

## Betaine / Multivitamin Formulation

|         |                |                |                                 |
|---------|----------------|----------------|---------------------------------|
| Version | Revision Date: | SDS Number:    | Date of last issue: 28.03.2025  |
| 3.0     | 14.04.2025     | 11513552-00004 | Date of first issue: 24.02.2025 |

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### 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Betaine / Multivitamin Formulation

Product code : Supastock

#### Manufacturer or supplier's details

Company : MSD

Address : Briahnager - Off Pune Nagar Road  
Wagholi - Pune - India 412 207

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

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### 2. HAZARDS IDENTIFICATION

#### Manufacture, Storage and Import of Hazardous Chemicals Rules 1989

##### Classification

Not classified as hazardous according to criteria laid down in Part I of Schedule-1.

##### GHS Classification

Not a hazardous substance or mixture.

##### GHS label elements

No hazard pictogram, no signal word, no hazard statement(s), no precautionary statement(s) required.

##### Additional Labelling

The following percentage of the mixture consists of ingredient(s) with unknown acute oral toxicity: 20 %

The following percentage of the mixture consists of ingredient(s) with unknown acute dermal toxicity: 20 %

The following percentage of the mixture consists of ingredient(s) with unknown acute inhalation toxicity: 20 %

The following percentage of the mixture consists of ingredient(s) with unknown hazards to the aquatic environment: 20 %

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

Dust contact with the eyes can lead to mechanical irritation.

## Betaine / Multivitamin Formulation

|         |                |                |                                 |
|---------|----------------|----------------|---------------------------------|
| Version | Revision Date: | SDS Number:    | Date of last issue: 28.03.2025  |
| 3.0     | 14.04.2025     | 11513552-00004 | Date of first issue: 24.02.2025 |

Contact with dust can cause mechanical irritation or drying of the skin.  
May form explosive dust-air mixture during processing, handling or other means.

### 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

#### Components

| Chemical name               | CAS-No.   | Concentration (% w/w) |
|-----------------------------|-----------|-----------------------|
| Starch                      | 9005-25-8 | $\geq 10 - < 20$      |
| 3,7-Dimethyl 2,6-octadienal | 5392-40-5 | $\geq 0.25 - < 1$     |
| Dimethyl octadienol         | 78-70-6   | $\geq 0.25 - < 1$     |
| (dl)-a-Tocopheryl acetate   | 7695-91-2 | $< 0.1$               |
| Betaine hydrochloride       | 590-46-5  | $< 0.1$               |
| Benzyl alcohol              | 100-51-6  | $< 0.1$               |
| Pyridoxine hydrochloride    | 58-56-0   | $< 0.1$               |
| Colecalciferol              | 67-97-0   | $\leq 0.0002$         |

### 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 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                                      | : 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 | : Contact with dust can cause mechanical irritation or drying of the skin.<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.                                                                                                                                                                               |

### 5. FIREFIGHTING MEASURES

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

## Betaine / Multivitamin Formulation

|         |                |                |                                 |
|---------|----------------|----------------|---------------------------------|
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| 3.0     | 14.04.2025     | 11513552-00004 | Date of first issue: 24.02.2025 |

media

- 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.  
Exposure to combustion products may be a hazard to health.
- Hazardous combustion products : Carbon oxides  
Nitrogen oxides (NO<sub>x</sub>)  
Chlorine compounds  
Metal oxides  
Oxides of phosphorus
- 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.  
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 : Sweep up or vacuum up spillage and collect in suitable container for disposal.  
Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air).  
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.  
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.  
Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

### 7. HANDLING AND STORAGE

- Technical measures : Static electricity may accumulate and ignite suspended dust

## Betaine / Multivitamin Formulation

Version 3.0      Revision Date: 14.04.2025      SDS Number: 11513552-00004      Date of last issue: 28.03.2025  
Date of first issue: 24.02.2025

causing an explosion.  
Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.

Local/Total ventilation : Use only with adequate ventilation.

Advice on safe handling : Do not get on skin or clothing.  
Avoid breathing dust.  
Do not swallow.  
Avoid contact with eyes.  
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.  
Take care to prevent spills, waste and minimize release to the environment.

