

# Flugestone Acetate Formulation

Version Revision Date: SDS Number: Date of last issue: 2024/04/06 6.0 2024/09/28 10821886-00006 Date of first issue: 2022/07/28

#### 1. PRODUCT AND COMPANY IDENTIFICATION

Chemical product name : Flugestone Acetate Formulation

Supplier's company name, address and phone number

Company name of supplier : MSD

Address : Kumagaya, Saitama Prefecture , Xicheng 810 MSD Co., Ltd.

Menuma factory

Telephone : 048-588-8411

E-mail address : EHSDATASTEWARD@msd.com

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

Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product Restrictions on use : Not applicable

#### 2. HAZARDS IDENTIFICATION

GHS classification of chemical product

Reproductive toxicity : Category 1B

Long-term (chronic) aquatic

hazard

Category 1

**GHS** label elements

Hazard pictograms





Signal word : Danger

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

H410 Very toxic to aquatic life with long lasting effects.

Precautionary statements : Prevention:

P201 Obtain special instructions before use.

P202 Do not handle until all safety precautions have been read

and understood.

P273 Avoid release to the environment.

P280 Wear protective gloves/ protective clothing/ eye protec-

tion/ face protection.



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Response:

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

attention.

P391 Collect spillage.

Storage:

P405 Store locked up.

Disposal:

P501 Dispose of contents/ container to an approved waste

disposal plant.

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

Important symptoms and outlines of the emergency assumed

Dust contact with the eyes can lead to mechanical irritation. Contact with dust can cause mechanical irritation or drying of

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)	ENCS No.
flugestone 17-acetate	2529-45-5	>= 2.5 - < 10	-

#### 4. FIRST AID MEASURES

delayed

General advice In the case of accident or if you feel unwell, seek medical ad-

vice 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

May damage fertility. May damage the unborn child. and effects, both acute and

Contact with dust can cause mechanical irritation or drying of

the skin.



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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

Alcohol-resistant foam Carbon dioxide (CO2)

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 prod: :

ucts

Carbon oxides

Specific extinguishing meth-

ods

Use extinguishing measures that are appropriate to local cir-

cumstances 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 emer-

gency procedures

Use personal protective equipment.

Follow safe handling advice (see section 7) and personal pro-

tective 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 con-

tainer 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 surfac-



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es, 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 deter-

mine which regulations are applicable.

Sections 13 and 15 of this SDS provide information regarding

certain local or national requirements.

## 7. HANDLING AND STORAGE

Handling

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.

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 as-

sessment

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. Oxidizing agents

Avoidance of contact

Hygiene measures : If exposure to chemical is likely during typical use, provide eye

flushing systems and safety showers close to the working

place.

When using do not eat, drink or smoke. Wash contaminated clothing before re-use.

The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the

use of administrative controls.

**Storage** 

Conditions for safe storage : Keep in properly labelled containers.

Store locked up. Keep tightly closed.

Store in accordance with the particular national regulations.

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

Strong oxidizing agents



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Packaging material : Unsuitable material: None known.

#### 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

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

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Concentration standard / Permissible concentration	Basis
flugestone 17-acetate	2529-45-5	TWA	0.2 μg/m3 (OEB 5)	Internal
		Wipe limit	2 μg /100 cm2	Internal

**Engineering measures** : Use closed processing systems or containment technologies

to control at source (e.g., glove boxes/isolators) and to pre-

vent 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 expo-

sure assessment demonstrates exposures outside the rec-

ommended guidelines, use respiratory protection.

Filter type

Hand protection

Particulates type

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, dis-

posable suits) to avoid exposed skin surfaces.

Use appropriate degowning techniques to remove potentially

contaminated clothing.



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Physical state : powder

Colour : white

Odour : odourless

Odour Threshold : No data available

Melting point/freezing point : No data available

Boiling point, initial boiling

point and boiling range

No data available

Flammability (solid, gas) : May form explosive dust-air mixture during processing, han-

dling or other means.

