

Altrenogest (0.22%) Formulation

Version 6.0 Revision Date: 2023/09/30 SDS Number: 5842508-00009 Date of last issue: 2023/04/04
Date of first issue: 2020/05/08

1. PRODUCT AND COMPANY IDENTIFICATION

Chemical product name : Altrenogest (0.22%) 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**

Long-term (chronic) aquatic hazard : Category 1

GHS label elements

Hazard pictograms :



Signal word : Warning

Hazard statements : H410 Very toxic to aquatic life with long lasting effects.

Precautionary statements :

Prevention:

P273 Avoid release to the environment.

Response:

P391 Collect spillage.

Disposal:

P501 Dispose of contents/ container to an approved waste disposal plant.

Altrenogest (0.22%) Formulation

Version 6.0 Revision Date: 2023/09/30 SDS Number: 5842508-00009 Date of last issue: 2023/04/04
 Date of first issue: 2020/05/08

Other hazards which do not result in classification

None known.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)	ENCS No.
Benzyl alcohol	100-51-6	$\geq 1 - < 10$	3-1011
altrenogest	850-52-2	$\geq 0.1 - < 0.25$	
2,6-Di-tert-butyl-p-cresol	128-37-0	$\geq 0.0025 - < 0.025$	3-540, 9-1805

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 : Flush eyes with water as a precaution.
 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 : None known.
- 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- : Exposure to combustion products may be a hazard to health.

Altrenogest (0.22%) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/04/04
6.0	2023/09/30	5842508-00009	Date of first issue: 2020/05/08

fighting
 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 firefighters : In the event of fire, wear self-contained breathing apparatus.
 Use personal protective equipment.

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.
 Prevent spreading over a wide area (e.g. by containment or oil barriers).
 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 : Soak up with inert absorbent material.
 For large spills, provide dyking or other appropriate containment to keep material from spreading. If dyked material can be pumped, store recovered material in appropriate container.
 Clean up remaining materials from spill with suitable absorbent.
 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

Handling

Technical measures : See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.

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 vapours or spray mist.
 Do not swallow.
 Avoid contact with eyes.

Altrenogest (0.22%) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/04/04
6.0	2023/09/30	5842508-00009	Date of first issue: 2020/05/08

Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment
 Keep container tightly closed.
 Take care to prevent spills, waste and minimize release to the environment.

Avoidance of contact : Oxidizing agents
 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.
 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

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 / Reference concentration / Permissible concentration	Basis
Benzyl alcohol	100-51-6	OEL-C	25 mg/m ³	JP OEL JSOH
	Further information: Skin sensitizing agent; Group 2 substances which probably induce allergic reactions in humans.			
altrenogest	850-52-2	TWA	1 µg/m ³ (OEB 4)	Internal
	Further information: Skin			
		Wipe limit	10 µg/100 cm ²	Internal
2,6-Di-tert-butyl-p-cresol	128-37-0	TWA (Inhalable fraction and vapor)	2 mg/m ³	ACGIH

Engineering measures : All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.
 Essentially no open handling permitted.

Altrenogest (0.22%) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/04/04
6.0	2023/09/30	5842508-00009	Date of first issue: 2020/05/08

Use closed processing systems or containment technologies. If handled in a laboratory, use a properly designed biosafety cabinet, fume hood, or other containment device if the potential exists for aerosolization. If this potential does not exist, handle over lined trays or benchtops.

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	:	Combined particulates and organic vapour 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.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state	:	liquid
Colour	:	No data available
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)	:	Not applicable
Flammability (liquids)	:	No data available
Lower explosion limit and upper explosion limit / flammability limit	:	
Upper explosion limit / Up- per flammability limit	:	No data available

Altrenogest (0.22%) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/04/04
6.0	2023/09/30	5842508-00009	Date of first issue: 2020/05/08

Lower explosion limit / Lower flammability limit	:	No data available
Flash point	:	No data available
Decomposition temperature	:	No data available
pH	:	No data available
Evaporation rate	:	No data available
Auto-ignition temperature	:	No data available
Viscosity	:	
Viscosity, kinematic	:	No data available
Solubility(ies)	:	
Water solubility	:	No data available
Partition coefficient: n- octanol/water	:	No data available
Vapour pressure	:	No data available
Density and / or relative density	:	
Relative density	:	No data available
Density	:	No data available
Relative vapour density	:	No data available
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	:	Can react with strong oxidizing agents.
Conditions to avoid	:	None known.
Incompatible materials	:	Oxidizing agents
Hazardous decomposition products	:	No hazardous decomposition products are known.

Altrenogest (0.22%) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/04/04
6.0	2023/09/30	5842508-00009	Date of first issue: 2020/05/08

11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure : Inhalation
Skin contact
Ingestion
Eye contact

Acute toxicity

Not classified based on available information.

