# SAFETY DATA SHEET

## INTELENCE

| Version | Revision Date: | SDS Number: | Date of last issue: 2023/12/15 |
|---|---|---|---|
| 5.3 | 2024/09/04 | 100000010296 | Date of first issue: 2014/07/09 |

### SECTION 1. IDENTIFICATION

Product name : INTELENCE
Substance name : INTELENCE 25-100 mg tablets
etravirine

**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: Antivirals for systemic use
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)**

Not a hazardous substance or mixture.

**GHS label elements**

Not a hazardous substance or mixture.

**Additional Labelling**

The following percentage of the mixture consists of ingredient(s) with unknown acute toxicity:
29.3 %

**Other hazards**

This Finished Pharmaceutical Product is non-hazardous based on chemical classification rules.

## SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Chemical nature : Solid

**Components**

| Chemical name | CAS-No. | Concentration (% w/w) |
|---|---|---|
| HYDROXYPROPYLMETHYLCELLULOSE (HPMC) | 9004-65-3 | >= 30 - < 50 |
| Cellulose | 9004-34-6 | >= 20 - < 30 |
| ETRAVIRINE | 269055-15-4 | >= 10 - < 20 |
| Octadecanoic acid, magnesium salt | 557-04-0 | >= 0.1 - < 1 |
| COLLOIDAL ANHYDROUS SILICA | 112945-52-5 | >= 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 soap and water.
If symptoms persist, call a physician.

In case of eye contact : Remove contact lenses.
Rinse immediately with plenty of water, also under the eyelids, for at least 5 minutes.
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.
Blood disorders
Diarrhoea
Kidney disorders
nausea
Rash

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. |
| 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 | : | Avoid breathing dust.<br>Evacuate personnel to safe areas.<br>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 + Small spills: Keep in suitable, closed containers for disposal. Treat recovered material as described in the section "Disposal considerations".<br>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.<br>Small spills: Moisten a towel, cover the spill, pick up the spill or use HEPA vacuum. |

## SECTION 7. HANDLING AND STORAGE

| | | |
|---|---|---|
| Advice on protection against fire and explosion | : | No data available |
| Advice on safe handling | : | Avoid inhalation, ingestion and contact with skin and eyes.<br>Keep away from heat and sources of ignition.<br>To avoid thermal decomposition, do not overheat.<br>Do not break, crush or spill this Finished Pharmaceutical Product.<br>Use personal protective equipment as required. |
| Conditions for safe storage | : | Keep away from heat and sources of ignition.<br>Keep containers tightly closed in a dry, cool and well-ventilated place. |

To maintain product quality, do not store in heat or direct sunlight.
Store at room temperature in the original container.

Recommended storage temperature : 59 - 77 °F / 15 - 25 °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 |
|---|---|---|---|---|
| HYDROXYPROPYLMETHYLCELLULOSE (HPMC) | 9004-65-3 | TWA | 10 mg/m3 | ACGIH |
| 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 |
| ETRAVIRINE | 269055-15-4 | TWA | 0.870 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. | | | |
| Octadecanoic acid, magnesium salt | 557-04-0 | TWA (Inhalable particulate matter) | 10 mg/m3 | ACGIH |
| | | TWA (Respirable particulate matter) | 3 mg/m3 | ACGIH |
| COLLOIDAL ANHYDROUS SILICA | 112945-52-5 | TWA (Dust) | 20 Million particles per cubic foot | OSHA Z-3 |

| | | | | |
|---|---|---|---|---|
| | | | (Silica) | |
| | | TWA (Dust) | 80 mg/m3 / %SiO2 (Silica) | OSHA Z-3 |
| | | TWA | 6 mg/m3 (Silica) | NIOSH REL |

**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.
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
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 : tablet

Colour : white, 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 | : | No data available |
| Upper explosion limit / Upper flammability limit | : | No data available |
| Lower explosion limit / Lower flammability limit | : | No data available |
| Vapour pressure | : | Not applicable |
| Relative vapour density | : | Not applicable |
| Relative density | : | No data available |
| Density | : | No data available |

Solubility(ies)

| | | |
|---|---|---|
| Water solubility | : | No data available |
| Partition coefficient: n-octanol/water | : | No data available |
| Decomposition temperature | : | No data available |

