according to the Globally Harmonized System



Flugestone Acetate Formulation

Version	Revision Date: 30.09.2023	SDS Number:	Date of last issue: 04.04.2023
3.1		10821895-00004	Date of first issue: 28.07.2022

1. PRODUCT AND COMPANY IDENTIFICATION

Product name	:	Flugestone Acetate Formulation					
Manufacturer or supplier's details							
Company	:	MSD					
Address	:	Briahnager - Off Pune Nagar Road Wagholi - Pune - India 412 207					
Telephone	:	+1-908-740-4000					
Emergency telephone number	:	+1-908-423-6000					
E-mail address	:	EHSDATASTEWARD@msd.com					
Recommended use of the chemical and restrictions on use							
Recommended use Restrictions on use	:	Veterinary product Not applicable					

2. HAZARDS IDENTIFICATION

Manufacture, Storage and Import of Hazardous Chemicals Rules 1989

Classification

Not classified as hazardous according to criteria laid down in Part I of Schedule-1.

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: P203 Obtain, read and follow all safety instructions before use. P273 Avoid release to the environment.

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P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response:

P318 IF exposed or concerned, get medical advice. 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.

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

4. FIRST AID MEASURES

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 and effects, both acute and 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.
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).

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١	Notes t	o physician	:	Treat symptomati	cally and supportively.
5. FIR	REFIGI	HTING MEASURES			
Suitable extinguishing media		:	Water spray Alcohol-resistant foam Carbon dioxide (CO2) Dry chemical		
		able extinguishing	:	None known.	
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- 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.	
	Special protective equipment for firefighters		:		e, wear self-contained breathing apparatus. tective equipment.
6. AC	CIDE	NTAL RELEASE MEA	SUF	RES	
t	Personal precautions, protec- tive equipment and emer- gency procedures		:	Follow safe hand	tective equipment. ing advice (see section 7) and personal pro- t recommendations (see section 8).
E	Environmental precautions		:	Retain and dispos	akage or spillage if safe to do so. se of contaminated wash water. should be advised if significant spillages
	Methods and materials for containment and cleaning up		:	tainer for disposa Avoid dispersal o with compressed	f dust in the air (i.e., clearing dust surfaces

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.

7. HANDLING AND STORAGE



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Technical measures		causing an explo Provide adequat	e precautions, such as electrical grounding			
L	ocal/Total ventilation		and bonding, or inert atmospheres. If sufficient ventilation is unavailable, use with local exhaust			
Advice on safe handling		 Do not get on sk Do not breathe o Do not swallow. Avoid contact wi Handle in accord practice, based o sessment Keep container t Minimize dust ge Keep container o Keep away from Take precaution 	lust. th eyes. lance with good industrial hygiene and safety on the results of the workplace exposure as-			
С	onditions for safe storage	: Keep in properly Store locked up. Keep tightly clos	labelled containers. ed.			
N	laterials to avoid		nce with the particular national regulations. the following product types: agents			

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parame- ters / 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 tech-
nology designed to prevent leakage of compounds into the
workplace.Percencel protective equipment

Personal protective equipment

Respiratory protection : If adequate local exhaust ventilation is not available or expo-

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Filter type Hand protection		ommended g	sure assessment demonstrates exposures outside the rec- ommended guidelines, use respiratory protection.Particulates type		
Ma	aterial	: Chemical-resi	istant gloves		
Remarks Eye protection		: Wear safety g If the work en mists or aeros Wear a faces	Consider double gloving. 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		
Skin a	and body protection	: Work uniform Additional boo being perform suits) to avoid Use appropria	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		
Hygie	ene measures	: If exposure to flushing syste place. When using d Wash contam The effective engineering c appropriate de industrial hygi	contaminated clothing. 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.		

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	:	powder
Colour	:	white
Odour	:	odourless
Odour Threshold	:	No data available
рН	:	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, han- dling or other means.

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	Flamma	ability (liquids)	:	Not applicable	
	Upper explosion limit / Upper flammability limit		:	No data available	
		explosion limit / Lower bility limit	:	No data available	
	Vapour	pressure	:	Not applicable	
	Relative	e vapour density	:	Not applicable	
	Relative	e density	:	No data available	9
	Density	,	:	No data available	9
	Solubili Wat	ty(ies) er solubility	:	partly miscible	
		n coefficient: n-	:	Not applicable	
	octanol Auto-ig	/water nition temperature	:	No data available	9
	Decom	position temperature	:	No data available	9
	Viscosi Visc	ty :osity, kinematic	:	Not applicable	
	Explosi	ve properties	:	Not explosive	
	Oxidizir	ng properties	:	The substance o	mixture is not classified as oxidizing.
	Molecu	lar weight	:	No data available	•
	Particle	esize	:	No data available)

10. STABILITY AND REACTIVITY

Reactivity Chemical stability Possibility of hazardous reac- tions	:	Not classified as a reactivity hazard. Stable under normal conditions. 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.
Incompatible materials Hazardous decomposition products	:	Oxidizing agents No hazardous decomposition products are known.

