

## Butorphanol Formulation

|         |                |              |                                 |
|---------|----------------|--------------|---------------------------------|
| Version | Revision Date: | SDS Number:  | Date of last issue: 2024/07/06  |
| 4.0     | 2024/12/03     | 918662-00019 | Date of first issue: 2016/10/03 |

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## 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Butorphanol Formulation

Other means of identification : Dolorex® (A006877)

**Manufacturer or supplier's details**

Company : MSD

Address : 126 E. Lincoln Avenue  
Rahway, New Jersey U.S.A. 07065

Telephone : +1-908-740-4000

Emergency telephone number : +1-908-423-6000

E-mail address : EHSDATASTEWARD@msd.com

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

Recommended use : Veterinary product

Restrictions on use : Not applicable

## 2. HAZARDS IDENTIFICATION

**GHS Classification**Specific target organ toxicity - : Category 2 (Central nervous system)  
single exposure (Oral)Specific target organ toxicity - : Category 2 (Blood, Central nervous system)  
repeated exposure (Oral)**GHS label elements**

Hazard pictograms :



Signal word : Warning

Hazard statements : H371 May cause damage to organs (Central nervous system) if  
swallowed.  
H373 May cause damage to organs (Blood, Central nervous  
system) through prolonged or repeated exposure if swallowed.Precautionary statements : **Prevention:**  
P260 Do not breathe mist or vapours.

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P264 Wash skin thoroughly after handling.  
P270 Do not eat, drink or smoke when using this product.

**Response:**

P308 + P311 IF exposed or concerned: Call a POISON CENTER/ doctor.

**Storage:**

P405 Store locked up.

**Disposal:**

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

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

None known.

**3. COMPOSITION/INFORMATION ON INGREDIENTS**

Substance / Mixture : Mixture

**Components**

| Chemical name   | CAS-No.    | Concentration (% w/w) |
|---|------------|-----------------------|
| 17-(cyclobutylmethyl)morphinan-3,14-diyl [S-(R*,R*)]-2,3-dihydroxysuccinate | 58786-99-5 | >= 1 -< 2.5           |

**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.  |
| In case of skin contact                                     | : In case of contact, immediately flush skin with soap and 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                                      | : Flush eyes with water as a precaution.<br>Get medical attention if irritation develops and persists.  |
| If swallowed  | : If swallowed, DO NOT induce vomiting.<br>Get medical attention.<br>Rinse mouth thoroughly with water.<br>Never give anything by mouth to an unconscious person.   |
| Most important symptoms and effects, both acute and delayed | : May cause damage to organs if swallowed.<br>May cause damage to organs through prolonged or repeated exposure if swallowed.   |
| 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).   |

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Notes to physician : Treat symptomatically and supportively.

**5. FIREFIGHTING MEASURES**

- Suitable extinguishing media : Water spray  
Alcohol-resistant foam  
Carbon dioxide (CO<sub>2</sub>)  
Dry chemical
- Unsuitable extinguishing media : None known.
- Specific hazards during fire-fighting : Exposure to combustion products may be a hazard to health.
- Hazardous combustion products : Carbon oxides
- Specific extinguishing methods : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.  
Use water spray to cool unopened containers.  
Remove undamaged containers from fire area if it is safe to do so.  
Evacuate area.
- Special protective equipment for firefighters : In the event of fire, wear self-contained breathing apparatus.  
Use personal protective equipment.

**6. ACCIDENTAL RELEASE MEASURES**

- Personal precautions, protective equipment and emergency procedures : Use personal protective equipment.  
Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).
- Environmental precautions : Avoid release to the environment.  
Prevent further leakage or spillage if safe to do so.  
Prevent spreading over a wide area (e.g. by containment or oil barriers).  
Retain and dispose of contaminated wash water.  
Local authorities should be advised if significant spillages cannot be contained.
- Methods and materials for containment and cleaning up : Soak up with inert absorbent material.  
For large spills, provide dyking or other appropriate containment to keep material from spreading. If dyked material can be pumped, store recovered material in appropriate container.  
Clean up remaining materials from spill with suitable absorbent.  
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 deter-

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mine which regulations are applicable.  
Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

