# SAFETY DATA SHEET

## Sulfamethoxazole / Trimethoprim Formulation

| Version | Revision Date: | SDS Number: | Date of last issue: 2024/09/28 |
|---|---|---|---|
| 10.0 | 2025/04/14 | 6289826-00015 | Date of first issue: 2020/08/25 |

## 1. PRODUCT AND COMPANY IDENTIFICATION

Chemical product name : Sulfamethoxazole / Trimethoprim Formulation

**Supplier's company name, address and phone number**

Company name of supplier : MSD

Address : 1-13-12, Kudan-kita, Chiyoda-ku, Tokyo, Japan

Telephone : 03-6272-1099

E-mail address : EHSDATASTEWARD@msd.com

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

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

Recommended use : Veterinary product

Restrictions on use : Not applicable

## 2. HAZARDS IDENTIFICATION

**GHS classification of chemical product**

Skin corrosion/irritation : Sub-category 1A

Serious eye damage/eye irritation : Category 1

Reproductive toxicity : Category 2

Specific target organ toxicity - repeated exposure : Category 2 (Bone marrow)

Short-term (acute) aquatic hazard : Category 1

Long-term (chronic) aquatic hazard : Category 1

**GHS label elements**

Hazard pictograms :

Signal word : Danger

Hazard statements : H314 Causes severe skin burns and eye damage.

H361d Suspected of damaging the unborn child.
H373 May cause damage to organs (Bone marrow) through prolonged or repeated exposure.
H410 Very 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 mist or vapours.
P264 Wash skin thoroughly after handling.
P273 Avoid release to the environment.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

**Response:**

P301 + P330 + P331 + P310 IF SWALLOWED: Rinse mouth. Do NOT induce vomiting. Immediately call a POISON CENTER/ doctor.
P303 + P361 + P353 + P310 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water or shower. Immediately call a POISON CENTER/ doctor.
P304 + P340 + P310 IF INHALED: Remove person to fresh air and keep comfortable for breathing. Immediately call a POISON CENTER/ doctor.
P305 + P351 + P338 + P310 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER/ doctor.
P308 + P313 IF exposed or concerned: 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 which do not result in classification**

Important symptoms and outlines of the emergency assumed : Corrosive to the respiratory tract.

## 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

**Components**

| Chemical name | CAS-No. | Concentration (% w/w) | ENCS No. |
|---|---|---|---|
| Sulfamethoxazole | 723-46-6 | >= 30 - < 40 | - |
| Trimethoprim | 738-70-5 | >= 1 - < 10 | - |
| Sodium hydroxide | 1310-73-2 | 5.0891 | 1-410 |

## 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>If not breathing, give artificial respiration.<br>If breathing is difficult, give oxygen.<br>Get medical attention immediately. |
| In case of skin contact | : | In case of contact, immediately flush skin with plenty of water for at least 15 minutes while removing contaminated clothing and shoes.<br>Get medical attention immediately.<br>Wash clothing before reuse.<br>Thoroughly clean shoes before reuse. |
| In case of eye contact | : | In case of contact, immediately flush eyes with plenty of water for at least 15 minutes.<br>If easy to do, remove contact lens, if worn.<br>Get medical attention immediately. |
| If swallowed | : | If swallowed, DO NOT induce vomiting.<br>If vomiting occurs have person lean forward.<br>Call a physician or poison control centre immediately.<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 | : | Causes digestive tract burns.<br>Corrosive to respiratory system.<br>Causes serious eye damage.<br>Suspected of damaging the unborn child.<br>May cause damage to organs through prolonged or repeated exposure.<br>Causes severe burns. |
| 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. |

## 5. FIREFIGHTING MEASURES

| | | |
|---|---|---|
| Suitable extinguishing media | : | Water spray<br>Alcohol-resistant foam<br>Carbon dioxide (CO2) |

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<br>Nitrogen oxides (NOx)<br>Sulphur 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. |

## 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>Prevent spreading over a wide area (e.g. by containment or oil barriers).<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 | : | Soak up with inert absorbent material.<br>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.<br>Clean up remaining materials from spill with suitable absorbent.<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. |

## 7. HANDLING AND STORAGE

**Handling**

Technical measures : See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.

