

**Molnupiravir Capsule Formulation**

|         |                |               |                                 |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number:   | Date of last issue: 14.04.2025  |
| 9.0     | 20.06.2025     | 6199214-00015 | Date of first issue: 24.08.2020 |

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**Section 1: Identification**

Product name : Molnupiravir Capsule Formulation

**Manufacturer or supplier's details**

Company : MSD

Address : 33 Whakatiki Street - Private Bag 908  
Upper Hutt - New Zealand

Telephone : 0800 800 543

Emergency telephone number : 0800 764 766 (0800 POISON) 0800 243 622 (0800  
CHEMCALL)

E-mail address : EHSDATASTEWARD@msd.com

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

Recommended use : Pharmaceutical

Restrictions on use : Not applicable

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**Section 2: Hazard identification****GHS Classification**

Specific target organ toxicity - repeated exposure (Oral) : Category 1 (Gastrointestinal tract)

**GHS label elements**

Hazard pictograms :



Signal word : Danger

Hazard statements : H372 Causes damage to organs (Gastrointestinal tract) through prolonged or repeated exposure if swallowed.

Precautionary statements : **Prevention:**  
P264 Wash skin thoroughly after handling.  
P270 Do not eat, drink or smoke when using this product.

**Response:**  
P314 Get medical advice/ attention if you feel unwell.

**Disposal:**

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P501 Dispose of contents/ container to an approved waste disposal plant.

**Other hazards which do not result in classification**

May form explosive dust-air mixture during processing, handling or other means.  
Dust contact with the eyes can lead to mechanical irritation.

**Section 3: Composition/information on ingredients**

Substance / Mixture : Mixture

**Components**

| Chemical name | CAS-No.      | Concentration (% w/w) |
|---------------|--------------|-----------------------|
| Cellulose     | 9004-34-6    | >= 70 -< 90           |
| Molnupiravir  | 2492423-29-5 | >= 70 -< 90           |

**Section 4: First-aid measures**

|   |  |
|---|--|
| General advice  | : In the case of accident or if you feel unwell, seek medical advice immediately.<br>When symptoms persist or in all cases of doubt seek medical advice.   |
| If inhaled  | : If inhaled, remove to fresh air.<br>Get medical attention if symptoms occur.   |
| In case of skin contact                                     | : In case of contact, immediately flush skin with plenty of water.<br>Remove contaminated clothing and shoes.<br>Get medical attention.<br>Wash clothing before reuse.<br>Thoroughly clean shoes before reuse. |
| In case of eye contact                                      | : If in eyes, rinse well with water.<br>Get medical attention if irritation develops and persists.   |
| If swallowed  | : If swallowed, DO NOT induce vomiting.<br>Get medical attention if symptoms occur.<br>Rinse mouth thoroughly with water.  |
| Most important symptoms and effects, both acute and delayed | : Causes damage to organs through prolonged or repeated exposure if swallowed.<br>Dust contact with the eyes can lead to mechanical irritation.  |
| Protection of first-aiders                                  | : First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).                                  |
| Notes to physician  | : Treat symptomatically and supportively.  |

**Section 5: Fire-fighting measures**

|                                |  |
|--------------------------------|--|
| Suitable extinguishing media   | : Water spray<br>Alcohol-resistant foam<br>Carbon dioxide (CO <sub>2</sub> )<br>Dry chemical |
| Unsuitable extinguishing media | : None known.  |

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|---|---|---|
| Specific hazards during fire-fighting         | : | Avoid generating dust; fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard.<br>Exposure to combustion products may be a hazard to health.                   |
| Hazardous combustion products                 | : | Carbon oxides<br>Metal oxides   |
| Specific extinguishing methods                | : | Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.<br>Use water spray to cool unopened containers.<br>Remove undamaged containers from fire area if it is safe to do so.<br>Evacuate area. |
| Special protective equipment for firefighters | : | In the event of fire, wear self-contained breathing apparatus.<br>Use personal protective equipment.  |
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**Section 6: Accidental release measures**

