (OECD 437)

Respiratory or skin sensitisation

Components:

APALUTAMIDE:

Test Type : Local lymph node assay (LLNA)
Species : Mouse
Result : The product is a skin sensitiser, sub-category 1B.

Germ cell mutagenicity

Components:

APALUTAMIDE:

Genotoxicity in vitro : Test system: Salmonella typhimurium
Method: Bacterial Reverse Mutation Test OECD 471
Result: negative
GLP: yes

Test system: Escherichia coli
Method: Bacterial Reverse Mutation Test OECD 471
Result: negative

GLP: yes

Test system: Human lymphocytes
Method: In vitro Mammalian Chromosome Aberration Test OECD 473
Result: negative
GLP: yes

Genotoxicity in vivo : Test Type: In vivo micronucleus test
Species: Rat
Method: In vivo Mammalian Erythrocyte Micronucleus Test OECD 474
Result: negative
GLP: yes

Test Type: comet assay
Species: Rat
Method: OECD Test Guideline 489
Result: negative

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

Carcinogenicity

Components:

APALUTAMIDE:

Species	:	Mouse, male
Application Route	:	Oral
Exposure time	:	26 weeks
Dose	:	0,3,10,30 mg/kg body weight
Frequency of Treatment	:	1 daily
NOAEL	:	30 mg/kg bw/day
Result	:	No evidence of carcinogenicity in animal studies.

Species	:	Rat, male
Application Route	:	Oral
Exposure time	:	24 month(s)
Dose	:	0,5,15,50 mg/kg body weight
Frequency of Treatment	:	1 daily
NOAEL	:	50 mg/kg bw/day
Target Organs	:	Mammary gland, Testes, Thyroid
Remarks	:	The observed tumors do not appear to be relevant for men.

Carcinogenicity - Assessment : No evidence of carcinogenicity.

IARC	Group 1: Carcinogenic to humans	
	7631-86-9	silicon dioxide
	(Silica dust, crystalline)	
OSHA	OSHA specifically regulated carcinogen	
	7631-86-9	silicon dioxide

(crystalline silica)

NTP	Known to be human carcinogen 7631-86-9 (Silica, Crystalline (Respirable Size))	silicon dioxide

Reproductive toxicity

Components:

APALUTAMIDE:

Effects on fertility	:	Test Type: Fertility/early embryonic development Species: Rat, male Application Route: Oral Dose: 25 - 150 mg/kg General Toxicity - Parent: NOAEL: 25 mg/kg body weight Fertility: NOAEL: 25 mg/kg body weight Early Embryonic Development: NOAEL: 25 mg/kg body weight GLP: yes Remarks: Adverse effects on sexual function and fertility.
Effects on foetal development	:	Species: Rat, female Application Route: Oral General Toxicity Maternal: NOAEL: 50 mg/kg Teratogenicity: NOAEL: < 25 mg/kg body weight Developmental Toxicity: NOAEL: < 25 mg/kg body weight Method: Developmental Toxicity Result: May damage the unborn child.
Reproductive toxicity - Assessment	:	Sufficient evidence of reprotoxicity based on animals.
Teratogenicity - Assessment	:	Sufficient evidence of adverse effects on development based on animals.

STOT - single exposure

Components:

APALUTAMIDE:

Exposure routes	:	Oral
Assessment	:	The substance or mixture is not classified as specific target organ toxicant, single exposure.

STOT - repeated exposure

Components:

APALUTAMIDE:

Exposure routes	:	Oral
Target Organs	:	male reproductive organs, Endocrine system, Central nervous system
Assessment	:	The substance or mixture is classified as specific target organ

toxicant, repeated exposure, category 2.