Local/Total ventilation : If sufficient ventilation is unavailable, use with local exhaust ventilation.

Advice on safe handling : Do not get on skin or clothing.
Do not breathe mist or vapours.
Do not swallow.
Do not get in 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
Keep container tightly closed.
Do not eat, drink or smoke when using this product.
Take care to prevent spills, waste and minimize release to the environment.

Avoidance of contact : Oxidizing agents
Acids

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.

**Storage**

Conditions for safe storage : Keep in properly labelled containers.
Store locked up.
Keep tightly closed.
Store in accordance with the particular national regulations.

Materials to avoid : Do not store with the following product types:
Strong oxidizing agents

Packaging material : Unsuitable material: None known.

## 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

**Threshold limit value and permissible exposure limits for each component in the work environment**

| Components | CAS-No. | Value type (Form of exposure) | Control parameters / Concentration standard / Permissible concentration | Basis |
|---|---|---|---|---|

| | | | | |
|---|---|---|---|---|
| Sulfamethoxazole | 723-46-6 | TWA | OEB 2 (>= 100 < 1000 µg/m3) | Internal |
| Trimethoprim | 738-70-5 | TWA | 400 µg/m3 (OEB 2) | Internal |
| Sodium hydroxide | 1310-73-2 | OEL-C | 2 mg/m3 | JP OEL JSOH |
| | | C | 2 mg/m3 | ACGIH |

**Engineering measures** : Use appropriate engineering controls and manufacturing technologies to control airborne concentrations (e.g., drip-less quick connections).
All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.
Laboratory operations do not require special containment.

**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 : Impermeable protective gloves

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.

## 9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state : suspension

Colour : white to off-white

Odour : No data available

Odour Threshold : No data available

Melting point/freezing point : No data available

Boiling point, initial boiling point and boiling range : No data available

Flammability (solid, gas) : Not applicable

Flammability (liquids) : No data available

| | | |
|---|---|---|
| Lower explosion limit and upper explosion limit / flammability limit | | |
| Upper explosion limit / Upper flammability limit | : | No data available |
| Lower explosion limit / Lower flammability limit | : | No data available |
| Flash point | : | No data available |
| Decomposition temperature | : | No data available |
| pH | : | 9.5 - 12.5 |
| Evaporation rate | : | No data available |
| Auto-ignition temperature | : | No data available |
| Viscosity | | |
| Viscosity, kinematic | : | No data available |
| Solubility(ies) | | |
| Water solubility | : | No data available |
| Partition coefficient: n-octanol/water | : | Not applicable |
| Vapour pressure | : | No data available |
| Density and / or relative density | | |
| Relative density | : | No data available |
| Density | : | 1.179 g/cm³ |
| Relative vapour density | : | No data available |
| Explosive properties | : | Not explosive |
| Oxidizing properties | : | The substance or mixture is not classified as oxidizing. |
| Molecular weight | : | No data available |
| Particle characteristics | | |
| Particle size | : | Not applicable |

## 10. STABILITY AND REACTIVITY

| | | |
|---|---|---|
| Reactivity | : | Not classified as a reactivity hazard. |
| Chemical stability | : | Stable under normal conditions. |
| Possibility of hazardous reac- | : | Can react with strong oxidizing agents. |

tions

| | | |
|---|---|---|
| Conditions to avoid | : | None known. |
| Incompatible materials | : | Oxidizing agents<br>Acids |
| Hazardous decomposition products | : | No hazardous decomposition products are known. |

## 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:**

**Sulfamethoxazole:**

| | | |
|---|---|---|
| Acute oral toxicity | : | LD50 (Mouse): 2,300 mg/kg |

**Trimethoprim:**

| | | |
|---|---|---|
| Acute oral toxicity | : | LD50 (Rat): 1,500 - 5,300 mg/kg<br><br>LD50 (Mouse): 1,910 - 7,000 mg/kg |
| Acute toxicity (other routes of administration) | : | LD50 (Rat): 400 - 500 mg/kg<br>Application Route: Intraperitoneal<br><br>LD50 (Dog): 90 mg/kg<br>Application Route: Intravenous<br><br>LD50 (Mouse): 132 mg/kg<br>Application Route: Intravenous |

**Sodium hydroxide:**

| | | |
|---|---|---|
| Acute inhalation toxicity | : | Assessment: Corrosive to the respiratory tract. |

**Skin corrosion/irritation**

Causes severe burns.