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

## 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

### Components with workplace control parameters

| Components                  | CAS-No.   | Value type<br>(Form of exposure)   | Control parameters / Permissible concentration | Basis    |
|-----------------------------|-----------|------------------------------------|------------------------------------------------|----------|
| Starch                      | 9005-25-8 | TWA                                | 10 mg/m3                                       | ACGIH    |
| 3,7-Dimethyl 2,6-octadienal | 5392-40-5 | TWA (Inhalable fraction and vapor) | 5 ppm                                          | ACGIH    |
| (dl)-a-Tocopheryl acetate   | 7695-91-2 | TWA                                | 5000 ug/m3 (OEB 1)                             | Internal |
| Betaine hydrochloride       | 590-46-5  | TWA                                | >= 100 < 1000 µg/m3 (OEB2)                     | Internal |
| Pyridoxine hydrochloride    | 58-56-0   | TWA                                | OEB 3 (>= 10 < 100 µg/m3)                      | Internal |
| Colecalciferol              | 67-97-0   | TWA                                | 5 µg/m3 (OEB 4)                                | Internal |
|                             |           | Wipe limit                         | 50 µg/100 cm²                                  | 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 recommended exposure limits. If exposure limits have not been

## Betaine / Multivitamin Formulation

|         |                |                |                                 |
|---------|----------------|----------------|---------------------------------|
| Version | Revision Date: | SDS Number:    | Date of last issue: 28.03.2025  |
| 3.0     | 14.04.2025     | 11513552-00004 | Date of first issue: 24.02.2025 |

established, maintain airborne levels as low as reasonably achievable.  
Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of the compound to uncontrolled areas (e.g., vacuum conveying from a closed system, packout head with inflatable seal from stationary container, ventilated enclosure, etc.).  
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.

### 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.  
Contaminated work clothing should not be allowed out of the workplace.  
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 : powder

Colour : yellow

## Betaine / Multivitamin Formulation

|         |                |                |                                 |
|---------|----------------|----------------|---------------------------------|
| Version | Revision Date: | SDS Number:    | Date of last issue: 28.03.2025  |
| 3.0     | 14.04.2025     | 11513552-00004 | Date of first issue: 24.02.2025 |

---

|                                                  |   |                                                                                 |
|--------------------------------------------------|---|---------------------------------------------------------------------------------|
| Odour                                            | : | characteristic                                                                  |
| 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                                                                  |
| 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                         | : |                                                                                 |

## Betaine / Multivitamin Formulation

|         |                |                |                                 |
|---------|----------------|----------------|---------------------------------|
| Version | Revision Date: | SDS Number:    | Date of last issue: 28.03.2025  |
| 3.0     | 14.04.2025     | 11513552-00004 | Date of first issue: 24.02.2025 |

Particle size : No data available

### 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.                                                                             |

### 11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure : Inhalation  
Skin contact  
Ingestion  
Eye contact

#### Acute toxicity

Not classified based on available information.

#### Components:

##### Starch:

|                       |   |                              |
|-----------------------|---|------------------------------|
| Acute oral toxicity   | : | LD50 (Rat): > 5,000 mg/kg    |
| Acute dermal toxicity | : | LD50 (Rabbit): > 2,000 mg/kg |

##### 3,7-Dimethyl 2,6-octadienal:

|                           |   |                                                                          |
|---------------------------|---|--------------------------------------------------------------------------|
| Acute oral toxicity       | : | LD50 (Rat, female): 4,895 mg/kg                                          |
| Acute inhalation toxicity | : | LC50 (Rat): > 0.68 mg/l<br>Exposure time: 7 h<br>Test atmosphere: vapour |
| Acute dermal toxicity     | : | LD50 (Rabbit): 2,250 mg/kg                                               |

##### Dimethyl octadienol:

|                           |   |                                                                                                                                  |
|---------------------------|---|----------------------------------------------------------------------------------------------------------------------------------|
| Acute oral toxicity       | : | LD50 (Rat): 2,790 mg/kg<br>Method: OECD Test Guideline 401<br>Remarks: The test was conducted equivalent or similar to guideline |
| Acute inhalation toxicity | : | LC50 (Mouse): > 3.2 mg/l<br>Exposure time: 90 min<br>Test atmosphere: vapour<br>Remarks: No test guideline followed              |

## Betaine / Multivitamin Formulation

|         |                |                |                                 |
|---------|----------------|----------------|---------------------------------|
| Version | Revision Date: | SDS Number:    | Date of last issue: 28.03.2025  |
| 3.0     | 14.04.2025     | 11513552-00004 | Date of first issue: 24.02.2025 |