## 7. HANDLING AND STORAGE

- Technical measures : See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.
- Local/Total ventilation : Use only with adequate ventilation.
- Advice on safe handling : Do not breathe mist or vapours.  
Do not swallow.  
Avoid contact with eyes.  
Avoid prolonged or repeated contact with skin.  
Wash skin thoroughly after handling.  
Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment  
Do not eat, drink or smoke when using this product.  
Take care to prevent spills, waste and minimize release to the environment.
- Conditions for safe storage : Keep in properly labelled containers.  
Store locked up.  
Store in accordance with the particular national regulations.
- Materials to avoid : Do not store with the following product types:  
Strong oxidizing agents

## 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

### Components with workplace control parameters

| Components  | CAS-No.    | Value type<br>(Form of exposure) | Control parameters / Permissible concentration | Basis    |
|---|------------|----------------------------------|--|----------|
| 17-(cyclobutylmethyl)morphinan-3,14-diyl [S-(R*,R*)]-2,3-dihydroxysuccinate | 58786-99-5 | TWA                              | 3 µg/m3 (OEB 4)                                | Internal |
|   |            | Wipe limit                       | 30 µg/100 cm <sup>2</sup>                      | Internal |
|   |            | STEL                             | 25 µg/m3                                       | Internal |

- Engineering measures** : The information below is intended for larger pilot/commercial-scale operations and manufacturing. For smaller scale, clinical, or pharmacy settings, site-specific internal risk assessment practices should be conducted to determine appropriate exposure control measures. The health hazard risks of handling this material are dependent on multiple factors, including but not limited to physical form and quantity handled. If applicable, use process enclosures, local exhaust ventilation (e.g., Biosafety Cabinet, Ventilated Balance Enclosures), or other engineering controls to maintain airborne levels below

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recommended exposure limits. If exposure limits have not been established, maintain airborne levels as low as reasonably achievable.

All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.

Essentially no open handling permitted.

Use closed processing systems or containment technologies. If handled in a laboratory, use a properly designed biosafety cabinet, fume hood, or other containment device if the potential exists for aerosolization. If this potential does not exist, handle over lined trays or benchtops.

**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.  
If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles.  
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.  
Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces.  
Use appropriate degowning techniques to remove potentially contaminated clothing.

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.

**9. PHYSICAL AND CHEMICAL PROPERTIES**

Appearance : liquid

Colour : colourless

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|  |   |  |
|--|---|--|
| 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          | : | 100 °C   |
| Flash point                                      | : | No data available  |
| Evaporation rate                                 | : | No data available  |
| Flammability (solid, gas)                        | : | Not applicable   |
| Flammability (liquids)                           | : | 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)                                  |   |  |
| Water solubility                                 | : | No data available  |
| Partition coefficient: n-octanol/water           | : | Not applicable   |
| Auto-ignition temperature                        | : | No data available  |
| Decomposition temperature                        | : | No data available  |
| Viscosity  |   |  |
| Viscosity, kinematic                             | : | No data available  |
| Explosive properties                             | : | Not explosive  |
| Oxidizing properties                             | : | The substance or mixture is not classified as oxidizing. |
| Particle characteristics                         |   |  |
| Particle size                                    | : | Not applicable   |

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**10. STABILITY AND REACTIVITY**

|                                    |   |  |
|------------------------------------|---|--|
| Reactivity                         | : | Not classified as a reactivity hazard.         |
| Chemical stability                 | : | Stable under normal conditions.                |
| Possibility of hazardous reactions | : | Can react with strong oxidizing agents.        |
| Conditions to avoid                | : | None known.                                    |
| Incompatible materials             | : | Oxidizing agents                               |
| Hazardous decomposition products   | : | No hazardous decomposition products are known. |

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**11. TOXICOLOGICAL INFORMATION**

|  |   |  |
|--|---|--|
| Information on likely routes of exposure | : | Inhalation<br>Skin contact<br>Ingestion<br>Eye contact |
|--|---|--|

**Acute toxicity**

Not classified based on available information.