Product:

Acute oral toxicity : Acute toxicity estimate: > 2,000 mg/kg
Method: Calculation method

Acute inhalation toxicity : Acute toxicity estimate: > 5 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Method: Calculation method

Components:

Benzyl alcohol:

Acute oral toxicity : LD50 (Rat): 1,620 mg/kg
Acute inhalation toxicity : LC50 (Rat): > 4.178 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Method: OECD Test Guideline 403

altrenogest:

Acute oral toxicity : LD50 (Rat): 177 mg/kg
LD50 (Dog): 400 mg/kg

2,6-Di-tert-butyl-p-cresol:

Acute oral toxicity : LD50 (Rat): > 6,000 mg/kg
Method: OECD Test Guideline 401
Acute dermal toxicity : LD50 (Rat): > 2,000 mg/kg
Method: OECD Test Guideline 402
Assessment: The substance or mixture has no acute dermal toxicity

Skin corrosion/irritation

Not classified based on available information.

Components:

Benzyl alcohol:

Altrenogest (0.22%) Formulation

Version 6.0 Revision Date: 2023/09/30 SDS Number: 5842508-00009 Date of last issue: 2023/04/04
Date of first issue: 2020/05/08

Species : Rabbit
Method : OECD Test Guideline 404
Result : No skin irritation

2,6-Di-tert-butyl-p-cresol:

Species : Rabbit
Method : OECD Test Guideline 404
Result : No skin irritation
Remarks : Based on data from similar materials

Serious eye damage/eye irritation

Not classified based on available information.

Components:**Benzyl alcohol:**

Species : Rabbit
Result : Irritation to eyes, reversing within 21 days
Method : OECD Test Guideline 405

2,6-Di-tert-butyl-p-cresol:

Species : Rabbit
Result : No eye irritation
Method : OECD Test Guideline 405
Remarks : Based on data from similar materials

Respiratory or skin sensitisation**Skin sensitisation**

Not classified based on available information.

Respiratory sensitisation

Not classified based on available information.

Components:**Benzyl alcohol:**

Test Type : Maximisation Test
Exposure routes : Skin contact
Species : Guinea pig
Method : OECD Test Guideline 406
Result : negative

2,6-Di-tert-butyl-p-cresol:

Test Type : Human repeat insult patch test (HRIPT)
Exposure routes : Skin contact
Species : Humans
Result : negative

Altrenogest (0.22%) Formulation

Version 6.0 Revision Date: 2023/09/30 SDS Number: 5842508-00009 Date of last issue: 2023/04/04
Date of first issue: 2020/05/08

Germ cell mutagenicity

Not classified based on available information.

Components:**Benzyl alcohol:**

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)
Result: negative

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
Species: Mouse
Application Route: Intraperitoneal injection
Result: negative

altrenogest:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)
Result: negative

Test Type: Chromosome aberration test in vitro
Result: negative

Test Type: DNA damage and repair, unscheduled DNA synthesis in mammalian cells (in vitro)
Result: negative

2,6-Di-tert-butyl-p-cresol:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)
Result: negative

Test Type: In vitro mammalian cell gene mutation test
Result: negative

Test Type: Chromosome aberration test in vitro
Result: negative

Genotoxicity in vivo : Test Type: Mutagenicity (in vivo mammalian bone-marrow cytogenetic test, chromosomal analysis)
Species: Rat
Application Route: Ingestion
Result: negative

Carcinogenicity

Not classified based on available information.

Components:**Benzyl alcohol:**

Species : Mouse
Application Route : Ingestion
Exposure time : 103 weeks

Altrenogest (0.22%) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/04/04
6.0	2023/09/30	5842508-00009	Date of first issue: 2020/05/08

Method	: OECD Test Guideline 451
Result	: negative

2,6-Di-tert-butyl-p-cresol:

Species	: Rat
Application Route	: Ingestion
Exposure time	: 22 Months
Result	: negative

Reproductive toxicity

Not classified based on available information.

Components:

Benzyl alcohol:

Effects on fertility	: Test Type: Fertility/early embryonic development Species: Rat Application Route: Ingestion Result: negative Remarks: Based on data from similar materials
Effects on foetal development	: Test Type: Embryo-foetal development Species: Mouse Application Route: Ingestion Result: negative

altrenogest:

Effects on fertility	: Test Type: Two-generation reproduction toxicity study Species: Rat Application Route: Oral Fertility: NOAEL: 0.016 mg/kg body weight Result: Effects on fertility, No effects on mating performance Test Type: Fertility/early embryonic development Species: Monkey, female Application Route: Oral Fertility: NOAEL: 0.004 mg/kg body weight
Reproductive toxicity - Assessment	: Clear evidence of adverse effects on sexual function and fertility, and/or on development, based on animal experiments

2,6-Di-tert-butyl-p-cresol:

Effects on fertility	: Test Type: Two-generation reproduction toxicity study Species: Rat Application Route: Ingestion Result: negative
Effects on foetal development	: Test Type: Embryo-foetal development Species: Rat Application Route: Ingestion

Altrenogest (0.22%) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/04/04
6.0	2023/09/30	5842508-00009	Date of first issue: 2020/05/08

Result: negative

STOT - single exposure

Not classified based on available information.