Repeated dose toxicity

Components:

APALUTAMIDE:

Species	:	Rat, male
NOAEL	:	< 25 mg/kg
Application Route	:	Oral
Exposure time	:	6 months
Number of exposures	:	once daily
Dose	:	25 - 75 - 150 mg/kg
GLP	:	yes
Target Organs	:	Endocrine system, male reproductive organs

Species	:	Dog, male
NOAEL	:	< 2.5 mg/kg
Application Route	:	Oral
Exposure time	:	9 months
Number of exposures	:	once daily
Dose	:	2,5 - 5 - 10 mg/kg
GLP	:	yes
Target Organs	:	Endocrine system, male reproductive organs

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

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

APALUTAMIDE:

Toxicity to fish	:	LC50 (Oncorhynchus mykiss (rainbow trout)): 6.9 mg/l Exposure time: 96 h Test Type: static test Method: OECD Test Guideline 203

GLP: yes

Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia magna (Water flea)): 10 mg/l Exposure time: 48 h Test Type: static test Method: OECD Test Guideline 202 GLP: yes
Toxicity to algae/aquatic plants	:	EC50 (Pseudokirchneriella subcapitata (green algae)): 9.5 mg/l End point: Growth rate Exposure time: 72 h Test Type: Growth inhibition Method: OECD Test Guideline 201 GLP: yes
Toxicity to fish (Chronic toxicity)	:	NOEC (Pimephales promelas (fathead minnow)): 0.0068 mg/l Exposure time: 60 d Test Type: Fish full life cycle toxicity test Method: OECD Test Guideline 210 GLP: yes
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	:	NOEC (Daphnia magna (Water flea)): 1.8 mg/l Exposure time: 21 d Test Type: Daphnia reproduction test Method: OECD Test Guideline 211 GLP: yes
M-Factor (Chronic aquatic toxicity)	:	1
Toxicity to microorganisms	:	EC10 (activated sludge): > 1,000 mg/l Exposure time: 10 min Test Type: Respiration inhibition Method: OECD Test Guideline 209 GLP: yes EC50 (activated sludge): > 1,000 mg/l Exposure time: 10 min Test Type: Respiration inhibition Method: OECD Test Guideline 209 GLP: yes

Persistence and degradability

Components:

APALUTAMIDE:

Biodegradability	:	aerobic Inoculum: activated sludge Result: Readily biodegradable. Exposure time: 28 d Method: OECD Test Guideline 301B GLP: yes

Stability in water	:	Test Type: aerobic Degradation half life (DT50): 30 d Method: OECD Test Guideline 308 GLP: yes Remarks: Fresh water 1 Test Type: aerobic Degradation half life (DT50): > 1,000 d Method: OECD Test Guideline 308 GLP: yes Remarks: sediment 1 Test Type: aerobic Degradation half life (DT50): 315 d Method: OECD Test Guideline 308 GLP: yes Remarks: total system 1 Test Type: aerobic Degradation half life (DT50): 32 d Method: OECD Test Guideline 308 GLP: yes Remarks: Fresh water 2 Test Type: aerobic Degradation half life (DT50): 105 d Method: OECD Test Guideline 308 GLP: yes Remarks: sediment 2 Test Type: aerobic Degradation half life (DT50): 92 d Method: OECD Test Guideline 308 GLP: yes Remarks: total system 2

Bioaccumulative potential

Components:

APALUTAMIDE:

Bioaccumulation	:	Remarks: No data available
Partition coefficient: n-octanol/water	:	log Pow: 2.91 pH: 7 Method: OECD Test Guideline 107 GLP: yes

titandioxide:

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

Octadecanoic acid, magnesium salt:

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

Mobility in soil

Components:

APALUTAMIDE:

Distribution among environmental compartments	:	Adsorption/Soil Koc: 656 - 889 Method: OECD Test Guideline 106 Adsorption/Activated sludge Koc: 516 - 601 Method: OECD Test Guideline 106

Other adverse effects

Components:

APALUTAMIDE:

Endocrine disrupting potential	:	May cause endocrine disruption.

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

UN number	:	UN 3077
Proper shipping name	:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (apalutamide)
Class	:	9
Packing group	:	III
Labels	:	9

IATA-DGR

UN/ID No.	:	UN 3077
Proper shipping name	:	Environmentally hazardous substance, solid, n.o.s. (apalutamide)
Class	:	9

Packing group	:	III
Labels	:	9
Packing instruction (cargo aircraft)	:	956
Packing instruction (LQ)	:	Y956
Packing instruction (EQ)	:	E1
Packing instruction (passenger aircraft)	:	956
Packing instruction (LQ)	:	Y956
Remarks	:	Special Provision A197: Environmentally hazardous substances, classified under UN 3077 or UN 3082, when transported in single or combination packagings containing a net quantity per single or inner packaging of 5 L or less for liquids or having a net mass of 5 kg or less for solids, are not subject to any other provisions of the IATA DGR provided the packagings meet the general provisions of IATA DGR 5.0.2.4.1, 5.0.2.6.1.1 and 5.0.2.8., This substance can be shipped under 'de minimi's quantities' provisions if the net quantity per inner package <= 1mL for liquids or <= 1g for solids and the net quantity per outer package does not exceed 100mL for liquids or 100g for solids and provided packaging provisions of IATA DGR §2.6.10 are met.

