

SAFETY DATA SHEET



Flugestone Acetate Formulation

Version 5.0 Revision Date: 14.04.2025 SDS Number: 10821885-00006 Date of last issue: 04.12.2024 Date of first issue: 28.07.2022

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Flugestone Acetate Formulation

Manufacturer or supplier's details

Company name of supplier : MSD
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@msd.com

Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product
Restrictions on use : Not applicable

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification

Reproductive toxicity : Category 1B

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

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/ face protection.

Response:

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

Storage:

P405 Store locked up.

Disposal:

SAFETY DATA SHEET



Flugestone Acetate Formulation

Version 5.0	Revision Date: 14.04.2025	SDS Number: 10821885-00006	Date of last issue: 04.12.2024 Date of first issue: 28.07.2022
----------------	------------------------------	-------------------------------	---

P501 Dispose of contents/ 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	CAS-No.	Concentration (% w/w)
flugestone 17-acetate	2529-45-5	>= 1 - < 5

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	: Contact with dust can cause mechanical irritation or drying of the skin. Dust contact with the eyes can lead to mechanical irritation. May damage fertility. May damage the unborn child. May cause damage to organs through prolonged or repeated exposure if swallowed.
Protection of first-aiders	: First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).
Notes to physician	: Treat symptomatically and supportively.

SECTION 5. FIRE-FIGHTING MEASURES

Suitable extinguishing media	: Water spray Alcohol-resistant foam Carbon dioxide (CO ₂) Dry chemical
Unsuitable extinguishing	: None known.

SAFETY DATA SHEET



Flugestone Acetate Formulation

Version 5.0	Revision Date: 14.04.2025	SDS Number: 10821885-00006	Date of last issue: 04.12.2024 Date of first issue: 28.07.2022
----------------	------------------------------	-------------------------------	---

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

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.

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.

SECTION 7. HANDLING AND STORAGE

Technical measures : Static electricity may accumulate and ignite suspended dust causing an explosion.
Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.

SAFETY DATA SHEET



Flugestone Acetate Formulation

Version 5.0 Revision Date: 14.04.2025 SDS Number: 10821885-00006 Date of last issue: 04.12.2024
Date of first issue: 28.07.2022

Local/Total ventilation	: If sufficient ventilation is unavailable, use with local exhaust ventilation.
Advice on safe handling	: Do not get on skin or clothing. Do not breathe 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.
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.
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/m3 (OEB 5)	Internal
		Wipe limit	2 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
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Flugestone Acetate Formulation

Version 5.0	Revision Date: 14.04.2025	SDS Number: 10821885-00006	Date of last issue: 04.12.2024 Date of first issue: 28.07.2022
----------------	------------------------------	-------------------------------	---

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.

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

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.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	: powder
Color	: white
Odor	: odorless
Odor Threshold	: No data available
pH	: No data available

SAFETY DATA SHEET



Flugestone Acetate Formulation

Version 5.0 Revision Date: 14.04.2025 SDS Number: 10821885-00006 Date of last issue: 04.12.2024
Date of first issue: 28.07.2022

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
Vapor pressure	:	Not applicable
Relative vapor density	:	Not applicable
Relative density	:	No data available
Density	:	No data available
Solubility(ies)		
Water solubility	:	partly miscible
Partition coefficient: n-octanol/water	:	Not applicable
Autoignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity		
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		
Particle size	:	No data available

SECTION 10. STABILITY AND REACTIVITY

Reactivity :

Not classified as a reactivity hazard.

SAFETY DATA SHEET



Flugestone Acetate Formulation

Version 5.0 Revision Date: 14.04.2025 SDS Number: 10821885-00006 Date of last issue: 04.12.2024
Date of first issue: 28.07.2022

Chemical stability	: Stable under normal conditions.
Possibility of hazardous reactions	: May form explosive dust-air mixture during processing, handling or other means. Can react with strong oxidizing agents.
Conditions to avoid	: Heat, flames and sparks. Avoid dust formation.
Incompatible materials	: Oxidizing agents
Hazardous decomposition products	: No hazardous decomposition products are known.

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.

SAFETY DATA SHEET



Flugestone Acetate Formulation

Version 5.0 Revision Date: 14.04.2025 SDS Number: 10821885-00006 Date of last issue: 04.12.2024
Date of first issue: 28.07.2022

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

||| Genotoxicity in vitro : Test Type: Mouse Lymphoma
Result: negative

||| Genotoxicity in vitro : 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

Flugestone Acetate Formulation

Version 5.0	Revision Date: 14.04.2025	SDS Number: 10821885-00006	Date of last issue: 04.12.2024 Date of first issue: 28.07.2022
----------------	------------------------------	-------------------------------	---

		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
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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SAFETY DATA SHEET



Flugestone Acetate Formulation

Version 5.0 Revision Date: 14.04.2025 SDS Number: 10821885-00006 Date of last issue: 04.12.2024 Date of first issue: 28.07.2022

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

Persistence and degradability

No data available

Bioaccumulative potential

No data available

Mobility in soil

No data available

Other adverse effects

No data available

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods

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

SECTION 14. TRANSPORT INFORMATION

International Regulations

UNRTDG

UN number : UN 3077
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.
(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.
(flugestone 17-acetate)
Class : 9
Packing group : III
Labels : Miscellaneous

SAFETY DATA SHEET



Flugestone Acetate Formulation

Version 5.0 Revision Date: 14.04.2025 SDS Number: 10821885-00006 Date of last issue: 04.12.2024
Date of first issue: 28.07.2022

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, N.O.S.
(flugestone 17-acetate)

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

NOM-002-SCT

UN number : UN 3077

Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.
(flugestone 17-acetate)

Class : 9

Packing group : III

Labels : 9

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.

SECTION 15. REGULATORY INFORMATION

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

Federal Law for the control of chemical precursors, essential chemical products and machinery for producing capsules, tablets and pills. : Not applicable

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

AICS : not determined

DSL : not determined

IECSC : not determined

SECTION 16. OTHER INFORMATION

SAFETY DATA SHEET



Flugestone Acetate Formulation

Version 5.0	Revision Date: 14.04.2025	SDS Number: 10821885-00006	Date of last issue: 04.12.2024 Date of first issue: 28.07.2022
----------------	------------------------------	-------------------------------	---

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Full text of other abbreviations

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

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/>

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

The information is considered as correct, but not exhaustive, and will be used only as a guide, which is based in the current knowledge of the substance or mixture, and is applicable to proper safety precautions for the product.

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