STOT - repeated exposure

Not classified based on available information.

Components:

altrenogest:

Exposure routes	: Oral
Target Organs	: Immune system, Adrenal gland
Assessment	: May cause damage to organs through prolonged or repeated exposure.

Exposure routes	: Oral
Target Organs	: Pituitary gland

2,6-Di-tert-butyl-p-cresol:

Assessment	: No significant health effects observed in animals at concentrations of 100 mg/kg bw or less.
------------	--

Repeated dose toxicity

Components:

Benzyl alcohol:

Species	: Rat
NOAEL	: 1.072 mg/l
Application Route	: inhalation (dust/mist/fume)
Exposure time	: 28 Days
Method	: OECD Test Guideline 412

altrenogest:

Species	: Rat
NOAEL	: 0.06 mg/kg
Application Route	: Oral
Exposure time	: 13 Weeks
Target Organs	: Immune system, male reproductive organs, female reproductive organs, Adrenal gland
Remarks	: Effects on fertility

Species	: Pig
NOAEL	: 0.004 mg/kg
Application Route	: Oral
Exposure time	: 13 Weeks
Target Organs	: male reproductive organs, female reproductive organs
Remarks	: Effects on fertility

Altrenogest (0.22%) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/04/04
6.0	2023/09/30	5842508-00009	Date of first issue: 2020/05/08

Species	: Pig
NOAEL	: 0.002 mg/kg
Application Route	: Oral
Exposure time	: 1 yr
Target Organs	: male reproductive organs, Pituitary gland
Remarks	: Effects on fertility

Species	: Horse
LOAEL	: 220 mg/kg
Application Route	: Oral
Exposure time	: 86 Days
Remarks	: No significant adverse effects were reported

2,6-Di-tert-butyl-p-cresol:

Species	: Rat
NOAEL	: 25 mg/kg
Application Route	: Ingestion
Exposure time	: 22 Months

Aspiration toxicity

Not classified based on available information.

Experience with human exposure

Components:

altrenogest:

Inhalation	: Symptoms: respiratory tract irritation
Skin contact	: Symptoms: Skin irritation
Eye contact	: Symptoms: Eye irritation

12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Benzyl alcohol:

Toxicity to fish	: LC50 (Pimephales promelas (fathead minnow)): 460 mg/l Exposure time: 96 h
Toxicity to daphnia and other aquatic invertebrates	: EC50 (Daphnia magna (Water flea)): 230 mg/l Exposure time: 48 h Method: OECD Test Guideline 202
Toxicity to algae/aquatic plants	: EC50 (Pseudokirchneriella subcapitata (green algae)): 770 mg/l Exposure time: 72 h

Altrenogest (0.22%) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/04/04
6.0	2023/09/30	5842508-00009	Date of first issue: 2020/05/08

	Method: OECD Test Guideline 201
	NOEC (Pseudokirchneriella subcapitata (green algae)): 310 mg/l
	Exposure time: 72 h
	Method: OECD Test Guideline 201
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	: NOEC (Daphnia magna (Water flea)): 51 mg/l Exposure time: 21 d Method: OECD Test Guideline 211
altrenogest:	
Toxicity to fish (Chronic toxicity)	: NOEC (Danio rerio (zebra fish)): 0.0004 µg/l Exposure time: 32 d Method: OECD Test Guideline 210
M-Factor (Chronic aquatic toxicity)	: 100,000
2,6-Di-tert-butyl-p-cresol:	
Toxicity to fish	: LC50 (Danio rerio (zebra fish)): > 0.57 mg/l Exposure time: 96 h Method: Directive 67/548/EEC, Annex V, C.1.
Toxicity to daphnia and other aquatic invertebrates	: EC50 (Daphnia magna (Water flea)): 0.48 mg/l Exposure time: 48 h Method: OECD Test Guideline 202
Toxicity to algae/aquatic plants	: ErC50 (Pseudokirchneriella subcapitata (green algae)): > 0.24 mg/l Exposure time: 72 h Method: OECD Test Guideline 201
	NOEC (Pseudokirchneriella subcapitata (green algae)): 0.24 mg/l Exposure time: 72 h Method: OECD Test Guideline 201
M-Factor (Acute aquatic toxicity)	: 1
Toxicity to fish (Chronic toxicity)	: NOEC (Oryzias latipes (Japanese medaka)): 0.053 mg/l Exposure time: 30 d Method: OECD Test Guideline 210
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	: NOEC (Daphnia magna (Water flea)): 0.316 mg/l Exposure time: 21 d
M-Factor (Chronic aquatic toxicity)	: 1
Toxicity to microorganisms	: EC50: > 10,000 mg/l Exposure time: 3 h Method: OECD Test Guideline 209