11. TOXICOLOGICAL INFORMATION





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	Informa exposu	ition on likely routes of re	:	Inhalation Skin contact Ingestion Eye contact	
		oxicity ssified based on availa onents:	ble	information.	
	-	one 17-acetate: oral toxicity	:	Remarks: No data	available
		orrosion/irritation ssified based on availa	ble	information.	
	-	one 17-acetate:	:	No data available	
		s eye damage/eye irri ssified based on availa			
	<u>Compo</u>	onents:			
	flugest Remark	one 17-acetate: <s< td=""><td>:</td><td>No data available Mild eye irritation</td><td></td></s<>	:	No data available Mild eye irritation	
	Respira	atory or skin sensitis	atio	n	
	Not clas	ensitisation ssified based on availa	ble	information.	
		atory sensitisation ssified based on availa onents:	ble	information.	
	flugest Remark	one 17-acetate:	:	No data available	
		ell mutagenicity ssified based on availa	ble	information.	
	Compo	onents:			
		one 17-acetate: xicity in vitro	:	Test Type: Microb Result: negative	ial mutagenesis assay (Ames test)
				Test Type: Mouse Result: negative	Lymphoma

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			Chromosomal aberration : Human lymphocytes ttive
Gen	otoxicity in vivo	: Remarks: No	o data available
	n cell mutagenicity - essment	: Weight of ev cell mutager	idence does not support classification as a germ
Not	cinogenicity classified based on avai nponents:	lable information.	
	estone 17-acetate:		
Rem	narks	: No data ava	ilable
Caro men	cinogenicity - Assess- t	: No data ava	ilable
-	roductive toxicity damage fertility. May da	amage the unborn	child.
	nponents:	J.	
flug	estone 17-acetate:		
Effe	cts on fertility	Species: Ra Application I General Tox	
Effe men	cts on foetal develop- t	Species: Ra Application I General Tox Teratogenici	
		Species: Ra Application I General Tox	
•	roductive toxicity - As- sment	ity, based or	ace of adverse effects on sexual function and fertil- a animal experiments., Clear evidence of adverse evelopment, based on animal experiments.

STOT - single exposure

Not classified based on available information.

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STO	STOT - repeated exposure					
Not c	Not classified based on available information.					
-						
Com	<u>ponents:</u>					

flugestone 17-acetate:

hagootono ni acotato.	
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
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- icity)	:	NOEC: < 0.0004 µg/l Exposure time: 32 d Species: Zebrafish Method: OECD Test Guideline 210 Remarks: Based on data from similar materials
M-Factor (Chronic aquatic toxicity)	:	100,000

Persistence and degradability

No data available





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No da	ccumulative potential ata available lity in soil			
	ata available			
••	r adverse effects ata available			
13. DISPC	SAL CONSIDERATION	NS		
Disp	osal methods			
Wast	e from residues			of waste into sewer. cordance with local regulations.
Conta	aminated packaging	:	Empty container	s should be taken to an approved waste han- ycling or disposal. specified: Dispose of as unused product.
14. TRAN	SPORT INFORMATION	I		
Inter	national Regulations			
	TDG umber er shipping name	:		ALLY HAZARDOUS SUBSTANCE, SOLID,
			N.O.S. (flugestone 17-a	acetate)
Labe	ing group	: : !	9 II 9 /es	
	-DGR			
UN/IE Prope) No. er shipping name		JN 3077 Environmentally (flugestone 17-a	hazardous substance, solid, n.o.s. acetate)
Class	s ing group		9 	
Labe	ing instruction (cargo	: 1	Viscellaneous 956	
Packi ger a	ing instruction (passen- ircraft)	: 9	956	
	onmentally hazardous	: !	/es	
UN n	5-Code umber er shipping name	:	JN 3077 ENVIRONMENT N.O.S. flugestone 17-a	ALLY HAZARDOUS SUBSTANCE, SOLID,
Label EmS	ing group	: ! : : !	ilugesione 17-a] II -A, S-F /es	σιαισ

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Transport in bulk according to IMO instruments

Not applicable for product as supplied.

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.

15. REGULATORY INFORMATION

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

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

AICS	:	not determined
DSL	:	not determined
IECSC	:	not determined

16. OTHER INFORMATION

Revision Date	:	30.09.2023
Further information	_	Internal technical data, data from row material CDCs, OFCD
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/
Date format	:	dd.mm.yyyy

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

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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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