



Version 3.1	Revision Date: 2023/09/30		S Number: 321894-00004	Date of last issue: 2023/04/04 Date of first issue: 2022/07/28
1. PROL	DUCT AND COMPANY IDE	=N I	IFICATION	
Pro	duct name	:	Flugestone Acet	ate Formulation
Ma	nufacturer or supplier's d	letai	ils	
Cor	mpany	:	MSD	
Ado	dress	:	126 E. Lincoln A Rahway, New Je	venue ersey U.S.A. 07065
Tele	ephone	:	908-740-4000	
Em	ergency telephone number	· :	1-908-423-6000	
E-m	nail address	:	EHSDATASTEV	VARD@msd.com
Red	commended use of the ch	nem	ical and restricti	ons on use
	commended use		Veterinary produ	uct
Res	strictions on use	:	Not applicable	
2. HAZA	RDS IDENTIFICATION			
GH	S Classification			
	productive toxicity	:	Category 1B	
Lon haz	ng-term (chronic) aquatic ard	:	Category 1	
GH	S label elements			
Haz	zard pictograms	:		¥
Sig	nal word	:	Danger	\checkmark

: H360FD May damage fertility. May damage the unborn child. H410 Very toxic to aquatic life with long lasting effects.

Precautionary statements

Hazard statements

Prevention:

2

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 protection/ 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

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 -< 10

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.
Protection of first-aiders	:	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



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Notes	s to physician	:		al for exposure exists (see section 8). cally and supportively.	
5. FIREFIC	GHTING MEASURES				
Suital	ble extinguishing media	:	: Water spray Alcohol-resistant foam Carbon dioxide (CO2)		
Unsui media	itable extinguishing a	:	Dry chemical None known.		
Speci fightir	ific hazards during fire- ng	:	concentrations, a potential dust exp	dust; fine dust dispersed in air in sufficient nd in the presence of an ignition source is a plosion hazard. bustion products may be a hazard to health.	
Haza ucts	rdous combustion prod-	:	Carbon oxides		
Speci ods	pecific extinguishing meth- ds		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 d so.		
	ial protective equipment efighters	:		e, wear self-contained breathing apparatus. tective equipment.	
6. ACCIDE	ENTAL RELEASE MEAS	SUF	RES		
tive e	Personal precautions, protec- tive equipment and emer- gency procedures		Follow safe hand	tective equipment. ling advice (see section 7) and personal pro- t recommendations (see section 8).	
Enviro	onmental 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		tainer for disposa Avoid dispersal o with compressed Dust deposits sho es, as these may leased into the at Local or national posal of this mate employed in the o mine which regula Sections 13 and	f dust in the air (i.e., clearing dust surfaces	



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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.
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 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

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

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			

Components with workplace control parameters

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.
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			ire the use of appropriate containment tech- to prevent leakage of compounds into the	
nal protective equip	ment			
Respiratory protection Filter type Hand protection		If adequate local exhaust ventilation is not available or expo- sure assessment demonstrates exposures outside the rec- ommended guidelines, use respiratory protection. Particulates type		
terial	:	Chemical-resistant gloves		
Remarks Eye protection		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 and body protection		Work uniform or Additional body task being perfo posable suits) to Use appropriate	garments should be used based upon the rmed (e.g., sleevelets, apron, gauntlets, dis- avoid exposed skin surfaces. degowning techniques to remove potentiall	
Hygiene measures		If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the work ing 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.		
	atory protection er type protection terial marks otection nd body protection	atory protection : er type : brotection : terial : marks : otection : nd body protection : ne measures :	nology designed workplace. nal protective equipment atory protection : If adequate local sure assessment ommended guid er type : Particulates type protection terial : Chemical-resistant marks : Consider double otection : Wear safety glass If the work envir mists or aerosol Wear a faceshier potential for dire aerosols. nd body protection : Work uniform or Additional body task being perfor posable suits) to Use appropriate contaminated cl be measures : If exposure to ch eye flushing sys- ing place. When using do a Wash contamina- The effective op engineering con appropriate deg- industrial hygien	

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	:	No data available

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range				
Flash	point	:	Not applicable	
Evapo	pration rate	:	Not applicable	
Flamm	nability (solid, gas)	:	May form explos dling or other me	ive dust-air mixture during processing, han- eans.
Flamr	nability (liquids)	:	Not applicable	
	r explosion limit / Upper nability limit	:	No data available	e
	r explosion limit / Lower nability limit	:	No data available	e
Vapoι	ur pressure	:	Not applicable	
Relati	ve vapour density	:	Not applicable	
Relati	ve density	:	No data available	e
Densi	ty	:	No data available	e
	ility(ies) ater solubility	:	partly miscible	
	on coefficient: n- ol/water	:	Not applicable	
	ignition temperature	:	No data available	e
Decor	mposition temperature	:	No data available	e
Viscos Vis	sity scosity, kinematic	:	Not applicable	
Explo	sive properties	:	Not explosive	
Oxidiz	zing properties	:	The substance o	r mixture is not classified as oxidizing.
Molec	cular weight	:	No data available	e
Partic	le size	:	No data available	e

10. STABILITY AND REACTIVITY

Reactivity	:	Not classified as a reactivity hazard.
Chemical stability	:	Stable under normal conditions.
Possibility of hazardous reac-	:	May form explosive dust-air mixture during processing, han-