**Product:**

|                     |   |  |
|---------------------|---|--|
| Acute oral toxicity | : | Acute toxicity estimate: > 2,000 mg/kg<br>Method: Calculation method |
|---------------------|---|--|

**Components:****17-(cyclobutylmethyl)morphinan-3,14-diyl [S-(R\*,R\*)]-2,3-dihydroxysuccinate:**

|                           |   |  |
|---------------------------|---|--|
| Acute oral toxicity       | : | LD50 (Mouse): 395 mg/kg<br>LD50 (Dog): > 50 mg/kg<br>LD50 (Monkey): > 50 mg/kg |
| Acute inhalation toxicity | : | Remarks: No data available   |
| Acute dermal toxicity     | : | Remarks: No data available   |

**Skin corrosion/irritation**

Not classified based on available information.

**Components:****17-(cyclobutylmethyl)morphinan-3,14-diyl [S-(R\*,R\*)]-2,3-dihydroxysuccinate:**

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

**Serious eye damage/eye irritation**

Not classified based on available information.

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**Components:****17-(cyclobutylmethyl)morphinan-3,14-diyl [S-(R\*,R\*)]-2,3-dihydroxysuccinate:**

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

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

Not classified based on available information.

**Respiratory sensitisation**

Not classified based on available information.

**Components:****17-(cyclobutylmethyl)morphinan-3,14-diyl [S-(R\*,R\*)]-2,3-dihydroxysuccinate:**

|                 |                                      |
|-----------------|--------------------------------------|
| Exposure routes | : Dermal                             |
| Assessment      | : Does not cause skin sensitisation. |
| Result          | : negative                           |

**Germ cell mutagenicity**

Not classified based on available information.

**Components:****17-(cyclobutylmethyl)morphinan-3,14-diyl [S-(R\*,R\*)]-2,3-dihydroxysuccinate:**

|                       |   |
|-----------------------|---|
| Genotoxicity in vitro | : Test Type: Bacterial reverse mutation assay (AMES)<br>Result: negative                                      |
|                       | Test Type: DNA damage and repair, unscheduled DNA synthesis in mammalian cells (in vitro)<br>Result: negative |

**Carcinogenicity**

Not classified based on available information.

**Components:****17-(cyclobutylmethyl)morphinan-3,14-diyl [S-(R\*,R\*)]-2,3-dihydroxysuccinate:**

|                   |            |
|-------------------|------------|
| Species           | : Rat      |
| Application Route | : Oral     |
| Exposure time     | : 2 Years  |
| Result            | : negative |

|                   |            |
|-------------------|------------|
| Species           | : Mouse    |
| Application Route | : Oral     |
| Exposure time     | : 2 Years  |
| Result            | : negative |



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**Reproductive toxicity**

Not classified based on available information.

**Components:****17-(cyclobutylmethyl)morphinan-3,14-diyl [S-(R\*,R\*)]-2,3-dihydroxysuccinate:**

|                                    |  |
|------------------------------------|--|
| Effects on fertility               | : Test Type: Fertility/early embryonic development<br>Species: Rat<br>Application Route: Oral<br>Fertility: LOAEL: 160 mg/kg body weight<br>Result: Effects on fertility   |
| Effects on foetal development      | : Test Type: Embryo-foetal development<br>Species: Rat<br>Application Route: Subcutaneous<br>Developmental Toxicity: LOAEL: 1 mg/kg body weight<br>Result: No teratogenic effects, Increased stillbirths<br><br>Test Type: Embryo-foetal development<br>Species: Rabbit<br>Application Route: Oral<br>Developmental Toxicity: LOAEL: 30 mg/kg body weight<br>Result: No teratogenic effects, Maternal toxicity observed., Postimplantation loss.<br><br>Test Type: Embryo-foetal development<br>Species: Rat<br>Application Route: Subcutaneous<br>Developmental Toxicity: LOAEL: 0.5 mg/kg body weight<br>Result: Maternal toxicity observed. |
| Reproductive toxicity - Assessment | : Some evidence of adverse effects on sexual function and fertility, based on animal experiments., Some evidence of adverse effects on development, based on animal experiments.   |

**STOT - single exposure**

May cause damage to organs (Central nervous system) if swallowed.