---

Acute dermal toxicity : LD50 (Rabbit): 5,610 mg/kg  
Method: OECD Test Guideline 402  
Remarks: The test was conducted equivalent or similar to guideline

### **(dl)-a-Tocopheryl acetate:**

Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg  
Acute dermal toxicity : LD50 (Rat): > 3,000 mg/kg  
Assessment: The substance or mixture has no acute dermal toxicity

### **Betaine hydrochloride:**

Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg  
Method: OECD Test Guideline 401  
Remarks: The test was conducted according to guideline  
Based on data from similar materials

### **Benzyl alcohol:**

Acute oral toxicity : LD50 (Rat): 1,200 mg/kg  
Acute inhalation toxicity : LC50 (Rat): > 5.4 mg/l  
Exposure time: 4 h  
Test atmosphere: dust/mist  
Method: OECD Test Guideline 403  
Assessment: The substance or mixture has no acute inhalation toxicity

### **Pyridoxine hydrochloride:**

Acute oral toxicity : LD50 (Rat): 4,000 mg/kg

### **Colecalciferol:**

Acute oral toxicity : LD50 (Rat, male): 35 mg/kg  
Acute inhalation toxicity : Acute toxicity estimate: 0.05 mg/l  
Exposure time: 4 h  
Test atmosphere: dust/mist  
Method: Expert judgement  
Acute dermal toxicity : Acute toxicity estimate: 50 mg/kg  
Method: Expert judgement

### **Skin corrosion/irritation**

Not classified based on available information.

### **Components:**

#### **3,7-Dimethyl 2,6-octadienal:**

Species : Rabbit

## Betaine / Multivitamin Formulation

|         |                |                |                                 |
|---------|----------------|----------------|---------------------------------|
| Version | Revision Date: | SDS Number:    | Date of last issue: 28.03.2025  |
| 3.0     | 14.04.2025     | 11513552-00004 | Date of first issue: 24.02.2025 |

---

Result : Skin irritation

### Dimethyl octadienol:

Species : Rabbit  
Method : OECD Test Guideline 404  
Result : Skin irritation  
Remarks : The test was conducted according to guideline

### (dl)-a-Tocopheryl acetate:

Species : Rabbit  
Method : OECD Test Guideline 404  
Result : No skin irritation

### Betaine hydrochloride:

Species : reconstructed human epidermis (RhE)  
Method : OECD Test Guideline 439  
Remarks : The test was conducted according to guideline

Result : No skin irritation

### Benzyl alcohol:

Species : Rabbit  
Method : OECD Test Guideline 404  
Result : No skin irritation

### Pyridoxine hydrochloride:

Species : Rabbit  
Result : No skin irritation

### Serious eye damage/eye irritation

Not classified based on available information.

### Components:

#### Starch:

Species : Rabbit  
Result : No eye irritation

### 3,7-Dimethyl 2,6-octadienal:

Species : Rabbit  
Result : Irritation to eyes, reversing within 21 days

### Dimethyl octadienol:

Species : Rabbit  
Method : OECD Test Guideline 405  
Result : Irritation to eyes, reversing within 21 days  
Remarks : The test was conducted equivalent or similar to guideline

## Betaine / Multivitamin Formulation

|         |                |                |                                 |
|---------|----------------|----------------|---------------------------------|
| Version | Revision Date: | SDS Number:    | Date of last issue: 28.03.2025  |
| 3.0     | 14.04.2025     | 11513552-00004 | Date of first issue: 24.02.2025 |

---

### **(dl)-a-Tocopheryl acetate:**

|         |   |                         |
|---------|---|-------------------------|
| Species | : | Rabbit                  |
| Method  | : | OECD Test Guideline 405 |
| Result  | : | No eye irritation       |

### **Betaine hydrochloride:**

|        |   |                                 |
|--------|---|---------------------------------|
| Result | : | Irreversible effects on the eye |
|--------|---|---------------------------------|

### **Benzyl alcohol:**

|         |   |                                              |
|---------|---|----------------------------------------------|
| Species | : | Rabbit                                       |
| Method  | : | OECD Test Guideline 405                      |
| Result  | : | Irritation to eyes, reversing within 21 days |

### **Pyridoxine hydrochloride:**

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

### **Colecalciferol:**

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

### **Starch:**

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

### **3,7-Dimethyl 2,6-octadienal:**

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

|            |   |                                                         |
|------------|---|---------------------------------------------------------|
| Assessment | : | Probability or evidence of skin sensitisation in humans |
|------------|---|---------------------------------------------------------|

