

Version	Revision Date: 2024/09/28	SDS Number:	Date of last issue: 2023/11/16
11.0		26111-00023	Date of first issue: 2014/10/28
-			

1. PRODUCT AND COMPANY IDENTIFICATION

Chemical product name	:	Trenbolone / Estradiol LA Formulation
Supplier's company name, ac Company name of supplier		ess and phone number 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

Carcinogenicity	:	Category 1A
Reproductive toxicity	:	Category 1A
Specific target organ toxicity - repeated exposure	:	Category 1 (Liver, Bone, Blood, Endocrine system)
Specific target organ toxicity - repeated exposure (Oral)	:	Category 1 (Endocrine system, Blood)
Short-term (acute) aquatic hazard	:	Category 3
Long-term (chronic) aquatic hazard	:	Category 1
GHS label elements Hazard pictograms	:	

Signal word





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Hazaı	rd statements	H372 Causes crine system) H372 Causes through prolor H402 Harmful	use cancer. damage fertility. May damage the unborn child damage to organs (Liver, Bone, Blood, Endo- through prolonged or repeated exposure. damage to organs (Endocrine system, Blood) nged or repeated exposure if swallowed. to aquatic life. kic to aquatic life with long lasting effects.
Preca	utionary statements	P202 Do not h and understoo P260 Do not b P264 Wash sl P270 Do not e P273 Avoid re	breathe dust. kin thoroughly after handling. eat, drink or smoke when using this product. elease to the environment. rotective gloves/ protective clothing/ eye protective
		Response: P308 + P313 attention. P391 Collect s	IF exposed or concerned: Get medical advice/
		Storage: P405 Store lo	cked up.
		Disposal: P501 Dispose disposal plant	of contents/ container to an approved waste
Other	^r hazards which do not	result in classifica	ation
•	tant symptoms and out- of the emergency as- d	Contact with o the skin.	with the eyes can lead to mechanical irritation. dust can cause mechanical irritation or drying c losive dust-air mixture during processing, han- means

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)	ENCS No.
17β-hydroxyestra-4,9,11-trien-3-	10161-34-9	>= 60 - < 70	-
one 17-acetate			
Estradiol	50-28-2	>= 2.5 - < 10	-
Magnesium stearate	557-04-0	>= 1 - < 10	2-611



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4. FIRST	AID MEASURES					
	eral advice	:	vice immediately	ccident or if you feel unwell, seek medical ad- /. s persist or in all cases of doubt seek medical		
lf inh	naled	:	If inhaled, remov			
In ca	ase of skin contact	:	of water. Remove contam Get medical atte Wash clothing b	ct, immediately flush skin with soap and plenty inated clothing and shoes. ntion.		
In ca	ase of eye contact	:	If in eyes, rinse	well with water.		
If sw	allowed	:	If swallowed, DC Get medical atte	ntion if irritation develops and persists. O NOT induce vomiting. ntion. roughly with water.		
	t important symptoms effects, both acute and yed	:	May cause canc May damage fer Causes damage exposure.			
Prote	ection 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			
Note	es to physician	:		ial for exposure exists (see section 8). tically and supportively.		
5. FIREF	IGHTING MEASURES					
Suita	able extinguishing media	:	Water spray Alcohol-resistan Carbon dioxide Dry chemical			
Unsu med	uitable extinguishing ia	:	None known.			
Spec fighti	cific hazards during fire- ing	:	concentrations, potential dust ex	g dust; fine dust dispersed in air in sufficient and in the presence of an ignition source is a plosion hazard. hbustion products may be a hazard to health.		
Haza ucts	ardous combustion prod-	:	Carbon oxides Metal oxides			

Use extinguishing measures that are appropriate to local cir-

Specific extinguishing meth- :



