

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



## Flugestone Acetate Formulation

|         |                |                |                                 |
|---------|----------------|----------------|---------------------------------|
| Version | Revision Date: | SDS Number:    | Date of last issue: 04.12.2024  |
| 5.0     | 14.04.2025     | 10823318-00008 | Date of first issue: 28.07.2022 |

### SECTION 1: Identification of the substance/mixture and of the company/undertaking

#### 1.1 Product identifier

Trade name : Flugestone Acetate Formulation

#### 1.2 Relevant identified uses of the substance or mixture and uses advised against

Use of the Sub-  
stance/Mixture : Veterinary product

Recommended restrictions  
on use : Not applicable

#### 1.3 Details of the supplier of the safety data sheet

Company : MSD  
Drynam Road  
K67 P263 Dublin, Ireland

Telephone : +1-908-740-4000

E-mail address of person  
responsible for the SDS : EHSDATASTEWARD@msd.com

#### 1.4 Emergency telephone number

+1-908-423-6000

### SECTION 2: Hazards identification

#### 2.1 Classification of the substance or mixture

##### Classification (REGULATION (EC) No 1272/2008)

|                                                |                                                             |
|------------------------------------------------|-------------------------------------------------------------|
| Reproductive toxicity, Category 1B             | H360FD: May damage fertility. May damage the unborn child.  |
| Long-term (chronic) aquatic hazard, Category 1 | H410: Very toxic to aquatic life with long lasting effects. |

#### 2.2 Label elements

##### Labelling (REGULATION (EC) No 1272/2008)

Hazard pictograms :



Signal word : Danger

Hazard statements : H360FD May damage fertility. May damage the unborn

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H410 child.  
Very toxic to aquatic life with long lasting effects.

### Precautionary statements : Prevention:

P201 Obtain special instructions before use.  
P273 Avoid release to the environment.  
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

### Response:

P308 + P313 IF exposed or concerned: Get medical advice/ attention.  
P391 Collect spillage.

### Storage:

P405 Store locked up.

### Hazardous components which must be listed on the label:

flugestone 17-acetate

### 2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

Ecological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Toxicological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

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

## SECTION 3: Composition/information on ingredients

### 3.2 Mixtures

#### Components

| Chemical name         | CAS-No.<br>EC-No.<br>Index-No.<br>Registration number | Classification                                                                       | Concentration<br>(% w/w) |
|-----------------------|-------------------------------------------------------|--------------------------------------------------------------------------------------|--------------------------|
| flugestone 17-acetate | 2529-45-5<br>219-776-9                                | Repr. 1B; H360FD<br>STOT RE 2; H373<br>(Adrenal gland)<br>Aquatic Chronic 1;<br>H410 | >= 2.5 - < 10            |

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|  |  |                                                 |  |
|--|--|-------------------------------------------------|--|
|  |  | M-Factor (Chronic aquatic toxicity):<br>100,000 |  |
|--|--|-------------------------------------------------|--|

For explanation of abbreviations see section 16.

### SECTION 4: First aid measures

#### 4.1 Description of 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.                                                                |
| 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).                                           |
| 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     | : 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.<br>Rinse mouth thoroughly with water.                                                                                                                 |

#### 4.2 Most important symptoms and effects, both acute and delayed

- |       |                                                                                                                                                                                                       |
|-------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Risks | : Contact with dust can cause mechanical irritation or drying of the skin.<br>Dust contact with the eyes can lead to mechanical irritation.<br><br>May damage fertility. May damage the unborn child. |
|-------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

#### 4.3 Indication of any immediate medical attention and special treatment needed

- |           |                                           |
|-----------|-------------------------------------------|
| Treatment | : Treat symptomatically and supportively. |
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### SECTION 5: Firefighting measures

#### 5.1 Extinguishing media

Suitable extinguishing media : Water spray  
Alcohol-resistant foam  
Carbon dioxide (CO<sub>2</sub>)  
Dry chemical

Unsuitable extinguishing media : None known.

#### 5.2 Special hazards arising from the substance or mixture

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

#### 5.3 Advice for firefighters

Special protective equipment for firefighters : In the event of fire, wear self-contained breathing apparatus.  
Use personal protective equipment.