### **Dimethyl octadienol:**

|                 |   |                               |
|-----------------|---|-------------------------------|
| Test Type       | : | Local lymph node assay (LLNA) |
| Exposure routes | : | Skin contact                  |
| Species         | : | Mouse                         |
| Method          | : | OECD Test Guideline 429       |
| Result          | : | positive                      |

## Betaine / Multivitamin Formulation

|         |                |                |                                 |
|---------|----------------|----------------|---------------------------------|
| Version | Revision Date: | SDS Number:    | Date of last issue: 28.03.2025  |
| 3.0     | 14.04.2025     | 11513552-00004 | Date of first issue: 24.02.2025 |

---

Remarks : The test was conducted according to guideline

Assessment : Probability or evidence of low to moderate skin sensitisation rate in humans

### **(dl)-a-Tocopheryl acetate:**

Test Type : Draize Test  
Exposure routes : Skin contact  
Species : Humans  
Result : negative

### **Betaine hydrochloride:**

Test Type : Local lymph node assay (LLNA)  
Exposure routes : Skin contact  
Species : Mouse  
Method : OECD Test Guideline 429  
Result : negative  
Remarks : The test was conducted according to guideline

### **Benzyl alcohol:**

Test Type : Human repeat insult patch test (HRIPT)  
Exposure routes : Skin contact  
Species : Humans  
Result : positive

Assessment : Probability or evidence of low to moderate skin sensitisation rate in humans

### **Pyridoxine hydrochloride:**

Test Type : Maximisation Test  
Exposure routes : Skin contact  
Species : Guinea pig  
Method : OECD Test Guideline 406  
Result : negative

### **Colecalciferol:**

Test Type : Maurer optimisation test  
Exposure routes : Skin contact  
Species : Guinea pig  
Result : negative

### **Germ cell mutagenicity**

Not classified based on available information.

### **Components:**

#### **Starch:**

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)  
Result: negative

## Betaine / Multivitamin Formulation

|         |                |                |                                 |
|---------|----------------|----------------|---------------------------------|
| Version | Revision Date: | SDS Number:    | Date of last issue: 28.03.2025  |
| 3.0     | 14.04.2025     | 11513552-00004 | Date of first issue: 24.02.2025 |

---

### 3,7-Dimethyl 2,6-octadienal:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)  
Result: negative

Test Type: In vitro mammalian cell gene mutation test  
Method: OECD Test Guideline 476  
Result: negative

Test Type: Chromosome aberration test in vitro  
Result: negative

Test Type: In vitro sister chromatid exchange assay in mammalian cells  
Result: positive

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)  
Species: Mouse  
Application Route: Ingestion  
Result: negative

### Dimethyl octadienol:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)  
Method: OECD Test Guideline 471  
Result: negative  
Remarks: The test was conducted equivalent or similar to guideline

Test Type: In vitro mammalian cell gene mutation test  
Method: OECD Test Guideline 476  
Result: negative  
Remarks: The test was conducted equivalent or similar to guideline

Test Type: Chromosome aberration test in vitro  
Method: OECD Test Guideline 473  
Result: negative  
Remarks: The test was conducted equivalent or similar to guideline

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)  
Species: Mouse  
Application Route: Ingestion  
Method: OECD Test Guideline 474  
Result: negative  
Remarks: The test was conducted according to guideline

### (dl)-a-Tocopheryl acetate:

Genotoxicity in vitro : Test Type: Chromosome aberration test in vitro  
Method: OECD Test Guideline 473  
Result: negative

## Betaine / Multivitamin Formulation

|         |                |                |                                 |
|---------|----------------|----------------|---------------------------------|
| Version | Revision Date: | SDS Number:    | Date of last issue: 28.03.2025  |
| 3.0     | 14.04.2025     | 11513552-00004 | Date of first issue: 24.02.2025 |

---

Test Type: Bacterial reverse mutation assay (AMES)  
Method: OECD Test Guideline 471  
Result: negative

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)  
Species: Mouse  
Application Route: Ingestion  
Result: negative

### **Betaine hydrochloride:**

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)  
Method: Directive 67/548/EEC, Annex, B.13/14  
Result: negative  
Remarks: The test was conducted according to guideline  
Based on data from similar materials

Test Type: In vitro mammalian cell gene mutation test  
Method: OECD Test Guideline 476  
Result: negative  
Remarks: The test was conducted according to guideline  
Based on data from similar materials