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ods		Use Rei so.	cumstances and the surrounding environment. Use water spray to cool unopened containers. Remove undamaged containers from fire area if it is safe t so. Evacuate area.				
	al protective equipment afighters			re, wear self-contained breathing apparatus. otective equipment.			
. ACCIDE	INTAL RELEASE MEAS	SURES					
tive ea	nal precautions, protec- quipment and emer- procedures	Fol	low safe han	otective equipment. dling advice (see section 7) and personal pro- nt recommendations (see section 8).			
Enviro	onmental precautions	Pre Rei Loc	event further l tain and disp	the environment. eakage or spillage if safe to do so. ose of contaminated wash water. s should be advised if significant spillages ined.			
	ods and materials for inment and cleaning up	tair Ave with Du es, lea Loo pos em mir See	Sweep up or vacuum up spillage and collect in suitable container for disposal. Avoid dispersal of dust in the air (i.e., clearing dust surfact with compressed air). Dust deposits should not be allowed to accumulate on surfact es, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration. Local or national regulations may apply to releases and diposal 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 regard certain local or national requirements.				
. HANDLI	ING AND STORAGE						
Hand	ling						
Techr	ical measures	cau Pro	ising an explo vide adequa	te precautions, such as electrical grounding			
Local/	Total ventilation	: Ifs	and bonding, or inert atmospheres. If sufficient ventilation is unavailable, use with local exhaust ventilation. Do not get on skin or clothing. Do not breathe dust. Do not swallow. Avoid contact with eyes. Wash skin thoroughly after handling.				
Advice	e on safe handling	: Do Do Do Avo					
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		nce of contact e measures		practice, based o sessment Keep container ti Minimize dust get Keep container c Keep away from Take precautiona Do not eat, drink Take care to prevenvironment. Oxidizing agents If exposure to che flushing systems place. When using do not Wash contaminat The effective ope engineering contr appropriate dego	neration and accumulation. losed when not in use. heat and sources of ignition. iry measures against static discharges. or smoke when using this product. rent spills, waste and minimize release to the emical is likely during typical use, provide eye and safety showers close to the working ot eat, drink or smoke. ted clothing before re-use. ration of a facility should include review of rols, proper personal protective equipment, wning and decontamination procedures, e monitoring, medical surveillance and the
;	Storag	e			
(Conditi	ons for safe storage	:	Store locked up. Keep tightly close	labelled containers. ed. nce with the particular national regulations.
I	Materia	als to avoid	:		the following product types:
I	Packag	jing material	:	Unsuitable mater	ial: 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 parame- ters / Concentra- tion standard / Permissible con- centration	Basis
17β-hydroxyestra-4,9,11-trien- 3-one 17-acetate	10161-34-9	TWA	0.2 µg/m3 (OEB 5)	Internal
		Wipe limit	2 µg/100 cm ²	Internal
Estradiol	50-28-2	TWA	0.05 µg/m3 (OEB 5)	Internal
	Further informa	ation: Skin		
		Wipe limit	0.5 µg/100 cm ²	Internal
Magnesium stearate	557-04-0	TWA (Inhal- able particu- late matter)	10 mg/m3	ACGIH



sion 0	Revision Date: 2024/09/28	SDS Number: 26111-00023		t issue: 2023/11/16 t issue: 2014/10/28	
			TWA (Res- pirable par- ticulate mat- ter)	3 mg/m3	ACGIH
Engir	neering measures	to control at vent leakage All engineer design and o protect prod No open har Totally enclo are required Operations r	processing system source (e.g., glov e of compounds ir ing controls shoul operated in accord ucts, workers, and ndling permitted. osed processes ar require the use of	ns or containment tere boxes/isolators) and to the workplace. d be implemented b dance with GMP prin d the environment. and materials transport appropriate contain akage of compound	nd to pre- y facility nciples to ort systems ment tech-
	onal protective equip				
Fil	iratory protection ter type protection	sure assess	ment demonstrate guidelines, use re	tilation is not availat es exposures outsid spiratory protection.	e the rec-
Ма	aterial	: Chemical-re	sistant gloves		
	emarks protection	: Wear safety If the work e mists or aero Wear a face	nvironment or act osols, wear the ap shield or other ful	e shields or goggles. ivity involves dusty opropriate goggles. I face protection if th he face with dusts,	conditions, here is a
Skin a	and body protection	: Work uniforr Additional be task being p posable suit	erformed (e.g., slo s) to avoid expose riate degowning te	uld be used based u eevelets, apron, gau	intlets, dis-

Physical state	:	powder
Colour	:	No data available
Odour	:	No data available
Odour Threshold	:	No data available
Melting point/freezing point	:	No data available