Flammability (liquids) : Not applicable

Lower explosion limit and upper explosion limit / flammability limit

Upper explosion limit / Up- :

per flammability limit

: No data available

Lower explosion limit / Lower flammability limit

No data available

Flash point : Not applicable

Decomposition temperature : No data available

pH : No data available

Evaporation rate : Not applicable

Auto-ignition temperature : 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

Density and / or relative density

Relative density : No data available

Density : No data available



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Relative vapour density : 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

#### 10. STABILITY AND REACTIVITY

Reactivity : Not classified as a reactivity hazard. Chemical stability : Stable under normal conditions.

Possibility of hazardous reac-

tions

May form explosive dust-air mixture during processing, han-

dling or other means.

Can react with strong oxidizing agents.

Conditions to avoid : Heat, flames and sparks.

Avoid dust formation.
Oxidizing agents

Incompatible materials

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:**

#### 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



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#### 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.

#### 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 - Assess- : No data available



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#### ment

#### 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-

ment

Test Type: Embryo-foetal development

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 - As-

sessment

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 con-

centrations of >10 to 100 mg/kg bw.

### Repeated dose toxicity

#### **Components:**

#### flugestone 17-acetate:

Species : Rat

NOAEL : 0.2 mg/kg

Application Route : Oral



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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.

#### 12. ECOLOGICAL INFORMATION

#### **Ecotoxicity**

#### **Components:**

flugestone 17-acetate:

Toxicity to fish (Chronic tox- : NOEC (Zebrafish): < 0.0004 μg/l

icity) Exposure time: 32 d

Method: OECD Test Guideline 210

Remarks: Based on data from similar materials

M-Factor (Chronic aquatic :

toxicity)

100,000

Persistence and degradability

No data available

Bioaccumulative potential

No data available

Mobility in soil

No data available

Hazardous to the ozone layer

Not applicable

Other adverse effects

No data available

#### 13. DISPOSAL CONSIDERATIONS

**Disposal methods** 

Waste from residues : Dispose of in accordance with local regulations.

Do not dispose of waste into sewer.

Contaminated packaging : Empty containers should be taken to an approved waste han-

dling site for recycling or disposal.

If not otherwise specified: Dispose of as unused product.



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#### 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

Packing instruction (cargo : 956

aircraft)

Packing instruction (passen: 956

ger aircraft)

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.

**National Regulations** 

Refer to section 15 for specific national regulation.

Special precautions for user

The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

ERG Code : 171



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#### 15. REGULATORY INFORMATION

## **Related Regulations**

#### Fire Service Law

Not applicable to dangerous materials / designated flammables.

#### **Chemical Substance Control Law**

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

#### **Industrial Safety and Health Law**

#### **Harmful Substances Prohibited from Manufacture**

Not applicable

#### **Harmful Substances Required Permission for Manufacture**

Not applicable

#### **Substances Prevented From Impairment of Health**

Not applicable

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

Not applicable

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

Not applicable

#### **Substances Subject to be Notified Names**

Not applicable

#### **Substances Subject to be Indicated Names**

Not applicable

# Skin and Eye Damage Substances for PPE Requirements (ISHL MO Art. 594-2)

Not applicable

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

Not applicable

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

Not applicable

## **Ordinance on Prevention of Lead Poisoning**

Not applicable

# Ordinance on Prevention of Tetraalkyl Lead Poisoning

Not applicable

#### **Ordinance on Prevention of Organic Solvent Poisoning**

Not applicable



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

Not applicable

#### Poisonous and Deleterious Substances Control Law

Not applicable

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

Not applicable

## **High Pressure Gas Safety Act**

Not applicable

#### **Explosive Control Law**

Not applicable

#### **Vessel Safety Law**

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

#### **Aviation Law**

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

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

Bulk transportation : Not classified as noxious liquid substance

Pack transportation : Classified as marine pollutant

#### **Narcotics and Psychotropics Control Act**

Narcotic or Psychotropic Raw Material (Export / Import Permission)

Not applicable

Specific Narcotic or Psychotropic Raw Material (Export / Import permission)

Not applicable

# Waste Disposal and Public Cleansing Law

Industrial waste

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

AICS : not determined

DSL : not determined

IECSC : not determined

#### **16. OTHER INFORMATION**

#### **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 Agen-

cy, http://echa.europa.eu/



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

Date format : yyyy/mm/dd

Full text of other abbreviations

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

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.

JP / EN