Test Type: Chromosome aberration test in vitro  
Method: Directive 67/548/EEC, Annex V, B.10.  
Result: negative  
Remarks: The test was conducted according to guideline  
Based on data from similar materials

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)  
Species: Mouse  
Application Route: Ingestion  
Method: OECD Test Guideline 474  
Result: negative  
Remarks: The test was conducted according to guideline  
Based on data from similar materials

### **Benzyl alcohol:**

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)  
Result: negative

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)  
Species: Mouse  
Application Route: Intraperitoneal injection  
Result: negative

### **Pyridoxine hydrochloride:**

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)  
Result: negative

# SAFETY DATA SHEET

according to the Globally Harmonized System



## Betaine / Multivitamin Formulation

|         |                |                |                                 |
|---------|----------------|----------------|---------------------------------|
| Version | Revision Date: | SDS Number:    | Date of last issue: 28.03.2025  |
| 3.0     | 14.04.2025     | 11513552-00004 | Date of first issue: 24.02.2025 |

### Colecalciferol:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)  
Method: OECD Test Guideline 471  
Result: equivocal

Test Type: In vitro mammalian cell gene mutation test  
Method: OECD Test Guideline 476  
Result: negative

Test Type: Chromosome aberration test in vitro  
Method: OECD Test Guideline 473  
Result: negative

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)  
Species: Rat  
Application Route: Ingestion  
Method: OECD Test Guideline 474  
Result: negative

Test Type: In vivo mammalian alkaline comet assay  
Species: Rat  
Application Route: Ingestion  
Result: positive

Germ cell mutagenicity - Assessment : Weight of evidence does not support classification as a germ cell mutagen.

### Carcinogenicity

Not classified based on available information.

### Components:

#### 3,7-Dimethyl 2,6-octadienal:

Species : Mouse  
Application Route : Ingestion  
Exposure time : 104 - 105 weeks  
Result : negative

#### (dl)-a-Tocopheryl acetate:

Species : Rat  
Application Route : Ingestion  
Exposure time : 104 weeks  
Result : negative

#### Betaine hydrochloride:

Species : Rat  
Application Route : Ingestion  
Exposure time : 104 weeks  
Method : OECD Test Guideline 453  
Result : negative  
Remarks : The test was conducted equivalent or similar to guideline

## Betaine / Multivitamin Formulation

|         |                |                |                                 |
|---------|----------------|----------------|---------------------------------|
| Version | Revision Date: | SDS Number:    | Date of last issue: 28.03.2025  |
| 3.0     | 14.04.2025     | 11513552-00004 | Date of first issue: 24.02.2025 |

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Based on data from similar materials

### **Benzyl alcohol:**

|                   |   |                         |
|-------------------|---|-------------------------|
| Species           | : | Mouse                   |
| Application Route | : | Ingestion               |
| Exposure time     | : | 103 weeks               |
| Method            | : | OECD Test Guideline 451 |
| Result            | : | negative                |

### **Reproductive toxicity**

Not classified based on available information.

### **Components:**

#### **3,7-Dimethyl 2,6-octadienal:**

|                      |   |                                                       |
|----------------------|---|-------------------------------------------------------|
| Effects on fertility | : | Test Type: One-generation reproduction toxicity study |
|                      |   | Species: Rat                                          |
|                      |   | Application Route: Ingestion                          |
|                      |   | Method: OECD Test Guideline 443                       |
|                      |   | Result: negative                                      |

|                               |   |                                                       |
|-------------------------------|---|-------------------------------------------------------|
| Effects on foetal development | : | Test Type: One-generation reproduction toxicity study |
|                               |   | Species: Rat                                          |
|                               |   | Application Route: Ingestion                          |
|                               |   | Method: OECD Test Guideline 443                       |
|                               |   | Result: negative                                      |

#### **Dimethyl octadienol:**

|                               |   |                                      |
|-------------------------------|---|--------------------------------------|
| Effects on foetal development | : | Test Type: Embryo-foetal development |
|                               |   | Species: Rat                         |
|                               |   | Application Route: Ingestion         |
|                               |   | Result: negative                     |
|                               |   | Remarks: No test guideline followed  |