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.

### SECTION 6: Accidental release measures

#### 6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions : Use personal protective equipment.  
Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

#### 6.2 Environmental precautions

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.

#### 6.3 Methods and material for containment and cleaning up

Methods for cleaning up : Sweep up or vacuum up spillage and collect in suitable container for disposal.

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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.

### 6.4 Reference to other sections

See sections: 7, 8, 11, 12 and 13.

## SECTION 7: Handling and storage

### 7.1 Precautions for safe handling

- |                         |   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
|-------------------------|---|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Technical measures      | : | Static electricity may accumulate and ignite suspended dust causing an explosion.<br>Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.                                                                                                                                                                                                                                                                                                                                                                            |
| Local/Total ventilation | : | If sufficient ventilation is unavailable, use with local exhaust ventilation.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| Advice on safe handling | : | Do not get on skin or clothing.<br>Do not breathe dust.<br>Do not swallow.<br>Avoid contact with eyes.<br>Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment<br>Keep container tightly closed.<br>Minimize dust generation and accumulation.<br>Keep container closed when not in use.<br>Keep away from heat and sources of ignition.<br>Take precautionary measures against static discharges.<br>Take care to prevent spills, waste and minimize release to the environment. |
| Hygiene measures        | : | If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. Wash contaminated clothing before re-use.<br>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.                                                            |

### 7.2 Conditions for safe storage, including any incompatibilities

- |                                               |   |                                                                                                                                           |
|-----------------------------------------------|---|-------------------------------------------------------------------------------------------------------------------------------------------|
| Requirements for storage areas and containers | : | Keep in properly labelled containers. Store locked up. Keep tightly closed. Store in accordance with the particular national regulations. |
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Advice on common storage : Do not store with the following product types:  
Strong oxidizing agents  
Self-reactive substances and mixtures  
Organic peroxides  
Explosives  
Gases

### 7.3 Specific end use(s)

Specific use(s) : No data available

## SECTION 8: Exposure controls/personal protection

### 8.1 Control parameters

#### Occupational Exposure Limits

|                    |                                                                                                             |
|--------------------|-------------------------------------------------------------------------------------------------------------|
| dusts non-specific | 4 mg/m <sup>3</sup><br>Value type (Form of exposure): OELV - 8 hrs (TWA) (Respirable dust)<br>Basis: IE OEL |
|                    | 10 mg/m <sup>3</sup><br>Value type (Form of exposure): OELV - 8 hrs (TWA) (inhalable dust)<br>Basis: IE OEL |

| Components            | CAS-No.   | Value type (Form of exposure) | Control parameters            | Basis    |
|-----------------------|-----------|-------------------------------|-------------------------------|----------|
| flugestone 17-acetate | 2529-45-5 | TWA                           | 0.2 µg/m <sup>3</sup> (OEB 5) | Internal |
|                       |           | Wipe limit                    | 2 µg /100 cm <sup>2</sup>     | Internal |

### 8.2 Exposure controls

#### 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 established, maintain airborne levels as low as reasonably achievable.

Use closed processing systems or containment technologies to control at source (e.g., glove boxes/isolators) and to prevent leakage of compounds into the workplace.

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

No open handling permitted.

Totally enclosed processes and materials transport systems are required.

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Operations require the use of appropriate containment technology designed to prevent leakage of compounds into the workplace.

### Personal protective equipment

|                          |   |                                                                                                                                                                                                                                                                                                                |
|--------------------------|---|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Eye/face protection      | : | Wear safety glasses with side shields or goggles.<br>If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles.<br>Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols. |
| Hand protection          | : |                                                                                                                                                                                                                                                                                                                |
| Material                 | : | Chemical-resistant gloves                                                                                                                                                                                                                                                                                      |
| Remarks                  | : | Consider double gloving.                                                                                                                                                                                                                                                                                       |
| Skin and body protection | : | Work uniform or laboratory coat.<br>Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces.<br>Use appropriate degowning techniques to remove potentially contaminated clothing.                    |
| Respiratory protection   | : | If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.<br>Equipment should conform to I.S. EN 143                                                                                                |
| Filter type              | : | Particulates type (P)                                                                                                                                                                                                                                                                                          |