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	ing point, initial boiling nt and boiling range	:	No data available	e			
Flar	nmability (solid, gas)	:	May form explosive dust-air mixture during processing, han- dling or other means.				
Flar	nmability (liquids)	:	: No data available				
ι	Lower explosion limit and upper Upper explosion limit / Up- per flammability limit						
	_ower explosion limit / _ower flammability limit	:	No data available	e			
Flas	sh point	:	Not applicable				
Dec	composition temperature	:	No data available	e			
pН		:	No data available	e			
Eva	poration rate	:	No data available	e			
Auto	o-ignition temperature	:	No data available	e			
	cosity ⁄iscosity, kinematic	:	No data available	e			
	ubility(ies) Water solubility	:	No data available	e			
	tition coefficient: n- anol/water	:	No data available	e			
Vap	oour pressure	:	No data available	e			
	nsity and / or relative dens Relative density	ity :	No data available	e			
[Density	:	No data available	e			
Rela	ative vapour density	:	No data available	e			
Exp	losive properties	:	Not explosive				
Oxi	dizing properties	:	The substance o	r mixture is not classified as oxidizing.			
Mol	ecular weight	:	No data available	e			
Par	ticle characteristics						



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Particle size		:	No data available	9		
10. STAB	ILITY 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.			
Cond	litions to avoid	:	Heat, flames and Avoid dust forma			
	npatible materials rdous decomposition ucts	:	Oxidizing agents			
11. TOXIC	COLOGICAL INFORMAT		N			
Information on likely routes of exposure		:	Inhalation Skin contact Ingestion Eye contact			
Acute toxicity Not classified based on available information. Components:			information.			
	nydroxyestra-4,9,11-trie	en-3	-one 17-acetate:			
Acute	e oral toxicity	:	LD50 (Rat): > 5,0	00 mg/kg		
			LD50 (Mouse): 2,	700 mg/kg		
II Estra	idiol:					
Acute	e oral toxicity	:	LD50 (Rat): > 2,0	00 mg/kg		
Acute toxicity (other routes of administration)		:	LD50 (Rat): > 300 mg/kg Application Route: Subcutaneous			
Magr	Magnesium stearate:					
Acute	e oral toxicity	 LD50 (Rat): > 2,000 mg/kg Method: OECD Test Guideline 423 Assessment: The substance or mixture has no acute ora icity Remarks: Based on data from similar materials 		est Guideline 423 substance or mixture has no acute oral tox-		
Acute dermal toxicity : LD50 (Rabbit): > 2,000 mg/kg Remarks: Based on data from similar materia						



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Skin corrosion/irritation

Not classified based on available information.

Components:

Magnesium stearate:

Species : Result : Remarks :	Rabbit
Result :	No skin irritation
Remarks :	Based on data from similar materials

Serious eye damage/eye irritation

Not classified based on available information.

Components:

Estradiol:

Result

: No eye irritation

Magnesium stearate:

Species : Result : Remarks :	Rabbit
Result :	No eye irritation
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:

Estradiol:

: Skin contact
: Guinea pig
: Does not cause skin sensitisation.
: negative

Magnesium stearate:

Test Type	: Maximisation Test
Exposure routes	: Skin contact
Species	: Guinea pig
Method	: OECD Test Guideline 406
Result	: negative
Species Method Result Remarks	: Based on data from similar materials

Germ cell mutagenicity

Not classified based on available information.



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Components:

17β-hydroxyestra-4,9,11-trien-3-one 17-acetate:						
Genotoxicity in vitro	:	Test Type: Bacterial reverse mutation assay (AMES) Test system: Salmonella typhimurium Result: negative				
		Test Type: Micronucleus test Test system: Chinese hamster fibroblasts Result: negative				
Genotoxicity in vivo	:	Test Type: Micronucleus test Species: Mouse Result: negative				
		Test Type: Micronucleus test Species: Rat Result: negative				
Germ cell mutagenicity - Assessment	:	Weight of evidence does not support classification as a germ cell mutagen.				
Estradiol:						
Genotoxicity in vitro	:	Test Type: DNA damage and repair, unscheduled DNA syn- thesis in mammalian cells (in vitro) Test system: mammalian cells Result: positive				
		Test Type: Chromosome aberration test in vitro Test system: mammalian cells Result: positive				
		Test Type: Chromosomal aberration Test system: mammalian cells Result: positive				
Genotoxicity in vivo	:	Test Type: Chromosomal aberration Species: Rat Cell type: Bone marrow Result: negative				
		Test Type: Chromosomal aberration Species: Mouse Cell type: Bone marrow Result: negative				
Magnesium stearate:						
Genotoxicity in vitro	:	Test Type: In vitro mammalian cell gene mutation test Result: negative Remarks: Based on data from similar materials				