- |   |   |  |
|---|---|--|
| Personal precautions, protective equipment and emergency procedures | : | Use personal protective equipment.<br>Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).   |
| Environmental precautions   | : | Avoid release to the environment.<br>Prevent further leakage or spillage if safe to do so.<br>Retain and dispose of contaminated wash water.<br>Local authorities should be advised if significant spillages cannot be contained.  |
| Methods and materials for containment and cleaning up               | : | Sweep up or vacuum up spillage and collect in suitable container for disposal.<br>Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air).<br>Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration.<br>Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable.<br>Sections 13 and 15 of this SDS provide information regarding certain local or national requirements. |
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**Section 7: Handling and storage**

- |                    |   |   |
|--------------------|---|---|
| Technical measures | : | Static electricity may accumulate and ignite suspended dust causing an explosion.<br>Provide adequate precautions, such as electrical grounding |
|--------------------|---|---|
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- II
- Local/Total ventilation : and bonding, or inert atmospheres.
- Advice on safe handling : Use only with adequate ventilation.
- Do not get on skin or clothing.
- Do not breathe dust.
- Do not swallow.
- Avoid contact with eyes.
- Wash skin thoroughly after handling.
- Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment
- Minimize dust generation and accumulation.
- Keep container closed when not in use.
- Keep away from heat and sources of ignition.
- Take precautionary measures against static discharges.
- Do not eat, drink or smoke when using this product.
- Take care to prevent spills, waste and minimize release to the environment.
- Hygiene measures : If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place.
- When using do not eat, drink or smoke.
- Wash contaminated clothing before re-use.
- The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.
- Conditions for safe storage : Keep in properly labelled containers.
- Store in accordance with the particular national regulations.
- Materials to avoid : Do not store with the following product types:
- Strong oxidizing agents

## Section 8: Exposure controls/personal protection

## Components with workplace control parameters

| Components   | CAS-No.      | Value type<br>(Form of exposure) | Control parameters / Permissible concentration | Basis    |
|--------------|--------------|----------------------------------|--|----------|
| Cellulose    | 9004-34-6    | WES-TWA                          | 10 mg/m <sup>3</sup>                           | NZ OEL   |
|              |              | TWA                              | 10 mg/m <sup>3</sup>                           | ACGIH    |
| Molnupiravir | 2492423-29-5 | TWA                              | 20 µg/m <sup>3</sup> (OEB 3)                   | Internal |
|              |              | Wipe limit                       | 200 µg/100cm <sup>2</sup>                      | Internal |

- Engineering measures** : All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.
- Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of the compound to uncontrolled areas (e.g., open-face con-

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tainment devices).  
Minimize open handling.

**Personal protective equipment**

|                          |   |  |
|--------------------------|---|--|
| Respiratory protection   | : | If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.   |
| Filter type              | : | Particulates type  |
| Hand protection          | : |  |
| Material                 | : | Chemical-resistant gloves  |
| Remarks                  | : | Consider double gloving.   |
| Eye protection           | : | Wear safety glasses with side shields or goggles.<br>If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles.<br>Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols. |
| Skin and body protection | : | Work uniform or laboratory coat.<br>Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces.<br>Use appropriate degowning techniques to remove potentially contaminated clothing.                    |

**Section 9: Physical and chemical properties**

|   |   |   |
|---|---|---|
| Appearance                              | : | powder  |
| Colour                                  | : | white to off-white  |
| Odour                                   | : | No data available   |
| Odour Threshold                         | : | No data available   |
| pH                                      | : | No data available   |
| Melting point/freezing point            | : | No data available   |
| Initial boiling point and boiling range | : | No data available   |
| Flash point                             | : | Not applicable  |
| Evaporation rate                        | : | Not applicable  |
| Flammability (solid, gas)               | : | May form explosive dust-air mixture during processing, handling or other means. |
| Flammability (liquids)                  | : | Not applicable  |