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tions		dling or other i Can react with	neans. strong oxidizing agents.
Incon	itions to avoid npatible materials rdous decomposition acts	 Heat, flames a Avoid dust foru Oxidizing ager No hazardous 	mation.
1. TOXIC		ATION	
Inforr expos	nation on likely routes sure	of : Inhalation Skin contact Ingestion Eye contact	
	e toxicity lassified based on ava	ilable information.	
Com	ponents:		
_	stone 17-acetate: e oral toxicity	: Remarks: No d	ata available
Not c	corrosion/irritation lassified based on ava ponents:	ilable information.	
	stone 17-acetate:	: No data availat	ble
Not c	ous eye damage/eye i lassified based on ava		
<u>Com</u>	ponents:		
fluge Rema	stone 17-acetate: arks	: No data availat Mild eye irritatio	
Resp	iratory or skin sensit	isation	
-	sensitisation lassified based on ava	ilable information.	
Not c	iratory sensitisation lassified based on ava	ilable information.	
Com	ponents:		
fluge Rema	stone 17-acetate: arks	: No data availat	ble





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Germ	cell mutagenicity		
	lassified based on ava	ilable information.	
<u>Comp</u>	oonents:		
fluge	stone 17-acetate:		
Geno	toxicity in vitro	: Test Type: I Result: nega	Aicrobial mutagenesis assay (Ames test) ative
		Test Type: I Result: nega	Aouse Lymphoma ative
			Chromosomal aberration : Human lymphocytes ative
Geno	toxicity in vivo	: Remarks: N	o data available
	cell mutagenicity -	: Weight of ev cell mutage	ridence does not support classification as a ge
	nogenicity lassified based on ava	ilable information.	
<u>Comp</u>	oonents:		
fluge : Rema	stone 17-acetate: arks	: No data ava	ilable
Carcii ment	nogenicity - Assess-	: No data ava	ilable
Repro	oductive toxicity		
May o	damage fertility. May d	amage the unborn	child.
<u>Comp</u>	oonents:		
fluge	stone 17-acetate:		
Effect	ts on fertility	Species: Ra Application General To	
Effect ment	ts on foetal develop-	Species: Ra Application General To	





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			Species: Rabbit Application Route General Toxicity I	vo-foetal development e: Oral Maternal: NOAEL: 0.01 mg/kg body weight sicity: NOAEL: 0.04 mg/kg body weight
	productive toxicity - As- sment	:	ity, based on anin	adverse effects on sexual function and fertil- nal experiments., Clear evidence of adverse pment, based on animal experiments.
	DT - single exposure classified based on avail	able	information.	
	DT - repeated exposure classified based on avail	able	information.	
<u>Co</u>	nponents:			
Exp Tar	gestone 17-acetate: posure routes get Organs sessment	:		e significant health effects in animals at con-) to 100 mg/kg bw.

Repeated dose toxicity

Components:

flugestone 17-acetate:

:	Rat
:	0.2 mg/kg
:	Oral
:	90 d
:	daily
:	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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2. ECOL	OGICAL INFORMATIO	N		
Ecot	oxicity			
<u>Com</u>	ponents:			
-	estone 17-acetate: Sity to fish (Chronic tox-	:		
M-Fa toxici	ictor (Chronic aquatic ity)	:	100,000	
	istence and degradabi ata available	lity		
	ccumulative potential ata available			
	i lity in soil ata available			
	r adverse effects ata available			
3. DISPO	OSAL CONSIDERATIO	NS		
Disp	osal methods			
Wast	e from residues	:		of waste into sewer. cordance with local regulations.
Conta	aminated packaging	:	Empty container dling site for rec	's should be taken to an approved waste han ycling or disposal. specified: Dispose of as unused product.
4. TRAN	SPORT INFORMATION	N		
Inter	national Regulations			
UNR				
	umber er shipping name	:	N.O.S.	TALLY HAZARDOUS SUBSTANCE, SOLID,
Class		:	(flugestone 17-a 9	acetate)
Pack Labe	ing group Is	:	 9	
	onmentally bazardous	:		

: UN 3077

Environmentally hazardous : yes

IATA-DGR UN/ID No.



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Prop Clas	per shipping name	:	Environmentally h (flugestone 17-ac 9	nazardous substance, solid, n.o.s. cetate)
	king group	:	III	
Lab		:	Miscellaneous	
Pac airci	king instruction (cargo aft)	:	956	
	king instruction (passen- aircraft)	:	956	
Ĕnv	ronmentally hazardous	:	yes	
IMD	G-Code			
UN	number	:	UN 3077	
Prop	per shipping name	:	ENVIRONMENTA	ALLY HAZARDOUS SUBSTANCE, SOLID,
			N.O.S.	
			(flugestone 17-ac	etate)
Clas	-	:	9	
	king group	:	III	
Lab		:	9	
	S Code	:	F-A, S-F	
Mar	ne pollutant	:	yes	

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

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

Minister of Industry Regulation No. 23/M-IND/PER/4/2013 concerning the Revision of Minister of Industry Regulation No. 87/M-IND/PER/9/2009 concerning Globally Harmonized System of Classification and Labelling of Chemicals.

Regulation of the Minister of Health No. 472 of 1996 on the Safeguarding of Substances Hazardous to Health

Hazardous substances that must be registered

: Not applicable

Government Regulation No. 74 of 2001 on the Management of Hazardous and Toxic Substances

Hazardous substances approved for use	:	Not applicable
Prohibited substances	:	Not applicable
Restricted substances	:	Not applicable





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Regulation of the Ministry of Trade No. 7 of 2022 on Distribution and Control of Hazardous Materials

Type of hazardous materials subject to distribution and : Not applicable control, Annex I

Type of hazardous materials subject to distribution and : Not applicable control, Annex II

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	:	2023/09/30
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/
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, Bioaccumu-

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lative 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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