Test Type: Chromosome aberration test in vitro Method: OECD Test Guideline 473 Result: negative Remarks: Based on data from similar materials Test Type: Bacterial reverse mutation assay (AMES) Result: negative Remarks: Based on data from similar materials Carcinogenicity May cause cancer. Components: 17β-hydroxyestra-4,9,11-trien-3-one 17-acetate: Species : Mouse, male and female Application Route : Oral Result : positive Target Organs : Liver Species : Rat, male and female Application Route : Oral Result : positive Target Organs : Liver Species : Mouse Application Route : Oral Result : positive Target Organs : Liver Species : Mouse Application Route : Ingestion Extradiol: : Species Species : Mouse Application Route : Ingestion Exposure time : 24 Months LOAEL : 100 µg/kg Result : positive Target Organs : Endocrine system	ersion 1.0	Revision Date: 2024/09/28		Number: I-00023	Date of last issue: 2023/11/16 Date of first issue: 2014/10/28
Method: OECD Test Guideline 473 Result: negative Remarks: Based on data from similar materials Test Type: Bacterial reverse mutation assay (AMES) Result: negative Remarks: Based on data from similar materials Carcinogenicity May cause cancer. Components: 17β-hydroxyestra-4,9,11-trien-3-one 17-acetate: Species Application Route Coral Result Species Itage Organs Exercision Route Species Itage Organs Estradiot Species Carcinogenicity - Assess- Mouse Application Route Itaget Organs Estradiol: Species Species Estradiol: Species Species Result Exposure time Exposure time Exposure time Species Result Species Exposure time Exposure time Exposure time Exposure time Species Result Exposure time					
Method: OECD Test Guideline 473 Result: negative Remarks: Based on data from similar materials Test Type: Bacterial reverse mutation assay (AMES) Result: negative Remarks: Based on data from similar materials Carcinogenicity May cause cancer. Components: 17β-hydroxyestra-4,9,11-trien-3-one 17-acetate: Species Application Route Coral Result Species Itage Organs Exercision Route Species Itage Organs Estradiot Species Carcinogenicity - Assess- Mouse Application Route Itaget Organs Estradiol: Species Species Estradiol: Species Species Result Exposure time Exposure time Exposure time Species Result Species Exposure time Exposure time Exposure time Exposure time Species Result Exposure time					
Result: negative Remarks: Based on data from similar materials Test Type: Bacterial reverse mutation assay (AMES) Result: negative Remarks: Based on data from similar materials Carcinogenicity May cause cancer. Components: 17β-hydroxyestra-4,9,11-trien-3-one 17-acetate: Species : Mouse, male and female Application Route : Oral Result : positive Target Organs : Liver Species : Rat, male and female Application Route : Oral Result : positive Target Organs : Liver Species : Rat, male and female Application Route : Oral Result : positive Target Organs : Liwited evidence of carcinogenicity in animal studies ment : Estradiol: Species : Mouse Application Route : Ipositive Target Organs : Emale reproductive organs Exposure time : 24 Months LOAEL : 20 mg/kg body weight Result : positive					
Remarks: Based on data from similar materials Test Type: Bacterial reverse mutation assay (AMES) Result: negative Remarks: Based on data from similar materials Carcinogenicity May cause cancer. Components: 17β-hydroxyestra-4,9,11-trien-3-one 17-acetate: Species : Mouse, male and female Application Route Application Route : Oral Result Result : positive Target Organs Species : Rat, male and female Application Route Application Route : Oral Result Result : positive Target Organs Target Organs : Liver Species : Mouse Application Route Carcinogenicity - Assess- ment : Limited evidence of carcinogenicity in animal studies ment Species : Mouse Application Route Species : Matheresult Species : Rat Application Route Application Route : Subcutaneous Exposure time Exposure time <t< td=""><td></td><td></td><td></td><td></td><td></td></t<>					
Test Type: Bacterial reverse mutation assay (AMES) Result: negative Remarks: Based on data from similar materials Carcinogenicity May cause cancer. Components: 17β-hydroxyestra-4,9,11-trien-3-one 17-acetate: Species : Mouse, male and female Application Route : Carcinogenicity Species : Mouse, male and female Application Route : Species : Result : Species : Result : Species : Application Route : Carcinogenicity - Assess- : Limited evidence of carcinogenicity in animal studies ment : Species : Application Route : Ingestion Exposure time : Exposure time : Exposure time : Species : Result : Target Organs : Species : Result : a					