## SECTION 9: Physical and chemical properties

### 9.1 Information on basic physical and chemical properties

|                                                  |   |                                                                                 |
|--------------------------------------------------|---|---------------------------------------------------------------------------------|
| Physical state                                   | : | powder                                                                          |
| Colour                                           | : | white                                                                           |
| Odour                                            | : | odourless                                                                       |
| Odour Threshold                                  | : | No data available                                                               |
| Melting point/freezing point                     | : | No data available                                                               |
| Initial boiling point and boiling range          | : | No data available                                                               |
| 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                    | : | No data available                                                               |

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flammability limit

Flash point : Not applicable

Auto-ignition temperature : No data available

Decomposition temperature : No data available

pH : No data available

Viscosity

Viscosity, kinematic : Not applicable

Solubility(ies)

Water solubility : partly miscible

Partition coefficient: n-octanol/water : Not applicable

Vapour pressure : Not applicable

Relative density : No data available

Density : No data available

Relative vapour density : Not applicable

Particle characteristics

Particle size : No data available

### 9.2 Other information

Explosives : Not explosive

Oxidizing properties : The substance or mixture is not classified as oxidizing.

Evaporation rate : Not applicable

Molecular weight : No data available

---

## SECTION 10: Stability and reactivity

### 10.1 Reactivity

Not classified as a reactivity hazard.

### 10.2 Chemical stability

Stable under normal conditions.

### 10.3 Possibility of hazardous reactions

Hazardous reactions : May form explosive dust-air mixture during processing, han-



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dling or other means.  
Can react with strong oxidizing agents.

### 10.4 Conditions to avoid

Conditions to avoid : Heat, flames and sparks.  
Avoid dust formation.

### 10.5 Incompatible materials

Materials to avoid : Oxidizing agents

### 10.6 Hazardous decomposition products

No hazardous decomposition products are known.

---

## SECTION 11: Toxicological information

### 11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

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

#### Acute toxicity

|| Not classified based on available information.

#### Components:

##### flugestone 17-acetate:

|| Acute oral toxicity : Remarks: No data available

#### Skin corrosion/irritation

|| Not classified based on available information.

#### Components:

##### flugestone 17-acetate:

|| Remarks : No data available

#### Serious eye damage/eye irritation

|| Not classified based on available information.

#### Components:

##### flugestone 17-acetate:

|| Remarks : No data available  
Mild eye irritation

#### Respiratory or skin sensitisation

##### Skin sensitisation

|| Not classified based on available information.

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### Respiratory sensitisation

Not classified based on available information.

#### Components:

##### flugestone 17-acetate:

Remarks : No data available

### Germ cell mutagenicity

Not classified based on available information.

#### Components:

##### flugestone 17-acetate:

Genotoxicity in vitro : Test Type: Microbial mutagenesis assay (Ames test)  
Result: negative

Test Type: Mouse Lymphoma  
Result: negative

Test Type: Chromosomal aberration  
Test system: Human lymphocytes  
Result: negative

Genotoxicity in vivo : Remarks: No data available

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

### Carcinogenicity

Not classified based on available information.

#### Components:

##### flugestone 17-acetate:

Remarks : No data available

Carcinogenicity - Assessment : No data available

### Reproductive toxicity

May damage fertility. May damage the unborn child.

#### Components:

##### flugestone 17-acetate:

Effects on fertility : Test Type: One-generation reproduction toxicity study  
Species: Rabbit  
Application Route: Oral  
General Toxicity - Parent: NOAEL: 0.003 mg/kg body weight  
Fertility: NOAEL: 0.003 mg/kg body weight

Effects on foetal develop- : Test Type: Embryo-foetal development

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Species: Rat  
Application Route: Oral  
General Toxicity Maternal: NOAEL: 0.1 mg/kg body weight  
Teratogenicity: NOAEL: 10 mg/kg body weight  
Embryo-foetal toxicity: NOAEL: 10 mg/kg body weight

Test Type: Embryo-foetal development  
Species: Rabbit  
Application Route: Oral  
General Toxicity Maternal: NOAEL: 0.01 mg/kg body weight  
Embryo-foetal toxicity: NOAEL: 0.04 mg/kg body weight

Reproductive toxicity - Assessment : Clear evidence of adverse effects on sexual function and fertility, based on animal experiments., Clear evidence of adverse effects on development, based on animal experiments.