Viscosity

| | | |
|---|---|---|
| Viscosity, dynamic | : | Not applicable |
| Viscosity, kinematic | : | Not applicable |
| Explosive 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 | : | Heat, flames and sparks.<br>To avoid thermal decomposition, do not overheat. |
| Incompatible materials | : | None known. |
| Hazardous decomposition products | : | None known. |

## SECTION 11. TOXICOLOGICAL INFORMATION

**Acute toxicity**

**Product:**

Acute oral toxicity : Acute toxicity estimate: 4,000 mg/kg
Method: Calculation method

Acute inhalation toxicity : Acute toxicity estimate: > 10 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Method: Calculation method

**Components:**

**Cellulose:**

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

**ETRAVIRINE:**

Acute oral toxicity : LD50 (Rat, male and female): > 640 mg/kg
Target Organs: Liver

Assessment: The component/mixture is moderately toxic after single ingestion.

**COLLOIDAL ANHYDROUS SILICA:**

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

Acute dermal toxicity : LD50 (Rabbit): > 5,000 mg/kg

**Skin corrosion/irritation**

**Components:**

**Cellulose:**

Species : Rabbit
Remarks : No skin irritation

**ETRAVIRINE:**

Species : Rabbit
Result : No skin irritation

**COLLOIDAL ANHYDROUS SILICA:**

Species : Rabbit
Result : No skin irritation

**Serious eye damage/eye irritation**

**Components:**

**Cellulose:**

| | | |
|---|---|---|
| Species | : | Rabbit |
| Remarks | : | No eye irritation |

**ETRAVIRINE:**

| | | |
|---|---|---|
| Result | : | Mild eye irritation |
| Method | : | In vitro BCOP (Bovine Corneal Opacity and Permeability) assay |

**COLLOIDAL ANHYDROUS SILICA:**

| | | |
|---|---|---|
| Species | : | Rabbit |
| Result | : | No eye irritation |

**Respiratory or skin sensitisation**

**Components:**

**Cellulose:**

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

**ETRAVIRINE:**

| | | |
|---|---|---|
| Test Type | : | Maximisation Test |
| Species | : | Guinea pig |
| Result | : | Not a skin sensitizer. |
| | | |
| Test Type | : | Local lymph node assay (LLNA) |
| Species | : | Mouse |
| Result | : | Not a skin sensitizer. |

**Germ cell mutagenicity**

**Components:**

**ETRAVIRINE:**

| | | |
|---|---|---|
| Genotoxicity in vitro | : | Test Type: Ames test<br>Result: negative<br><br>Test Type: A mouse lymphoma test<br>Result: negative<br><br>Test Type: Chromosome aberration test in vitro<br>Test system: Human lymphocytes<br>Result: negative<br><br>Test Type: Chromosome aberration test in vitro<br>Test system: mouse lymphoma cells |

Result: negative

Genotoxicity in vivo : Test Type: in vivo assay
Species: Mouse
Cell type: Bone marrow
Result: negative

**Carcinogenicity**

**Components:**

**ETRAVIRINE:**

| | | |
|---|---|---|
| Species | : | Mouse |
| Application Route | : | Oral |
| Exposure time | : | 24 m |
| Dose | : | 50, 200, 400 mg/kg body weight |
| Result | : | No evidence of carcinogenicity in animal studies. |

| | | |
|---|---|---|
| Species | : | Rat |
| Application Route | : | Oral |
| Exposure time | : | 24 m |
| Dose | : | 40, 200, 600 mg/kg body weight |
| Result | : | No evidence of carcinogenicity in animal studies. |

**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:**

**ETRAVIRINE:**

Effects on fertility : Species: Rat
Application Route: Oral
Dose: 506 mg/kg
Remarks: Fertility and developmental toxicity tests did not reveal any effect on reproduction.