**Components:****17-(cyclobutylmethyl)morphinan-3,14-diyl [S-(R\*,R\*)]-2,3-dihydroxysuccinate:**

|               |                            |
|---------------|----------------------------|
| Target Organs | : Central nervous system   |
| Assessment    | : Causes damage to organs. |

**STOT - repeated exposure**

May cause damage to organs (Blood, Central nervous system) through prolonged or repeated exposure if swallowed.

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**Components:****17-(cyclobutylmethyl)morphinan-3,14-diyl [S-(R\*,R\*)]-2,3-dihydroxysuccinate:**

|               |   |
|---------------|---|
| Target Organs | : Blood, Central nervous system                                   |
| Assessment    | : Causes damage to organs through prolonged or repeated exposure. |

**Repeated dose toxicity****Components:****17-(cyclobutylmethyl)morphinan-3,14-diyl [S-(R\*,R\*)]-2,3-dihydroxysuccinate:**

|                   |                                 |
|-------------------|---------------------------------|
| Species           | : Rat                           |
| LOAEL             | : 0.4 mg/kg                     |
| Application Route | : Subcutaneous                  |
| Exposure time     | : 6 Months                      |
| Target Organs     | : Blood, Central nervous system |

|                   |                          |
|-------------------|--------------------------|
| Species           | : Monkey                 |
| LOAEL             | : 0.15 mg/kg             |
| Application Route | : Intramuscular          |
| Exposure time     | : 6 Months               |
| Target Organs     | : Central nervous system |

|                   |                            |
|-------------------|----------------------------|
| Species           | : Dog                      |
| LOAEL             | : 0.1 mg/kg                |
| Application Route | : Intramuscular            |
| Exposure time     | : 3 Months                 |
| Symptoms          | : reduced body weight gain |

**Aspiration toxicity**

Not classified based on available information.

**Experience with human exposure****Components:****17-(cyclobutylmethyl)morphinan-3,14-diyl [S-(R\*,R\*)]-2,3-dihydroxysuccinate:**

|           |   |
|-----------|---|
| Ingestion | : Symptoms: Drowsiness, Sweating, Nausea, Dizziness, Vertigo, Palpitation, respiratory depression |
|-----------|---|

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**12. ECOLOGICAL INFORMATION****Ecotoxicity****Components:****17-(cyclobutylmethyl)morphinan-3,14-diyl [S-(R\*,R\*)]-2,3-dihydroxysuccinate:**

|   |  |
|---|--|
| Toxicity to daphnia and other aquatic invertebrates | : EC50 (Daphnia magna (Water flea)): 38.1 mg/l<br>Exposure time: 48 h<br>Method: OECD Test Guideline 202 |
|---|--|

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**Persistence and degradability**

No data available

**Bioaccumulative potential**

No data available

**Mobility in soil**

No data available

**Other adverse effects**

No data available

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**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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**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 |
| 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 |

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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.

**Special precautions for user**

Not applicable

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**15. REGULATORY INFORMATION****Safety, health and environmental regulations/legislation specific for the substance or mixture**

**Minister of Industry Regulation No. 23/M-IND/PER/4/2013 concerning the Revision of Minister of Industry Regulation No. 87/M-IND/PER/9/2009 concerning Globally Harmonized System of Classification and Labelling of Chemicals.**

**Regulation of the Minister of Health No. 472 of 1996 on the Safeguarding of Substances Hazardous to Health**

Hazardous substances that must be registered : Not applicable

**Government Regulation No. 74 of 2001 on the Management of Hazardous and Toxic Substances**

Hazardous substances approved for use : Not applicable

Prohibited substances : Not applicable

Restricted substances : Not applicable

**Regulation of the Ministry of Trade No. 7 of 2022 on Distribution and Control of Hazardous Materials**

Type of hazardous materials subject to distribution and control, Annex I : Not applicable

Type of hazardous materials subject to distribution and control, Annex II : Not applicable

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

AICS : not determined

DSL : not determined

IECSC : not determined

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**16. OTHER INFORMATION**

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**Further information**

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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 : yyyy/mm/dd

**Full text of other abbreviations**

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; 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; WHMIS - Workplace Hazardous Materials Information System

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 is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.

# SAFETY DATA SHEET



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