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|  |   |  |
|--|---|--|
| 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)<br>Water solubility              | : | No data available  |
| Partition coefficient: n-octanol/water           | : | Not applicable   |
| Auto-ignition temperature                        | : | No data available  |
| Decomposition temperature                        | : | No data available  |
| Viscosity<br>Viscosity, kinematic                | : | Not applicable   |
| Explosive properties                             | : | Not explosive  |
| Oxidizing properties                             | : | The substance or mixture is not classified as oxidizing. |
| Molecular weight                                 | : | No data available  |
| Particle characteristics<br>Particle size        | : | No data available  |

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**Section 10: Stability and reactivity**

|                                    |   |  |
|------------------------------------|---|--|
| Reactivity                         | : | Not classified as a reactivity hazard.   |
| Chemical stability                 | : | Stable under normal conditions.  |
| Possibility of hazardous reactions | : | May form explosive dust-air mixture during processing, handling or other means.<br>Can react with strong oxidizing agents. |
| Conditions to avoid                | : | Heat, flames and sparks.<br>Avoid dust formation.  |
| Incompatible materials             | : | Oxidizing agents   |
| Hazardous decomposition products   | : | No hazardous decomposition products are known.   |

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**Section 11: Toxicological information**

Exposure routes : Inhalation  
Skin contact  
Ingestion  
Eye contact

**Acute toxicity**

Not classified based on available information.

**Components:****Cellulose:**

Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg  
Acute inhalation toxicity : LC50 (Rat): > 5.8 mg/l  
Exposure time: 4 h  
Test atmosphere: dust/mist  
Acute dermal toxicity : LD50 (Rabbit): > 2,000 mg/kg

**Molnupiravir:**

Acute oral toxicity : LD0 (Rat): 2,000 mg/kg  
LD0 (Dog): 2,000 mg/kg

**Skin corrosion/irritation**

Not classified based on available information.

**Components:****Molnupiravir:**

Species : reconstructed human epidermis (RhE)  
Method : EpiDerm  
Result : Mild skin irritation

**Serious eye damage/eye irritation**

Not classified based on available information.

**Components:****Molnupiravir:**

Species : Bovine cornea  
Result : No eye irritation  
Method : Bovine cornea (BCOP)

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

Not classified based on available information.

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**Respiratory sensitisation**

Not classified based on available information.

**Chronic toxicity****Germ cell mutagenicity**

Not classified based on available information.

**Components:****Cellulose:**

|                       |   |  |
|-----------------------|---|--|
| Genotoxicity in vitro | : | Test Type: Bacterial reverse mutation assay (AMES)<br>Result: negative   |
|                       |   | Test Type: In vitro mammalian cell gene mutation test<br>Result: negative  |
| Genotoxicity in vivo  | : | Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)<br>Species: Mouse<br>Application Route: Ingestion<br>Result: negative |

**Molnupiravir:**

|                                     |   |  |
|-------------------------------------|---|--|
| Genotoxicity in vitro               | : | Test Type: Ames test<br>Result: positive   |
|                                     |   | Test Type: Micronucleus test<br>Test system: human lymphoblastoid cells<br>Result: negative  |
| Genotoxicity in vivo                | : | Test Type: Micronucleus test<br>Species: Rat<br>Cell type: Bone marrow<br>Application Route: Oral<br>Result: negative  |
|                                     |   | Test Type: Mutagenicity (in vivo mammalian bone-marrow cytogenetic test, chromosomal analysis)<br>Species: Rat<br>Cell type: Bone marrow<br>Result: equivocal            |
|                                     |   | Test Type: Mutagenicity (in vivo mammalian bone-marrow cytogenetic test, chromosomal analysis)<br>Species: Transgenic rat<br>Application Route: Oral<br>Result: negative |
| Germ cell mutagenicity - Assessment | : | Weight of evidence does not support classification as a germ cell mutagen.   |



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**Carcinogenicity**

Not classified based on available information.

**Components:****Cellulose:**

|                   |   |           |
|-------------------|---|-----------|
| Species           | : | Rat       |
| Application Route | : | Ingestion |
| Exposure time     | : | 72 weeks  |
| Result            | : | negative  |

**Reproductive toxicity**

Not classified based on available information.