**Components:**

**Sulfamethoxazole:**

| | | |
|---|---|---|
| Species | : | Rabbit |

| | | |
|---|---|---|
| Result | : | No skin irritation |

**Sodium hydroxide:**

| | | |
|---|---|---|
| Result | : | Corrosive after 3 minutes or less of exposure |

**Serious eye damage/eye irritation**

Causes serious eye damage.

**Components:**

**Sodium hydroxide:**

| | | |
|---|---|---|
| Result | : | Irreversible effects on the eye |
| Remarks | : | Based on skin corrosivity. |

**Respiratory or skin sensitisation**

**Skin sensitisation**

Not classified based on available information.

**Respiratory sensitisation**

Not classified based on available information.

**Components:**

**Sulfamethoxazole:**

| | | |
|---|---|---|
| Test Type | : | Magnusson-Kligman-Test |
| Exposure routes | : | Skin contact |
| Species | : | Guinea pig |
| Result | : | negative |

**Trimethoprim:**

| | | |
|---|---|---|
| Test Type | : | Maximisation Test |
| Exposure routes | : | Dermal |
| Species | : | Guinea pig |
| Result | : | Not a skin sensitizer. |

**Sodium hydroxide:**

| | | |
|---|---|---|
| Test Type | : | Human repeat insult patch test (HRIPT) |
| Exposure routes | : | Skin contact |
| Result | : | negative |

**Germ cell mutagenicity**

Not classified based on available information.

**Components:**

**Sulfamethoxazole:**

| | | |
|---|---|---|
| Genotoxicity in vitro | : | Test Type: Bacterial reverse mutation assay (AMES)<br>Result: negative |

| | | |
|---|---|---|
| | | Test Type: Chromosome aberration test in vitro<br>Result: negative |
| Genotoxicity in vivo | : | Test Type: Mutagenicity (in vivo mammalian bone-marrow cytogenetic test, chromosomal analysis)<br>Species: Humans<br>Result: negative |

**Trimethoprim:**

| | | |
|---|---|---|
| Genotoxicity in vitro | : | Test Type: Bacterial reverse mutation assay (AMES)<br>Result: negative<br><br>Test Type: Chromosomal aberration<br>Result: negative<br><br>Test Type: In vitro mammalian cell gene mutation test<br>Result: negative<br><br>Test Type: DNA damage and repair, unscheduled DNA synthesis in mammalian cells (in vitro)<br>Result: negative |
| Genotoxicity in vivo | : | Test Type: Micronucleus test<br>Species: Rat<br>Result: negative<br><br>Test Type: Chromosomal aberration<br>Species: Humans<br>Result: negative |

**Carcinogenicity**

Not classified based on available information.

**Components:**

**Sulfamethoxazole:**

| | | |
|---|---|---|
| Species | : | Mouse |
| Application Route | : | Ingestion |
| Exposure time | : | 26 weeks |
| Result | : | negative |

**Reproductive toxicity**

Suspected of damaging the unborn child.

**Components:**

**Trimethoprim:**

| | | |
|---|---|---|
| Effects on fertility | : | Test Type: Fertility<br>Species: Rat<br>Application Route: Oral<br>Fertility: NOAEL: 70 mg/kg body weight |