#### **(dl)-a-Tocopheryl acetate:**

|                      |   |                                                               |
|----------------------|---|---------------------------------------------------------------|
| Effects on fertility | : | Test Type: Reproduction/Developmental toxicity screening test |
|                      |   | Species: Rat                                                  |
|                      |   | Application Route: Ingestion                                  |
|                      |   | Result: negative                                              |

|                               |   |                                      |
|-------------------------------|---|--------------------------------------|
| Effects on foetal development | : | Test Type: Embryo-foetal development |
|                               |   | Species: Rabbit                      |
|                               |   | Application Route: Ingestion         |
|                               |   | Result: negative                     |

### **Benzyl alcohol:**

|                      |   |                                                  |
|----------------------|---|--------------------------------------------------|
| Effects on fertility | : | Test Type: Fertility/early embryonic development |
|                      |   | Species: Rat                                     |
|                      |   | Application Route: Ingestion                     |

## Betaine / Multivitamin Formulation

|         |                |                |                                 |
|---------|----------------|----------------|---------------------------------|
| Version | Revision Date: | SDS Number:    | Date of last issue: 28.03.2025  |
| 3.0     | 14.04.2025     | 11513552-00004 | Date of first issue: 24.02.2025 |

---

Result: negative  
Remarks: Based on data from similar materials

Effects on foetal development : Test Type: Embryo-foetal development  
Species: Mouse  
Application Route: Ingestion  
Result: negative

### **Pyridoxine hydrochloride:**

Effects on foetal development : Test Type: Embryo-foetal development  
Species: Rat  
Application Route: Ingestion  
Result: negative

### **STOT - single exposure**

Not classified based on available information.

### **STOT - repeated exposure**

Not classified based on available information.

### **Components:**

#### **Colecalciferol:**

Exposure routes : Ingestion  
Target Organs : Kidney, Blood, Bone  
Assessment : Shown to produce significant health effects in animals at concentrations of 10 mg/kg bw or less.

### **Repeated dose toxicity**

### **Components:**

#### **Starch:**

Species : Rat  
NOAEL :  $\geq 2,000$  mg/kg  
Application Route : Skin contact  
Exposure time : 28 Days  
Method : OECD Test Guideline 410

#### **3,7-Dimethyl 2,6-octadienal:**

Species : Rat, female  
LOAEL : 335 mg/kg  
Application Route : Ingestion  
Exposure time : 14 Weeks

#### **Dimethyl octadienol:**

Species : Rat, male  
NOAEL :  $\geq 497.9$  mg/kg  
Application Route : Ingestion  
Exposure time : 96 Days  
Method : OECD Test Guideline 408

# SAFETY DATA SHEET

according to the Globally Harmonized System



## Betaine / Multivitamin Formulation

|         |                |                |                                 |
|---------|----------------|----------------|---------------------------------|
| Version | Revision Date: | SDS Number:    | Date of last issue: 28.03.2025  |
| 3.0     | 14.04.2025     | 11513552-00004 | Date of first issue: 24.02.2025 |

Remarks : The test was conducted according to guideline

Species : Rat

NOAEL : 250 mg/kg

Application Route : Skin contact

Exposure time : 91 Days

Method : OECD Test Guideline 411

Remarks : The test was conducted equivalent or similar to guideline

### (dl)-a-Tocopheryl acetate:

Species : Rat

NOAEL : 500 mg/kg

Application Route : Ingestion

Exposure time : 90 Days

### Betaine hydrochloride:

Species : Rat

LOAEL : > 100 mg/kg

Application Route : Ingestion

Exposure time : 90 Days

Method : OECD Test Guideline 408

Remarks : The test was conducted according to guideline  
Based on data from similar materials

### Benzyl alcohol:

Species : Rat

NOAEL : 1.072 mg/l

Application Route : inhalation (dust/mist/fume)

Exposure time : 28 Days

Method : OECD Test Guideline 412

### Colecalciferol:

Species : Rat

NOAEL : 0.06 mg/kg

LOAEL : 0.3 mg/kg

Application Route : Ingestion

Exposure time : 90 Days

Method : OECD Test Guideline 408

### Aspiration toxicity

Not classified based on available information.