IMDG-Code

UN number	:	UN 3077
Proper shipping name	:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (apalutamide)
Class	:	9
Packing group	:	III
Labels	:	9
EmS Code	:	F-A, S-F
Marine pollutant	:	yes
Remarks	:	3.3. Special Provision 375: Environmentally Hazardous Substances/Marine Pollutants, classified under UN 3077 or UN 3082, packaged in single or combination packagings containing a net quantity per single of inner packaging of 5L or less for liquids or having a net mass per single of inner packaging of 5kg or less for solids are not subject to the IMDG provided the packagings meet the general requirements of 4.1.1.1, 4.1.1.2, and 4.1.1.4 to 4.1.1.8., This substance can be shipped under 'de minimi's quantities' provisions if the net quantity per inner package <= 1mL for liquids or <= 1g for solids and the net quantity per outer package does not exceed 100mL for liquids or 100g for solids and provided packaging provisions of ADR/RID/ADN/IMDG §3.5.1.4 are met.

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

UN/ID/NA number	:	UN 3077
Proper shipping name	:	Environmentally hazardous substance, solid, n.o.s. (apalutamide)
Class	:	9

Packing group	:	III
Labels	:	9
ERG Code	:	171
Marine pollutant	:	yes
Remarks	:	49 CFR 171.4 - Marine Pollutant Exception: Except when transporting aboard a vessel, the requirements of this subchapter do not apply to non-bulk packagings transported by motor vehicles, rail cars, and aircraft., This substance can be shipped under 'de minimi's quantities' provisions if the net quantity per inner package <= 1mL for liquids or <= 1g for solids and the net quantity per outer package does not exceed 100mL for liquids or 100g for solids and provided packaging provisions of 49 CFR 173.4b are met.

Special precautions for user
The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

SECTION 15. REGULATORY INFORMATION

US State Regulations

Massachusetts Right To Know

microcrystalline cellulose	9004-34-6
DIOXOSILANE	7631-86-9

Pennsylvania Right To Know

microcrystalline cellulose	9004-34-6
Hydroxypropyl Methylcellulose Acetate Succinate	71138-97-1
APALUTAMIDE	956104-40-8
croscarmellose sodium	74811-65-7
DIOXOSILANE	7631-86-9

Maine Chemicals of High Concern

DIOXOSILANE	7631-86-9

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 Prop. 65

WARNING: This product can expose you to chemicals including DIOXOSILANE, which is/are known to the State of California to cause cancer. For more information go to www.P65Warnings.ca.gov.

California List of Hazardous Substances

DIOXOSILANE	7631-86-9

California Permissible Exposure Limits for Chemical Contaminants

microcrystalline cellulose	9004-34-6
DIOXOSILANE	7631-86-9

California Regulated Carcinogens

DIOXOSILANE	7631-86-9

Other regulations

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

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

Restricted to professional users.

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 CARC	:	OSHA Specifically Regulated Chemicals/Carcinogens
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
OSHA Z-3	:	USA. Occupational Exposure Limits (OSHA) - Table Z-3 Mineral Dusts
ACGIH / STEL	:	Short term exposure limit
ACGIH / TWA	:	Time weighted average
ACGIH / TWA	:	8-hour, time-weighted average
J&J OEL/PBOEL HHC / STV	:	STV: Surface Target Value
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 CARC / PEL	:	Permissible exposure limit (PEL)
OSHA P0 / TWA	:	8-hour time weighted average
OSHA Z-1 / TWA	:	8-hour time weighted average
OSHA Z-3 / 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 Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

Revision Date : 2026/01/09

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

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.

US / EN