| | | |
|---|---|---|
| | | Result: No effects on fertility |
| Effects on foetal development | : | Test Type: Development<br>Species: Rat<br>Application Route: Oral<br>Developmental Toxicity: LOAEL: 70 mg/kg body weight<br>Result: Effects on newborn<br>Remarks: Maternal toxicity observed.<br><br>Test Type: Development<br>Species: Rat<br>Application Route: Oral<br>Developmental Toxicity: LOAEL: 70 mg/kg body weight<br>Result: Embryotoxic effects.<br>Remarks: Maternal toxicity observed.<br><br>Test Type: Development<br>Species: Rat<br>Application Route: Oral<br>Developmental Toxicity: LOAEL: 15 mg/kg body weight<br>Result: Embryotoxic effects., Teratogenic effects<br><br>Test Type: Development<br>Species: Hamster<br>Application Route: Oral<br>Developmental Toxicity: LOAEL: 1.7 mg/kg body weight<br>Result: Embryotoxic effects., No teratogenic effects<br><br>Test Type: Development<br>Species: Rabbit<br>Application Route: Oral<br>Developmental Toxicity: LOAEL: 100 mg/kg body weight<br>Result: Embryotoxic effects., No teratogenic effects |
| Reproductive toxicity - Assessment | : | Suspected of damaging the unborn child. |

**STOT - single exposure**

Not classified based on available information.

**STOT - repeated exposure**

May cause damage to organs (Bone marrow) through prolonged or repeated exposure.

**Components:**

**Trimethoprim:**

| | | |
|---|---|---|
| Target Organs | : | Bone marrow |
| Assessment | : | Causes damage to organs through prolonged or repeated exposure. |

**Repeated dose toxicity**

**Components:**

**Trimethoprim:**

| | | |
|---|---|---|
| Species | : | Rat |
| NOAEL | : | 100 mg/kg |
| LOAEL | : | 300 mg/kg |
| Application Route | : | Oral |
| Exposure time | : | 6 Months |
| Target Organs | : | Bone marrow, Liver, Pituitary gland, Thyroid |

| | | |
|---|---|---|
| Species | : | Rat |
| LOAEL | : | 300 mg/kg |
| Application Route | : | Oral |
| Exposure time | : | 3 Months |
| Target Organs | : | Bone marrow |

| | | |
|---|---|---|
| Species | : | Dog |
| NOAEL | : | 2.5 mg/kg |
| LOAEL | : | 45 mg/kg |
| Application Route | : | Oral |
| Exposure time | : | 3 Months |
| Target Organs | : | Blood, Thyroid |

**Aspiration toxicity**

Not classified based on available information.

**Experience with human exposure**

**Components:**

**Trimethoprim:**

| | | |
|---|---|---|
| Ingestion | : | Target Organs: Bone marrow<br>Symptoms: Abdominal pain, Nausea, Vomiting, skin rash, Dizziness, Headache, mental depression, confusion |

## 12. ECOLOGICAL INFORMATION

**Ecotoxicity**

**Components:**

**Sulfamethoxazole:**

| | | |
|---|---|---|
| Toxicity to fish | : | LC50 (Oryzias latipes (Japanese medaka)): 562.5 mg/l<br>Exposure time: 96 h |
| Toxicity to daphnia and other aquatic invertebrates | : | EC50 (Ceriodaphnia dubia (water flea)): 0.21 mg/l<br>Exposure time: 48 h |
| Toxicity to algae/aquatic | : | EC50 (Synechococcus leopoliensis (blue-green algae)): |

| | | |
|---|---|---|
| plants | | 0.0268 mg/l<br>Exposure time: 96 h<br><br>NOEC (Synechococcus leopoliensis (blue-green algae)): 0.0059 mg/l<br>Exposure time: 96 h |
| M-Factor (Acute aquatic toxicity) | : | 10 |
| Toxicity to fish (Chronic toxicity) | : | NOEC (Danio rerio (zebra fish)): 0.533 mg/l<br>Exposure time: 21 d |
| Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) | : | NOEC (Daphnia magna (Water flea)): 0.01 mg/l<br>Exposure time: 30 d |
| M-Factor (Chronic aquatic toxicity) | : | 10 |
| Toxicity to microorganisms | : | NOEC (activated sludge): 3.76 mg/l<br>Method: OECD Test Guideline 301D |