### STOT - single exposure

Not classified based on available information.

### STOT - repeated exposure

Not classified based on available information.

### Components:

#### flugestone 17-acetate:

Exposure routes : Oral  
Target Organs : Adrenal gland  
Assessment : Shown to produce significant health effects in animals at concentrations of >10 to 100 mg/kg bw.

### Repeated dose toxicity

### Components:

#### flugestone 17-acetate:

Species : Rat  
NOAEL : 0.2 mg/kg  
Application Route : Oral  
Exposure time : 90 d  
Number of exposures : daily  
Target Organs : Adrenal gland

### Aspiration toxicity

Not classified based on available information.

## 11.2 Information on other hazards

### Endocrine disrupting properties

Not classified based on available information.

### Product:

Assessment : The substance/mixture does not contain components considered to have endocrine disrupting properties according to

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REACH Article 57(f) or Commission Delegated regulation  
(EU) 2017/2100 or Commission Regulation (EU) 2018/605 at  
levels of 0.1% or higher.

### Experience with human exposure

#### Components:

**flugestone 17-acetate:**

|| General Information : May cause adverse reproductive effects.

## SECTION 12: Ecological information

### 12.1 Toxicity

#### Components:

**flugestone 17-acetate:**

|| Toxicity to fish (Chronic toxicity) : NOEC: < 0.0004 µg/l  
Exposure time: 32 d  
Species: Zebrafish  
Method: OECD Test Guideline 210  
Remarks: Based on data from similar materials

|| M-Factor (Chronic aquatic toxicity) : 100,000

### 12.2 Persistence and degradability

No data available

### 12.3 Bioaccumulative potential

No data available

### 12.4 Mobility in soil

No data available

### 12.5 Results of PBT and vPvB assessment

#### Product:

Assessment : This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

### 12.6 Endocrine disrupting properties

#### Product:

Assessment : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

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### 12.7 Other adverse effects

No data available

## SECTION 13: Disposal considerations

### 13.1 Waste treatment methods

|                        |                                                                                                                                                                                                                                                                                                                      |
|------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Product                | : Dispose of in accordance with local regulations.<br>According to the European Waste Catalogue, Waste Codes are not product specific, but application specific.<br>Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities.<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.                                                                                                                                                        |

## SECTION 14: Transport information

### 14.1 UN number or ID number

|      |           |
|------|-----------|
| ADN  | : UN 3077 |
| ADR  | : UN 3077 |
| RID  | : UN 3077 |
| IMDG | : UN 3077 |
| IATA | : UN 3077 |

### 14.2 UN proper shipping name

|      |                                                                                 |
|------|---------------------------------------------------------------------------------|
| ADN  | : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.<br>(flugestone 17-acetate) |
| ADR  | : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.<br>(flugestone 17-acetate) |
| RID  | : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.<br>(flugestone 17-acetate) |
| IMDG | : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.<br>(flugestone 17-acetate) |
| IATA | : Environmentally hazardous substance, solid, n.o.s.<br>(flugestone 17-acetate) |

### 14.3 Transport hazard class(es)

|     | Class | Subsidiary risks |
|-----|-------|------------------|
| ADN | : 9   |                  |

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|             |   |   |
|-------------|---|---|
| <b>ADR</b>  | : | 9 |
| <b>RID</b>  | : | 9 |
| <b>IMDG</b> | : | 9 |
| <b>IATA</b> | : | 9 |

