

# SAFETY DATA SHEET

according to the Hazardous Products Regulations



## Flugestone Acetate Formulation

Version 3.1      Revision Date: 09/30/2023      SDS Number: 10821890-00004      Date of last issue: 04/04/2023  
Date of first issue: 07/28/2022

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### SECTION 1. IDENTIFICATION

Product name : Flugestone Acetate Formulation  
Other means of identification : No data available

#### Manufacturer or supplier's details

Company name of supplier : Merck & Co., Inc  
Address : 126 E. Lincoln Avenue  
Rahway, New Jersey U.S.A. 07065  
Telephone : 908-740-4000  
Emergency telephone : 1-908-423-6000  
E-mail address : EHSDATASTEWARD@merck.com

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

Recommended use : Veterinary product  
Restrictions on use : Not applicable


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### SECTION 2. HAZARDS IDENTIFICATION

#### GHS classification in accordance with the Hazardous Products Regulations

Reproductive toxicity : Category 1B  
Specific target organ toxicity : Category 2 (Adrenal gland)  
- repeated exposure (Oral)

#### GHS label elements

Hazard pictograms : 

Signal Word : Danger

Hazard Statements : H360FD May damage fertility. May damage the unborn child.  
H373 May cause damage to organs (Adrenal gland) through prolonged or repeated exposure if swallowed.

Precautionary Statements : **Prevention:**  
P201 Obtain special instructions before use.  
P202 Do not handle until all safety precautions have been read and understood.  
P260 Do not breathe dust.  
P280 Wear protective gloves, protective clothing, eye protection and face protection.

**Response:**  
P308 + P313 IF exposed or concerned: Get medical attention.

**Storage:**  
P405 Store locked up.

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### Disposal:

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

### Other hazards

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

Substance / Mixture : Mixture

### Components

| Chemical name         | Common Name/Synonym | CAS-No.   | Concentration (% w/w) |
|-----------------------|---------------------|-----------|-----------------------|
| flugestone 17-acetate | No data available   | 2529-45-5 | 4                     |

## SECTION 4. FIRST AID MEASURES

General advice : In the case of accident or if you feel unwell, seek medical advice immediately.  
When symptoms persist or in all cases of doubt seek medical advice.

If inhaled : If inhaled, remove to fresh air.  
Get medical attention.

In case of skin contact : In case of contact, immediately flush skin with soap and plenty of water.  
Remove contaminated clothing and shoes.  
Get medical attention.  
Wash clothing before reuse.  
Thoroughly clean shoes before reuse.

In case of eye contact : If in eyes, rinse well with water.  
Get medical attention if irritation develops and persists.

If swallowed : If swallowed, DO NOT induce vomiting.  
Get medical attention.  
Rinse mouth thoroughly with water.

Most important symptoms and effects, both acute and delayed : May damage fertility. May damage the unborn child.  
May cause damage to organs through prolonged or repeated exposure if swallowed.  
Contact with dust can cause mechanical irritation or drying of the skin.  
Dust contact with the eyes can lead to mechanical irritation.

Protection of first-aiders : First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).

Notes to physician : Treat symptomatically and supportively.

## SECTION 5. FIRE-FIGHTING MEASURES

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- Suitable extinguishing media : Water spray  
Alcohol-resistant foam  
Carbon dioxide (CO<sub>2</sub>)  
Dry chemical
- Unsuitable extinguishing media : None known.
- Specific hazards during fire fighting : 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
- 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 fire-fighters : In the event of fire, wear self-contained breathing apparatus.  
Use personal protective equipment.
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### SECTION 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.
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### SECTION 7. HANDLING AND STORAGE

- Technical measures : Static electricity may accumulate and ignite suspended dust causing an explosion.

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- Local/Total ventilation : Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.  
: If sufficient ventilation is unavailable, use with local exhaust ventilation.
- Advice on safe handling : Do not get on skin or clothing.  
: Do not breathe 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  
: Keep container tightly closed.  
: 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 labeled containers.  
: Store locked up.  
: Keep tightly closed.  
: Store in accordance with the particular national regulations.
- Materials to avoid : Do not store with the following product types:  
: Strong oxidizing agents  
: Self-reactive substances and mixtures  
: Organic peroxides  
: Explosives  
: Gases

### SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

#### Ingredients with workplace control parameters

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

- Engineering measures** : 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.  
Operations require the use of appropriate containment technology designed to prevent leakage of compounds into the workplace.