**Trimethoprim:**

| | | |
|---|---|---|
| Toxicity to fish | : | LC50 (Pimephales promelas (fathead minnow)): 100 mg/l<br>Exposure time: 96 h |
| Toxicity to daphnia and other aquatic invertebrates | : | EC50 (Daphnia magna Straus): 92 mg/l<br>Exposure time: 48 h |
| Toxicity to algae/aquatic plants | : | EC50 (Pseudokirchneriella subcapitata (microalgae)): 80.3 mg/l<br>Exposure time: 72 h<br><br>NOEC (Pseudokirchneriella subcapitata (green algae)): 16 mg/l<br>Exposure time: 72 h<br><br>EC50 (Anabaena flos-aquae): 253 mg/l<br>Exposure time: 72 h<br><br>EC10 (Anabaena flos-aquae): 26 mg/l<br>Exposure time: 72 h |
| Toxicity to fish (Chronic toxicity) | : | NOEC (Zebrafish): 0.157 mg/l<br>Exposure time: 21 d |
| Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) | : | NOEC (Daphnia magna (Water flea)): 6 mg/l<br>Exposure time: 21 d |
| Toxicity to microorganisms | : | EC10: 16.7 mg/l<br>Exposure time: 3 hrs<br>Test Type: Respiration inhibition<br>Method: OECD Test Guideline 209 |

EC50: > 1,000 mg/l
Exposure time: 3 hrs
Test Type: Respiration inhibition
Method: OECD Test Guideline 209

**Persistence and degradability**

**Components:**

**Sulfamethoxazole:**

| | | |
|---|---|---|
| Biodegradability | : | Result: Not readily biodegradable.<br>Biodegradation: 0 %<br>Exposure time: 28 d<br>Method: OECD Test Guideline 301D |

**Trimethoprim:**

| | | |
|---|---|---|
| Biodegradability | : | Result: Not readily biodegradable.<br>Biodegradation: 4 %<br>Exposure time: 28 d<br>Method: OECD Test Guideline 301D<br><br>Result: Not inherently biodegradable.<br>Biodegradation: 0 %<br>Exposure time: 28 d<br>Method: OECD Test Guideline 302B |

**Bioaccumulative potential**

**Components:**

**Sulfamethoxazole:**

| | | |
|---|---|---|
| Bioaccumulation | : | Species: Cyprinus carpio (Carp)<br>Bioconcentration factor (BCF): < 120 |
| Partition coefficient: n-octanol/water | : | log Pow: 0.89 |

**Trimethoprim:**

| | | |
|---|---|---|
| Partition coefficient: n-octanol/water | : | log Pow: 0.91 |

**Mobility in soil**

No data available

**Hazardous to the ozone layer**

Not applicable

**Other adverse effects**

No data available

## 13. DISPOSAL CONSIDERATIONS

**Disposal methods**

| | | |
|---|---|---|
| Waste from residues | : | Dispose of in accordance with local regulations.<br>Do not dispose of waste into sewer. |
| 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. |

## 14. TRANSPORT INFORMATION

**International Regulations**

**UNRTDG**

| | | |
|---|---|---|
| UN number | : | UN 1824 |
| Proper shipping name | : | SODIUM HYDROXIDE SOLUTION |
| Class | : | 8 |
| Packing group | : | II |
| Labels | : | 8 |
| Environmentally hazardous | : | no |

**IATA-DGR**

| | | |
|---|---|---|
| UN/ID No. | : | UN 1824 |
| Proper shipping name | : | Sodium hydroxide solution |
| Class | : | 8 |
| Packing group | : | II |
| Labels | : | Corrosive |
| Packing instruction (cargo aircraft) | : | 855 |
| Packing instruction (passenger aircraft) | : | 851 |

**IMDG-Code**

| | | |
|---|---|---|
| UN number | : | UN 1824 |
| Proper shipping name | : | SODIUM HYDROXIDE SOLUTION (Sulfamethoxazole) |
| Class | : | 8 |
| Packing group | : | II |
| Labels | : | 8 |
| EmS Code | : | F-A, S-B |
| Marine pollutant | : | yes |

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

Not applicable for product as supplied.

**National Regulations**

Refer to section 15 for specific national regulation.

