

Flugestone Acetate Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 04.04.2023

 3.1
 30.09.2023
 10821887-00004
 Date of first issue: 28.07.2022

SECTION 1. IDENTIFICATION

Product name : Flugestone Acetate Formulation

Manufacturer or supplier's details

Company : MSD

Address : Talcahuano 750, 6th floor, Ciudad Autonoma

Buenos Aires, Argentina C1013AAP

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

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.

Response:



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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

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	>= 2,5 -< 5

SECTION 4. FIRST AID MEASURES

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

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

Protection of first-aiders

delayed

May damage fertility. May damage the unborn child.

Contact with dust can cause mechanical irritation or drying of

the skin.

Dust contact with the eyes can lead to mechanical irritation. 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 (CO2)

Dry chemical None known.

Unsuitable extinguishing

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 prod-

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 fire-fighters

In the event of fire, wear self-contained breathing apparatus.

Use personal protective equipment.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protec- : tive equipment and emer-

gency 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

Static electricity may accumulate and ignite suspended dust Technical measures

causing an explosion.

Provide adequate precautions, such as electrical grounding



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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

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/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 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



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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.

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

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

handling or other means.



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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

No data available Autoignition temperature

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 size No data available

SECTION 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,

handling or other means.

Can react with strong oxidizing agents.

Heat, flames and sparks. Conditions to avoid

Avoid dust formation.

Incompatible materials

Hazardous decomposition

Oxidizing agents

No hazardous decomposition products are known. products

SECTION 11. TOXICOLOGICAL INFORMATION



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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.

Components:

flugestone 17-acetate:

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

Result: negative

Test Type: Mouse Lymphoma

Result: negative



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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-

ment

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

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.



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Components:

flugestone 17-acetate:

Routes of exposure : 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
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.

SECTION 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



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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

Packing instruction (cargo

aircraft)

956

Packing instruction (passen-

acking ins

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.



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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

Argentina. Carcinogenic Substances and Agents : Not applicable

Registry.

Control of precursors and essential chemicals for the

preparation of drugs.

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

Revision Date : 30.09.2023 Date format : dd.mm.yyyy

Further information

Sources of key data used to compile the Material Safety

Data Shoot

Data Sheet

Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agen-

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

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 Con-



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centration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

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

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