Altrenogest (0.22%) Formulation

Version 6.0 Revision Date: 2023/09/30 SDS Number: 5842508-00009 Date of last issue: 2023/04/04
Date of first issue: 2020/05/08

II**Persistence and degradability****Components:****Benzyl alcohol:**

Biodegradability : Result: Readily biodegradable.
Biodegradation: 92 - 96 %
Exposure time: 14 d

2,6-Di-tert-butyl-p-cresol:

Biodegradability : Result: Not readily biodegradable.
Biodegradation: 4.5 %
Exposure time: 28 d
Method: OECD Test Guideline 301C

Bioaccumulative potential**Components:****Benzyl alcohol:**

Partition coefficient: n-octanol/water : log Pow: 1.05

altrenogest:

Partition coefficient: n-octanol/water : log Pow: 3.78

2,6-Di-tert-butyl-p-cresol:

Bioaccumulation : Species: Cyprinus carpio (Carp)
Bioconcentration factor (BCF): 330 - 1,800

Partition coefficient: n-octanol/water : log Pow: 5.1

Mobility in soil**Components:****altrenogest:**

Distribution among environmental compartments : log Koc: 3.3

Hazardous to the ozone layer

Not applicable

Other adverse effects

No data available

Altrenogest (0.22%) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/04/04
6.0	2023/09/30	5842508-00009	Date of first issue: 2020/05/08

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 handling site for recycling or disposal.
If not otherwise specified: Dispose of as unused product.

14. TRANSPORT INFORMATION**International Regulations****UNRTDG**

UN number : UN 3082
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,
N.O.S.
(altrenogest)
Class : 9
Packing group : III
Labels : 9
Environmentally hazardous : yes

IATA-DGR

UN/ID No. : UN 3082
Proper shipping name : Environmentally hazardous substance, liquid, n.o.s.
(altrenogest)
Class : 9
Packing group : III
Labels : Miscellaneous
Packing instruction (cargo aircraft) : 964
Packing instruction (passenger aircraft) : 964
Environmentally hazardous : yes

IMDG-Code

UN number : UN 3082
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,
N.O.S.
(altrenogest)
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.

Altrenogest (0.22%) Formulation

Version 6.0 Revision Date: 2023/09/30 SDS Number: 5842508-00009 Date of last issue: 2023/04/04
Date of first issue: 2020/05/08

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

15. REGULATORY INFORMATION

Related Regulations

Fire Service Law

Not applicable to dangerous materials / designated flammables.

Chemical Substance Control Law

Priority Assessment Chemical Substance

Chemical name	Number
2,6-Di-tert-butyl-4-methylphenol	64

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

Article 57-2 (Enforcement Order Table 9)

Chemical name	Concentration (%)	Remarks
Benzyl alcohol	>=1 - <10	-

Substances Subject to be Indicated Names

Article 57 (Enforcement Order Article 18)

Chemical name	Remarks
benzyl alcohol	-

Ordinance on Prevention of Hazards Due to Specified Chemical Substances

Not applicable

Ordinance on Prevention of Lead Poisoning

Not applicable

Altrenogest (0.22%) Formulation

Version 6.0 Revision Date: 2023/09/30 SDS Number: 5842508-00009 Date of last issue: 2023/04/04
Date of first issue: 2020/05/08

Ordinance on Prevention of Tetraalkyl Lead Poisoning

Not applicable

Ordinance on Prevention of Organic Solvent Poisoning

Not applicable

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 : Noxious liquid substance(Category Z)

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

Altrenogest (0.22%) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/04/04
6.0	2023/09/30	5842508-00009	Date of first issue: 2020/05/08

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 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.

Date format : yyyy/mm/dd

Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)
 JP OEL JSOH : Japan. The Japan Society for Occupational Health. Recommendation of Occupational Exposure Limits

ACGIH / TWA : 8-hour, time-weighted average
 JP OEL JSOH / OEL-C : Occupational Exposure Limit-Ceiling

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

Altrenogest (0.22%) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/04/04
6.0	2023/09/30	5842508-00009	Date of first issue: 2020/05/08

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