### 14.4 Packing group

|                              |       |
|------------------------------|-------|
| <b>ADN</b>                   |       |
| Packing group                | : III |
| Classification Code          | : M7  |
| Hazard Identification Number | : 90  |
| Labels                       | : 9   |

|                              |       |
|------------------------------|-------|
| <b>ADR</b>                   |       |
| Packing group                | : III |
| Classification Code          | : M7  |
| Hazard Identification Number | : 90  |
| Labels                       | : 9   |
| Tunnel restriction code      | : (-) |

|                              |       |
|------------------------------|-------|
| <b>RID</b>                   |       |
| Packing group                | : III |
| Classification Code          | : M7  |
| Hazard Identification Number | : 90  |
| Labels                       | : 9   |

|               |            |
|---------------|------------|
| <b>IMDG</b>   |            |
| Packing group | : III      |
| Labels        | : 9        |
| EmS Code      | : F-A, S-F |

|                                      |                 |
|--------------------------------------|-----------------|
| <b>IATA (Cargo)</b>                  |                 |
| Packing instruction (cargo aircraft) | : 956           |
| Packing instruction (LQ)             | : Y956          |
| Packing group                        | : III           |
| Labels                               | : Miscellaneous |

|                                          |                 |
|------------------------------------------|-----------------|
| <b>IATA (Passenger)</b>                  |                 |
| Packing instruction (passenger aircraft) | : 956           |
| Packing instruction (LQ)                 | : Y956          |
| Packing group                            | : III           |
| Labels                                   | : Miscellaneous |

### 14.5 Environmental hazards

|                           |       |
|---------------------------|-------|
| <b>ADN</b>                |       |
| Environmentally hazardous | : yes |

|                           |       |
|---------------------------|-------|
| <b>ADR</b>                |       |
| Environmentally hazardous | : yes |

|                           |       |
|---------------------------|-------|
| <b>RID</b>                |       |
| Environmentally hazardous | : yes |

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### IMDG

Marine pollutant : yes

### IATA (Passenger)

Environmentally hazardous : yes

### IATA (Cargo)

Environmentally hazardous : yes

### 14.6 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.

### 14.7 Maritime transport in bulk according to IMO instruments

Remarks : Not applicable for product as supplied.

## SECTION 15: Regulatory information

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

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII) : Not applicable

REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59). : Not applicable

Regulation (EU) No 2024/590 on substances that deplete the ozone layer : Not applicable

Regulation (EU) 2019/1021 on persistent organic pollutants (recast) : Not applicable

Regulation (EU) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals : Not applicable

REACH - List of substances subject to authorisation (Annex XIV) : Not applicable

Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances.

|    |                          |                     |                     |
|----|--------------------------|---------------------|---------------------|
| E1 | ENVIRONMENTAL<br>HAZARDS | Quantity 1<br>100 t | Quantity 2<br>200 t |
|----|--------------------------|---------------------|---------------------|

### Other regulations:

Take note of Directive 92/85/EEC regarding maternity protection or stricter national regulations, where applicable.

Take note of Directive 94/33/EC on the protection of young people at work or stricter national regulations, where applicable.

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

AICS : not determined

DSL : not determined

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IECSC : not determined

### 15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

## SECTION 16: Other information

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

### Full text of H-Statements

H360FD : May damage fertility. May damage the unborn child.  
H373 : May cause damage to organs through prolonged or repeated exposure if swallowed.  
H410 : Very toxic to aquatic life with long lasting effects.

### Full text of other abbreviations

Aquatic Chronic : Long-term (chronic) aquatic hazard  
Repr. : Reproductive toxicity  
STOT RE : Specific target organ toxicity - repeated exposure  
IE OEL : Ireland. List of Chemical Agents and Carcinogens with Occupational Exposure Limit Values - Code of Practice, Schedule 1 and 2  
IE OEL / OELV - 8 hrs (TWA) : Occupational exposure limit value (8-hour reference period)

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by Road; AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; 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; 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; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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



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tative) 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; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of Very High Concern; TCSI - Taiwan Chemical Substance Inventory; TECI - Thailand Existing Chemicals Inventory; TRGS - Technical Rule for Hazardous Substances; TSCA - Toxic Substances Control Act (United States); UN - United Nations; vPvB - Very Persistent and Very Bioaccumulative

### 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/>

### Classification of the mixture:

|                   |        |
|-------------------|--------|
| Repr. 1B          | H360FD |
| Aquatic Chronic 1 | H410   |

### Classification procedure:

|                    |
|--------------------|
| Calculation method |
| Calculation method |

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

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.

IE / EN