Species: Rat
Application Route: Oral
Dose: 1000 mg/kg
General Toxicity - Parent: NOAEL: 1,000 mg/kg

Species: Rabbit
Application Route: Oral
Dose: 375 mg/kg
General Toxicity - Parent: NOAEL: 125 mg/kg

| | | |
|---|---|---|
| Effects on foetal development | : | Remarks: Did not show teratogenic effects in animal experiments. |

**STOT - single exposure**

**Components:**

**ETRAVIRINE:**

| | | |
|---|---|---|
| Remarks | : | No data available |

**STOT - repeated exposure**

**Components:**

**ETRAVIRINE:**

| | | |
|---|---|---|
| Assessment | : | The substance or mixture is not classified as specific target organ toxicant, repeated exposure. |

**Repeated dose toxicity**

**Components:**

**ETRAVIRINE:**

| | | |
|---|---|---|
| Species | : | Rat |
| NOAEL | : | 320 mg/kg |
| Application Route | : | Oral |
| Exposure time | : | 1 month |
| Number of exposures | : | 24h |

**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:**

**HYDROXYPROPYLMETHYLCELLULOSE (HPMC):**

Toxicity to fish : Remarks: No data available

**Cellulose:**

Toxicity to fish : Remarks: No data available

**ETRAVIRINE:**

Toxicity to algae/aquatic plants : EC50 (Scenedesmus subspicatus (fresh water algae)): > 4.9 µg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

NOEC (Scenedesmus subspicatus (fresh water algae)): 4.9 µg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

ErC50 (Pseudokirchneriella subcapitata (green algae)): > 0.0049 mg/l
End point: Growth rate
Exposure time: 72 h
Test Type: Growth inhibition
Method: OECD Test Guideline 201
GLP: yes

EbC50 (Pseudokirchneriella subcapitata (green algae)): > 0.0049 mg/l
End point: Growth rate
Exposure time: 72 h
Test Type: Growth inhibition
Method: OECD Test Guideline 201
GLP: yes

NOEC (Pseudokirchneriella subcapitata (green algae)): 0.0049 mg/l
End point: Growth rate
Exposure time: 72 h
Test Type: Growth inhibition
Method: OECD Test Guideline 201
GLP: yes

M-Factor (Acute aquatic toxicity) : 100

Toxicity to fish (Chronic : NOEC (Danio rerio (zebra fish)): 0.01 mg/l

| | | |
|---|---|---|
| toxicity) | | Exposure time: 35 Days<br>Method: OECD Test Guideline 210<br><br>NOEC (Brachydanio rerio (zebrafish)): 0.01 mg/l<br>Exposure time: 28 d<br>Test Type: Fish early-life stage (FELS) toxicity test (OECD 210)<br>Method: OECD Test Guideline 210<br>GLP: yes |
| Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) | : | NOEC (Daphnia magna (Water flea)): 0.0091 mg/l<br>Exposure time: 21 Days<br>Test Type: Daphnia reproduction test<br>Method: OECD Test Guideline 211<br>GLP: yes<br><br>NOEC (Chironomus riparius (Midge larvae)): 0.02 mg/l<br>Exposure time: 28 d<br>Test Type: Toxicity to sediment dwelling organisms<br>Method: OECD Test Guideline 219<br>GLP: yes |
| Toxicity to microorganisms | : | EC50 (activated sludge): > 1,000 mg/l<br>Exposure time: 3 h<br>Test Type: Respiration inhibition<br>Method: OECD Test Guideline 209<br>GLP: yes<br><br>NOEC (activated sludge): >= 1,000 mg/l<br>Exposure time: 3 h<br>Test Type: Respiration inhibition<br>Method: OECD Test Guideline 209<br>GLP: yes<br><br>NOEC (Soil microorganisms): 100 mg/kg<br>Exposure time: 28 d<br>Test Type: Nitrogen transformation<br>Method: OECD Test Guideline 216<br>GLP: yes |
| Toxicity to soil dwelling organisms | : | Test Type: Reproduction Test<br>NOEC (Springtail (Collembola)): > 1,000 mg/kg<br>Exposure time: 28 d<br>Method: ISO 11267<br>GLP: yes<br><br>LC50 (Eisenia fetida (earthworms)): > 1,000 mg/kg<br>Exposure time: 14 d<br>Method: OECD TG 207<br><br>Test Type: Acute toxicity<br>EC50 (Eisenia fetida (earthworms)): > 1,000 mg/kg<br>Exposure time: 14 d |

Method: OECD Test Guideline 207
GLP: yes

Test Type: Acute toxicity
NOEC (Eisenia fetida (earthworms)): 1,000 mg/kg
Exposure time: 14 d
Method: OECD Test Guideline 207
GLP: yes