## 12. ECOLOGICAL INFORMATION

### Ecotoxicity

#### Components:

#### 3,7-Dimethyl 2,6-octadienal:

Toxicity to fish : LC50 (Leuciscus idus (Golden orfe)): 6.78 mg/l

## Betaine / Multivitamin Formulation

|         |                |                |                                 |
|---------|----------------|----------------|---------------------------------|
| Version | Revision Date: | SDS Number:    | Date of last issue: 28.03.2025  |
| 3.0     | 14.04.2025     | 11513552-00004 | Date of first issue: 24.02.2025 |

---

Exposure time: 96 h  
Method: DIN 38412

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 6.8 mg/l  
Exposure time: 48 h

Toxicity to algae/aquatic plants : ErC50 ( Desmodesmus subspicatus (green algae)): 103.8 mg/l  
Exposure time: 72 h

EC10 ( Desmodesmus subspicatus (green algae)): 3 mg/l  
Exposure time: 72 h

Toxicity to microorganisms : EC50 (activated sludge): 160 mg/l  
Exposure time: 30 min  
Method: OECD Test Guideline 209

### Dimethyl octadienol:

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): 27.8 mg/l  
Exposure time: 96 h  
Method: OECD Test Guideline 203  
Remarks: The test was conducted according to guideline

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 59 mg/l  
Exposure time: 48 h  
Method: OECD Test Guideline 202  
Remarks: The test was conducted according to guideline

Toxicity to algae/aquatic plants : ErC50 ( Desmodesmus subspicatus (green algae)): 156.7 mg/l  
Exposure time: 96 h

EC10 ( Desmodesmus subspicatus (green algae)): 54.3 mg/l  
Exposure time: 96 h

Toxicity to microorganisms : EC10 (activated sludge): > 100 mg/l  
Exposure time: 3 h  
Method: OECD Test Guideline 209  
Remarks: The test was conducted according to guideline

### (dl)-a-Tocopheryl acetate:

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): > 100 mg/l  
Exposure time: 96 h  
Method: OECD Test Guideline 203

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): > 100 mg/l  
Exposure time: 48 h  
Method: OECD Test Guideline 202

Toxicity to algae/aquatic plants : ErC50 ( Pseudokirchneriella subcapitata (green algae)): > 100 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201

## Betaine / Multivitamin Formulation

|         |                |                |                                 |
|---------|----------------|----------------|---------------------------------|
| Version | Revision Date: | SDS Number:    | Date of last issue: 28.03.2025  |
| 3.0     | 14.04.2025     | 11513552-00004 | Date of first issue: 24.02.2025 |

---

NOEC ( *Pseudokirchneriella subcapitata* (green algae)): >= 100 mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

Toxicity to microorganisms : EC50: > 927 mg/l  
Exposure time: 30 min  
Method: ISO 8192

Toxicity to fish (Chronic toxicity) : NOEC: 100 mg/l  
Exposure time: 28 d  
Species: *Oncorhynchus mykiss* (rainbow trout)

### **Betaine hydrochloride:**

Toxicity to daphnia and other aquatic invertebrates : EC50 (*Daphnia magna* (Water flea)): > 100 mg/l  
Exposure time: 48 h  
Method: OECD Test Guideline 202  
Remarks: The test was conducted according to guideline  
Based on data from similar materials

Toxicity to algae/aquatic plants : ErC50 ( *Desmodesmus subspicatus* (green algae)): > 100 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201  
Remarks: The test was conducted according to guideline  
Based on data from similar materials

EC10 ( *Desmodesmus subspicatus* (green algae)): > 1 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201  
Remarks: The test was conducted according to guideline  
Based on data from similar materials

### **Benzyl alcohol:**

Toxicity to fish : LC50 (*Pimephales promelas* (fathead minnow)): 460 mg/l  
Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates : EC50 (*Daphnia magna* (Water flea)): 230 mg/l  
Exposure time: 48 h  
Method: OECD Test Guideline 202

Toxicity to algae/aquatic plants : EC50 ( *Pseudokirchneriella subcapitata* (green algae)): 770 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201

NOEC ( *Pseudokirchneriella subcapitata* (green algae)): 310 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201

Toxicity to daphnia and other : NOEC: 51 mg/l

## Betaine / Multivitamin Formulation

|         |                |                |                                 |
|---------|----------------|----------------|---------------------------------|
| Version | Revision Date: | SDS Number:    | Date of last issue: 28.03.2025  |
| 3.0     | 14.04.2025     | 11513552-00004 | Date of first issue: 24.02.2025 |

---

aquatic invertebrates (Chronic toxicity)

Exposure time: 21 d  
Species: *Daphnia magna* (Water flea)  
Method: OECD Test Guideline 211

### **Pyridoxine hydrochloride:**

Toxicity to fish : LC50 (*Oncorhynchus mykiss* (rainbow trout)): > 100 mg/l  
Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates : EC50 (*Daphnia magna* (Water flea)): > 100 mg/l  
Exposure time: 48 h