Result: negative Remarks: Based on data from similar materials Carcinogenicity May cause cancer. Components: 17β-hydroxyestra-4,9,11-trien-3-one 17-acetate: Species Mouse, male and female Application Route : Target Organs : Liver Species : Application Route : Oral Result : Target Organs : Liver Species : Application Route : Target Organs : Pancreas Carcinogenicity - Assess- : Limited evidence of carcinogenicity in animal studies ment Estradiol: Species : Species : Application Route : Ingestion Exposure time : Exposure time : Species : Result : Target Organs : Species : Result :					
Carcinogenicity May cause cancer. Components: 17β-hydroxyestra-4,9,11-trien-3-one 17-acetate: Species : May cause cancer. Species : Mouse, male and female Application Route : Oral Result : Target Organs : Liver Species : Application Route : Application Route : Oral Result : Target Organs : Pancreas Carcinogenicity - Assess- : Limited evidence of carcinogenicity in animal studies ment Species : Mouse Application Route : Ingestion Extradiol: Species : Species : Application Route : Ingestion Exposure time : Species : Result : Applicatio					
Carcinogenicity May cause cancer. Components: 17β-hydroxyestra-4,9,11-trien-3-one 17-acetate: Species Mouse, male and female Application Route : May cause cancer. Species : Application Route : Species : Species : Application Route : Oral Result : Species : Application Route : Carcinogenicity - Assess- : Limited evidence of carcinogenicity in animal studies ment Species : Species : Mouse Application Route : Ingestion Application Route : Ingestion Exposure time : Exposure time : Exposure time : Species : Result : Target Organs : female reproductive organs Species :					
May cause cancer. Components: 17β-hydroxyestra-4,9,11-trien-3-one 17-acetate: Species : Mouse, male and female Application Route : Oral Result : positive Target Organs : Liver Species : Rat, male and female Application Route : Oral Result : positive Target Organs : Pancreas Carcinogenicity - Assess- : Limited evidence of carcinogenicity in animal studies ment Estradiol: Species : Mouse Application Route : Ingestion Exposure time : 24 Months LOAEL : 100 µg/kg Result : positive Target Organs : female reproductive organs Species : Rat Application Route : Subcutaneous Exposure time : 13 weeks LOAEL : 20 mg/kg body weight Result : positive Target Organs : Endocrine system Carcinogenicity - Assess- : Positive evidence from human epidemiological studies ment Parceas Application Route : Endocrine system Carcinogenicity - Assess- : Positive evidence from human epidemiological studies ment Application Route toxicity May damage fertility. May damage the unborn child. Components:				ciliaiks. Das	
Components: 17β-hydroxyestra-4,9,11-trien-3-one 17-acetate: Species : Application Route : Target Organs : Liver Species : Application Route : Species : Result : Species : Result : Species : Result : Target Organs : Variance : Carcinogenicity - Assess- : Limited evidence of carcinogenicity in animal studies ment : Species : Application Route : Ingestion Application Route : Ingestion Exposure time : Ingestion Exposure time : Ingestion Result : Species : Application Route : Species : Application Route : Subcutaneou					
Tβ-hydroxyestra-4,9,11-trien-3-one 17-acetate: Species : Application Route : Oral Result : Target Organs : Liver Species : Result : Species : Result : Species : Result : Species : Result : Pancreas Carcinogenicity - Assess- : Limited evidence of carcinogenicity in animal studies ment Species : Species : Application Route : Ingestion Result : Species : Mouse Application Route : Species : Result : DOAEL : Positive Target Organs : Result : Application Route : Subcutaneous	May o	cause cancer.			
Species : Mouse, male and female Application Route : Oral Result : positive Target Organs : Liver Species : Rat, male and female Application Route : Oral Result : positive Target Organs : Pancreas Carcinogenicity - Assess- : Limited evidence of carcinogenicity in animal studies ment : Pancreas Species : Mouse Application Route : Ingestion Extradiol: : Species Species : Mouse Application Route : Ingestion Exposure time : 24 Months LOAEL : 100 µg/kg Result : positive Target Organs : female reproductive organs Species : Rat Application Route : Subcutaneous Exposure time : 13 weeks LOAEL	Com	ponents:			