Plant toxicity : NOEC: 76 mg/kg
Test period: 21 d
Species: Terrestrial plants
Method: OECD Test Guideline 208
GLP: yes

**COLLOIDAL ANHYDROUS SILICA:**

Toxicity to fish : LC50 (Danio rerio (zebra fish)): > 10,000 mg/l
Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): > 10,000 mg/l
Exposure time: 24 h

**Persistence and degradability**

**Components:**

**HYDROXYPROPYLMETHYLCELLULOSE (HPMC):**

Biodegradability : Remarks: No data available

**ETRAVIRINE:**

Stability in water : Test Type: aerobic
Degradation half life (DT50): 0.6 d
Method: OECD Test Guideline 308
GLP: yes
Remarks: Fresh water 1

Degradation half life (DT90): 1.1 d
Method: OECD Test Guideline 308
Remarks: aerobic

Test Type: aerobic
Degradation half life (DT50): 2 d
Method: OECD Test Guideline 308
GLP: yes
Remarks: Fresh water 2

Degradation half life (DT90): 3.6 d
Method: OECD Test Guideline 308
Remarks: aerobic

Test Type: anaerobic
Degradation half life (DT50): 3.2 d

Method: OECD Test Guideline 308
GLP: yes
Remarks: Fresh water 1

**COLLOIDAL ANHYDROUS SILICA:**

Biodegradability : Remarks: No data available

**Bioaccumulative potential**

**Components:**

**HYDROXYPROPYLMETHYLCELLULOSE (HPMC):**

Bioaccumulation : Remarks: No data available

**ETRAVIRINE:**

Bioaccumulation : Species: Oncorhynchus mykiss (rainbow trout)
Bioconcentration factor (BCF): 370.3
Exposure time: 14 d
Method: OECD Test Guideline 305
GLP: yes

Species: Oncorhynchus mykiss (rainbow trout)
Bioconcentration factor (BCF): 476.9
Exposure time: 14 d
Method: OECD Test Guideline 305
GLP: yes

Partition coefficient: n-octanol/water : Pow: 3.4
Method: OECD Test Guideline 117
GLP: yes

**Octadecanoic acid, magnesium salt:**

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

**COLLOIDAL ANHYDROUS SILICA:**

Bioaccumulation : Remarks: No data available

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

**Mobility in soil**

**Components:**

**HYDROXYPROPYLMETHYLCELLULOSE (HPMC):**

Distribution among environmental compartments : Remarks: No data available

**ETRAVIRINE:**

| | | |
|---|---|---|
| Distribution among environmental compartments | : | Adsorption/HPLC<br>Koc: 16617<br>Method: OECD Test Guideline 121 |
| Stability in soil | : | Test Type: Aerobic transformation in soil<br>Dissipation time: 587 Days<br>Method: OECD Test Guideline 307<br>GLP: yes |

**COLLOIDAL ANHYDROUS SILICA:**

| | | |
|---|---|---|
| Distribution among environmental compartments | : | Remarks: No data available |

**Other adverse effects**

**Components:**

**HYDROXYPROPYLMETHYLCELLULOSE (HPMC):**

| | | |
|---|---|---|
| Results of PBT and vPvB assessment | : | No information available. |
| Additional ecological information | : | No data available |

**COLLOIDAL ANHYDROUS SILICA:**

| | | |
|---|---|---|
| Results of PBT and vPvB assessment | : | No information available. |
| 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**

**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 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**

| | |
|---|---|
| HYDROXYPROPYLMETHYLCELLULOSE (HPMC) | 9004-65-3 |
| Cellulose | 9004-34-6 |
| alpha-D-Glucopyranose, 4-O-beta-D-galactopyranosyl-, hydrate (1:1) | 5989-81-1 |
| ETRAVIRINE | 269055-15-4<br>74811-65-7 |

**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 |

**The components of this product are reported in the following inventories:**
: This product is not subject to TSCA and TSCA 12(b) Export notification because Food, Drugs and cosmetic products are exempt.

**Other regulations**

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.

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 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 / 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 |
| 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 : 2024/09/04

**Date and Number Formats**

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

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|---|---|---|---|
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