**Components:****Cellulose:**

|                      |   |   |
|----------------------|---|---|
| Effects on fertility | : | Test Type: One-generation reproduction toxicity study<br>Species: Rat<br>Application Route: Ingestion<br>Result: negative |
|----------------------|---|---|

|                               |   |  |
|-------------------------------|---|--|
| Effects on foetal development | : | Test Type: Fertility/early embryonic development<br>Species: Rat<br>Application Route: Ingestion<br>Result: negative |
|-------------------------------|---|--|

**Molnupiravir:**

|                               |   |  |
|-------------------------------|---|--|
| Effects on foetal development | : | Test Type: Embryo-foetal development<br>Species: Rat<br>Application Route: Oral<br>Developmental Toxicity: LOAEL: > 200 mg/kg body weight<br>Symptoms: Effects on embryofoetal and postnatal development<br>Result: No effects on fertility and early embryonic development were detected.<br>Remarks: Not classified due to data which are conclusive although insufficient for classification. |
|-------------------------------|---|--|

**STOT - single exposure**

Not classified based on available information.

**STOT - repeated exposure**

Causes damage to organs (Gastrointestinal tract) through prolonged or repeated exposure if swallowed.

**Components:****Molnupiravir:**

|                 |   |      |
|-----------------|---|------|
| Exposure routes | : | Oral |
|-----------------|---|------|

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Target Organs : Gastrointestinal tract  
Assessment : Causes damage to organs through prolonged or repeated exposure.

**Repeated dose toxicity****Components:****Cellulose:**

Species : Rat  
NOAEL :  $\geq 9,000$  mg/kg  
Application Route : Ingestion  
Exposure time : 90 Days

**Molnupiravir:**

Species : Rat  
LOAEL : 2,000 mg/kg  
Exposure time : 7 d  
Target Organs : Stomach

Species : Dog  
LOAEL : 300 mg/kg  
Exposure time : 7 d  
Target Organs : Gastrointestinal tract  
Symptoms : tachycardia, decreased activity, decrease in appetite, Diarrhoea, Vomiting

Species : Rat  
NOAEL : 500 mg/kg  
Exposure time : 28 d

Species : Dog  
NOAEL : 6 mg/kg  
LOAEL : 17 mg/kg  
Exposure time : 28 d  
Target Organs : Gastrointestinal tract  
Symptoms : decreased activity, Gastrointestinal tract damage, decrease in appetite

**Aspiration toxicity**

Not classified based on available information.

**Experience with human exposure****Components:****Molnupiravir:**

General Information : Symptoms: Headache, Gastrointestinal disturbance  
Remarks: The most common side effects are:  
Symptoms: Back pain

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**Section 12: Ecological information****Ecotoxicity****Components:****Cellulose:**

Toxicity to fish : LC50 (Oryzias latipes (Japanese medaka)): > 100 mg/l  
Exposure time: 48 h  
Remarks: Based on data from similar materials

**Molnupiravir:**

Toxicity to algae/aquatic plants : EC10 (Raphidocelis subcapitata (freshwater green alga)): 89 mg/l  
End point: Growth  
Exposure time: 72 h  
Method: OECD Test Guideline 201

Toxicity to fish (Chronic toxicity) : EC10 (Pimephales promelas (fathead minnow)): 5.8 mg/l  
Exposure time: 32 d  
Method: OECD Test Guideline 210

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : EC10 (Daphnia magna (Water flea)): > 8.8 mg/l  
Exposure time: 21 d  
Method: OECD Test Guideline 211  
Remarks: No toxicity at the limit of solubility

Toxicity to microorganisms : EC10: 143.1 mg/l  
Exposure time: 3 h  
Test Type: Respiration inhibition of activated sludge  
Method: OECD Test Guideline 209

**Ecotoxicology Assessment**

Acute aquatic toxicity : This product has no known ecotoxicological effects.