### **Colecalciferol:**

Toxicity to fish : LL50 (*Danio rerio* (zebra fish)): > 100 mg/l  
Exposure time: 96 h  
Method: OECD Test Guideline 203

Toxicity to daphnia and other aquatic invertebrates : EL50 (*Daphnia magna* (Water flea)): > 100 mg/l  
Exposure time: 48 h  
Method: OECD Test Guideline 202

Toxicity to algae/aquatic plants : EL50 (*Scenedesmus capricornutum* (fresh water algae)): > 100 mg/l  
Exposure time: 96 h  
Method: OECD Test Guideline 201

## **Persistence and degradability**

### **Components:**

#### **3,7-Dimethyl 2,6-octadienal:**

Biodegradability : Result: Readily biodegradable.  
Biodegradation: > 90 %  
Exposure time: 28 d  
Method: Directive 67/548/EEC Annex V, C.4.D.

#### **Dimethyl octadienol:**

Biodegradability : Result: Readily biodegradable.  
Biodegradation: 64.2 %  
Exposure time: 28 d  
Method: OECD Test Guideline 301D  
Remarks: The test was conducted according to guideline

#### **(dl)-a-Tocopheryl acetate:**

Biodegradability : Result: Not readily biodegradable.  
Biodegradation: 21.7 - 31 %  
Exposure time: 28 d  
Method: OECD Test Guideline 301C

#### **Benzyl alcohol:**

Biodegradability : Result: Readily biodegradable.

# SAFETY DATA SHEET

according to the Globally Harmonized System



## Betaine / Multivitamin Formulation

|         |                |                |                                 |
|---------|----------------|----------------|---------------------------------|
| Version | Revision Date: | SDS Number:    | Date of last issue: 28.03.2025  |
| 3.0     | 14.04.2025     | 11513552-00004 | Date of first issue: 24.02.2025 |

Biodegradation: 92 - 96 %  
Exposure time: 14 d

### Pyridoxine hydrochloride:

Biodegradability : Result: Readily biodegradable.  
Biodegradation: 94 %  
Exposure time: 28 d  
Method: OECD Test Guideline 301E

### Colecalciferol:

Biodegradability : Result: Not readily biodegradable.  
Biodegradation: <= 7 %  
Exposure time: 28 d  
Method: OECD Test Guideline 301C

### Bioaccumulative potential

#### Components:

#### 3,7-Dimethyl 2,6-octadienal:

Partition coefficient: n-octanol/water : log Pow: 2.76

#### Dimethyl octadienol:

Partition coefficient: n-octanol/water : log Pow: 2.84  
Method: OECD Test Guideline 107  
Remarks: The test was conducted equivalent or similar to guideline

#### Betaine hydrochloride:

Partition coefficient: n-octanol/water : log Pow: -4.93  
Remarks: Calculation

#### Benzyl alcohol:

Partition coefficient: n-octanol/water : log Pow: 1.05

#### Pyridoxine hydrochloride:

Partition coefficient: n-octanol/water : log Pow: 4.32

#### Colecalciferol:

Partition coefficient: n-octanol/water : log Pow: > 6.2  
Method: OECD Test Guideline 107

#### Mobility in soil

No data available

## Betaine / Multivitamin Formulation

|         |                |                |                                 |
|---------|----------------|----------------|---------------------------------|
| Version | Revision Date: | SDS Number:    | Date of last issue: 28.03.2025  |
| 3.0     | 14.04.2025     | 11513552-00004 | Date of first issue: 24.02.2025 |

### Other adverse effects

No data available

## 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. |

## 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 IMO instruments

Not applicable for product as supplied.

### Special precautions for user

Not applicable

## 15. REGULATORY INFORMATION

### Safety, health and environmental regulations/legislation specific for the substance or mixture

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

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

## 16. OTHER INFORMATION

Revision Date : 14.04.2025

### 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.

# SAFETY DATA SHEET

according to the Globally Harmonized System



## Betaine / Multivitamin Formulation

|         |                |                |                                 |
|---------|----------------|----------------|---------------------------------|
| Version | Revision Date: | SDS Number:    | Date of last issue: 28.03.2025  |
| 3.0     | 14.04.2025     | 11513552-00004 | Date of first issue: 24.02.2025 |

Date format : dd.mm.yyyy

### Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)

ACGIH / TWA : 8-hour, 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; 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.

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