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### Personal protective equipment

- Respiratory protection : If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.
- Filter type : Particulates type
- Hand protection
- Material : Chemical-resistant gloves
- Remarks : Consider double gloving.
- Eye protection : Wear safety glasses with side shields or goggles.  
If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles.  
Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.
- Skin and body protection : Work uniform or laboratory coat.  
Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces.  
Use appropriate degowning techniques to remove potentially contaminated clothing.
- Hygiene measures : If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place.  
When using do not eat, drink or smoke.  
Wash contaminated clothing before re-use.  
The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

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### SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

- Appearance : powder
- Color : white
- Odor : odorless
- Odor 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

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|  |   |   |
|--|---|---|
| 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   |
| Vapor pressure                                   | : | Not applicable  |
| Relative vapor density                           | : | Not applicable  |
| Relative density                                 | : | No data available   |
| Density  | : | No data available   |
| Solubility(ies)<br>Water solubility              | : | partly miscible   |
| Partition coefficient: n-octanol/water           | : | Not applicable  |
| Autoignition 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 size                                    | : | No data available   |

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### SECTION 10. STABILITY AND REACTIVITY

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

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### SECTION 11. TOXICOLOGICAL INFORMATION

#### 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 sensitization

##### Skin sensitization

Not classified based on available information.

##### Respiratory sensitization

Not classified based on available information.

#### Components:

##### flugestone 17-acetate:

Remarks : No data available

#### Germ cell mutagenicity

Not classified based on available information.

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### 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 fetal development : Test Type: Embryo-fetal development  
Species: Rat  
Application Route: Oral  
General Toxicity Maternal: NOAEL: 0.1 mg/kg body weight  
Teratogenicity: NOAEL: 10 mg/kg body weight  
Embryo-fetal toxicity.: NOAEL: 10 mg/kg body weight

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



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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

May cause damage to organs (Adrenal gland) through prolonged or repeated exposure if swallowed.

#### Components:

##### flugestone 17-acetate:

Routes of exposure : 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.

### Experience with human exposure

#### Components:

##### flugestone 17-acetate:

General Information : May cause adverse reproductive effects.

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## SECTION 12. ECOLOGICAL INFORMATION

### Ecotoxicity

#### Components:

##### flugestone 17-acetate:

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

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### Persistence and degradability

No data available

### Bioaccumulative potential

No data available

### Mobility in soil

No data available

### Other adverse effects

No data available

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## SECTION 13. DISPOSAL CONSIDERATIONS

### Disposal methods

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

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## SECTION 14. TRANSPORT INFORMATION

### International Regulations

#### UNRTDG

|                           |   |  |
|---------------------------|---|--|
| UN number                 | : | UN 3077  |
| Proper shipping name      | : | ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,<br>N.O.S.<br>(flugestone 17-acetate) |
| Class                     | : | 9  |
| Packing group             | : | III  |
| Labels                    | : | 9  |
| Environmentally hazardous | : | yes  |

#### IATA-DGR

|  |   |   |
|--|---|---|
| UN/ID No.                                | : | UN 3077   |
| Proper shipping name                     | : | Environmentally hazardous substance, solid, n.o.s.<br>(flugestone 17-acetate) |
| Class                                    | : | 9   |
| Packing group                            | : | III   |
| Labels                                   | : | Miscellaneous   |
| Packing instruction (cargo aircraft)     | : | 956   |
| Packing instruction (passenger aircraft) | : | 956   |
| Environmentally hazardous                | : | yes   |

#### IMDG-Code

|                      |   |  |
|----------------------|---|--|
| UN number            | : | UN 3077  |
| Proper shipping name | : | ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,<br>N.O.S.<br>(flugestone 17-acetate) |

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|                  |   |          |
|------------------|---|----------|
| Class            | : | 9        |
| Packing group    | : | III      |
| Labels           | : | 9        |
| EmS Code         | : | F-A, S-F |
| Marine pollutant | : | yes      |

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

Not applicable for product as supplied.

### Domestic regulation

#### TDG

|                      |   |  |
|----------------------|---|--|
| UN number            | : | UN 3077  |
| Proper shipping name | : | ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,<br>N.O.S.<br>(flugestone 17-acetate) |
| Class                | : | 9  |
| Packing group        | : | III  |
| Labels               | : | 9  |
| ERG Code             | : | 171  |
| Marine pollutant     | : | yes(flugestone 17-acetate)   |

### 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.

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## SECTION 15. REGULATORY INFORMATION

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

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

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## SECTION 16. OTHER INFORMATION

### Full text of other abbreviations

AiIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemi-

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cal 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

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

Revision Date : 09/30/2023  
Date format : mm/dd/yyyy

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.

CA / Z8