**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.

**ERG Code** : 154

## 15. REGULATORY INFORMATION

**Related Regulations**

**Fire Service Law**

Not applicable to dangerous materials / designated flammables.

**Chemical Substance Control Law**

Not applicable for Specified Chemical Substance, Monitoring Chemical Substance and Priority Assessment Chemical Substance.

**Industrial Safety and Health Law**

**Harmful Substances Prohibited from Manufacture**

Not applicable

**Harmful Substances Required Permission for Manufacture**

Not applicable

**Substances Prevented From Impairment of Health**

Not applicable

**Circular concerning Information on Chemicals having Mutagenicity - Annex 2: Information on Existing Chemicals having Mutagenicity**

Not applicable

**Circular concerning Information on Chemicals having Mutagenicity - Annex 1: Information on Notified Substances having Mutagenicity**

Not applicable

**Substances Subject to be Notified Names**

Law Article 57-2 (Ministerial Order Article 34-2 Appended Table 2)

| Chemical name | Concentration (%) | Remarks |
|---|---|---|
| 5-[(3,4,5-trimethoxyphenyl)methyl]pyrimidine-2,4-diamine | >=1 - <10 | - |
| Sodium hydroxide | >=1 - <10 | - |

**Substances Subject to be Indicated Names**

Law Article 57 (Ministerial Order Article 30 Appended Table 2)

| Chemical name | Remarks |
|---|---|
| 5-[(3,4,5-trimethoxyphenyl)methyl]pyrimidine-2,4-diamine | - |
| Sodium hydroxide | - |

**Skin and Eye Damage Substances (ISHL MO Art. 594-2)**

| Chemical name |
|---|
| Sodium hydroxide |

**Carcinogenic Substances (Article 577-2 of the Occupational Health and Safety Regulations)**

Not applicable

**Ordinance on Prevention of Hazards Due to Specified Chemical Substances**

Not applicable

**Ordinance on Prevention of Lead Poisoning**

Not applicable

**Ordinance on Prevention of Tetraalkyl Lead Poisoning**

Not applicable

**Ordinance on Prevention of Organic Solvent Poisoning**

Not applicable

**Enforcement Order of the Industrial Safety and Health Law - Attached table 1 (Dangerous Substances)**

Not applicable

**Poisonous and Deleterious Substances Control Law**

Deleterious substance

| Chemical name | Cabinet Order Number |
|---|---|
| Preparations containing sodium hydroxide | 68 |

**Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof**

Not applicable

**High Pressure Gas Safety Act**

Not applicable

**Explosive Control Law**

Not applicable

**Vessel Safety Law**

Corrosive substances (Article 2 and 3 of rules on shipping and storage of dangerous goods and its Attached Table 1)

**Aviation Law**

Corrosive substances (Article 194 of The Enforcement Rules of Aviation Law and its Attached Table 1)

**Marine Pollution and Sea Disaster Prevention etc Law**

Bulk transportation : Not classified as noxious liquid substance

Pack transportation : Classified as marine pollutant

**Narcotics and Psychotropics Control Act**

Narcotic or Psychotropic Raw Material (Export / Import Permission)
Not applicable
Specific Narcotic or Psychotropic Raw Material (Export / Import permission)
Not applicable

**Waste Disposal and Public Cleansing Law**

Industrial waste

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

DSL : not determined

| | | |
|---|---|---|
| AICS | : | not determined |
| IECSC | : | not determined |

## 16. OTHER INFORMATION

In this SDS, if the concentration of substances subject to notification under the Industrial Safety and Health Law is indicated as a range, it includes cases where it is a trade secret.

**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 | : | yyyy/mm/dd |

**Full text of other abbreviations**

| | | |
|---|---|---|
| ACGIH | : | USA. ACGIH Threshold Limit Values (TLV) |
| JP OEL JSOH | : | Japan. The Japan Society for Occupational Health. Recommendation of Occupational Exposure Limits |
| ACGIH / C | : | Ceiling limit |
| JP OEL JSOH / OEL-C | : | Occupational Exposure Limit-Ceiling |

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.

JP / EN