Chronic aquatic toxicity : This product has no known ecotoxicological effects.

**Persistence and degradability****Components:****Cellulose:**

Biodegradability : Result: Readily biodegradable.

**Molnupiravir:**

Biodegradability : Result: Readily biodegradable.  
Biodegradation: 81 %  
Exposure time: 28 d  
Method: OECD Test Guideline 314

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**Bioaccumulative potential****Components:****Molnupiravir:**

|  |   |                          |
|--|---|--------------------------|
| Partition coefficient: n-octanol/water | : | log Pow: -0.534<br>pH: 7 |
|--|---|--------------------------|

**Mobility in soil****Components:****Molnupiravir:**

|   |   |  |
|---|---|--|
| Distribution among environmental compartments | : | OECD Test Guideline 106<br>log Koc: 1.45 |
|---|---|--|

**Other adverse effects**

No data available

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**Section 13: Disposal considerations****Disposal methods**

|                        |   |   |
|------------------------|---|---|
| Waste from residues    | : | Do not dispose of waste into sewer.<br>Dispose of in accordance with local regulations.   |
| Contaminated packaging | : | Empty containers should be taken to an approved waste handling site for recycling or disposal.<br>If not otherwise specified: Dispose of as unused product. |

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**Section 14: Transport information****International Regulations****UNRTDG**

|                           |   |                |
|---------------------------|---|----------------|
| UN number                 | : | Not applicable |
| Proper shipping name      | : | Not applicable |
| Class                     | : | Not applicable |
| Subsidiary risk           | : | Not applicable |
| Packing group             | : | Not applicable |
| Labels                    | : | Not applicable |
| Environmentally hazardous | : | no             |

**IATA-DGR**

|                                      |   |                |
|--------------------------------------|---|----------------|
| UN/ID No.                            | : | Not applicable |
| Proper shipping name                 | : | Not applicable |
| Class                                | : | Not applicable |
| Subsidiary risk                      | : | Not applicable |
| Packing group                        | : | Not applicable |
| Labels                               | : | Not applicable |
| Packing instruction (cargo aircraft) | : | Not applicable |

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Packing instruction (passenger aircraft) : Not applicable

**IMDG-Code**

UN number : Not applicable  
Proper shipping name : Not applicable  
Class : Not applicable  
Subsidiary risk : Not applicable  
Packing group : Not applicable  
Labels : Not applicable  
EmS Code : Not applicable  
Marine pollutant : Not applicable

**Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code**

Not applicable for product as supplied.

**National Regulations****NZS 5433**

UN number : Not applicable  
Proper shipping name : Not applicable  
Class : Not applicable  
Subsidiary risk : Not applicable  
Packing group : Not applicable  
Labels : Not applicable  
Hazchem Code : Not applicable

**Special precautions for user**

Not applicable

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**Section 15: Regulatory information****Safety, health and environmental regulations/legislation specific for the substance or mixture****HSNO Approval Number**

HSR100425 Pharmaceutical Active Ingredients Group Standard

Tolerable Exposure Limits (TEL)

Not applicable

Environmental Exposure Limits (EEL)

Not applicable

**HSW Controls**

Certified handler certificate not required.

Tracking hazardous substance not required.

Refer to the Health and Safety at Work (Hazardous Substances) Regulations 2017, for further information.

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

AICS : not determined

DSL : not determined

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IECSC : not determined

**Section 16: Other information**

Revision Date : 20.06.2025

**Further information**Sources of key data used to compile the Safety Data Sheet : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, <http://echa.europa.eu/>

Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

Date format : dd.mm.yyyy

**Full text of other abbreviations**ACGIH : USA. ACGIH Threshold Limit Values (TLV)  
NZ OEL : New Zealand. Workplace Exposure Standards for Atmospheric ContaminantsACGIH / TWA : 8-hour, time-weighted average  
NZ OEL / WES-TWA : Workplace Exposure Standard - Time Weighted average

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TECL - Thailand Existing Chemicals Inventory; TSCA - Toxic Sub-

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stances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

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