Application Route : Oral Result Result : positive positive Target Organs : Liver Species : Rat, male and female Application Route : Result : positive Target Organs : Pancreas Carcinogenicity - Assess- ment : Limited evidence of carcinogenicity in animal studies Species : Mouse Application Route : Ingestion Exposure time : 24 Months LOAEL : 100 µg/kg Result : positive Target Organs : female reproductive organs Species : Rat Application Route : Subcutaneous Exposure time : 13 weeks LOAEL : 20 mg/kg body weight Result : positive Target Organs : Endocrine system LOAEL : 20 mg/kg body weight Result : positive Target Organs : <	17β-ł	nydroxyestra-4,9,11-ti	rien-3-or	ne 17-acetat	e:
Result : positive Target Organs : Liver Species : Rat, male and female Application Route : Oral Result : positive Target Organs : Pancreas Carcinogenicity - Assess- : Limited evidence of carcinogenicity in animal studies ment : Species : Species : Mouse Application Route : Ingestion Estradiol: : 100 µg/kg Result : positive Target Organs : female reproductive organs LOAEL : 100 µg/kg Result : positive Target Organs : female reproductive organs Species : Rat Application Route : Subcutaneous Exposure time : 13 weeks LOAEL : 20 mg/kg body weight Result : positive Target Organs : Endocrine system			: M	ouse, male a	and female
Target Organs : Liver Species : Rat, male and female Application Route : Oral Result : positive Target Organs : Pancreas Carcinogenicity - Assess- : Limited evidence of carcinogenicity in animal studies ment : Species : Species : Mouse Application Route : Ingestion Exposure time : 24 Months LOAEL : 100 µg/kg Result : positive Target Organs : female reproductive organs Species : Rat Application Route : Subcutaneous Exposure time : 13 weeks LOAEL : 20 mg/kg body weight Result : positive Target Organs : Endocrine system Carcinogenicity - Assess- : Positive evidence from human epidemiological studies ment : ment : Result					
Species : Rat, male and female Application Route : Oral Result : positive Target Organs : Pancreas Carcinogenicity - Assess- ment : Limited evidence of carcinogenicity in animal studies Species : Mouse Application Route : Ingestion Exposure time : 24 Months LOAEL : 100 µg/kg Result : positive Target Organs : female reproductive organs Species : Rat Application Route : positive Target Organs : female reproductive organs Species : Rat Application Route : Subcutaneous Exposure time : 13 weeks LOAEL : 20 mg/kg body weight Result : positive Target Organs : Endocrine system Carcinogenicity - Assess- : Positive evidence from human epidemiological studies ment					
Application Route : Oral Result : positive Target Organs : Pancreas Carcinogenicity - Assessment : Limited evidence of carcinogenicity in animal studies Estradiol: Species : Limited evidence of carcinogenicity in animal studies Species : Mouse Application Route : Application Route : Ingestion Exposure time : Exposure time : : 24 Months LOAEL : LOAEL : 100 µg/kg Result : positive Target Organs : female reproductive organs : : Species : Rat Application Route : Subcutaneous : : Exposure time : : 13 weeks : LOAEL : 20 mg/kg body weight Result : : positive : Target Organs : Endocrine system Carcinogenicity - Assess-ment : : Positive evidence from human epidemiological studies ment	Targe	et Organs	. LI	ver	
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Target Organs:PancreasCarcinogenicity - Assess- ment:Limited evidence of carcinogenicity in animal studiesEstradiol:Species:MouseApplication Route:IngestionExposure time:24 MonthsLOAEL:100 µg/kgResult:positiveTarget Organs:female reproductive organsSpecies:RatApplication Route:SubcutaneousExposure time:13 weeksLOAEL:20 mg/kg body weightResult:positiveTarget Organs:Endocrine systemCAEL:20 mg/kg body weightResult:positiveTarget Organs:Endocrine systemCarcinogenicity - Assess- ment:Positive evidence from human epidemiological studies mentReproductive toxicity May damage fertility. May damage the unborn child.Components:17β-hydroxyestra-4,9,11-trien-3-one 17-acetate::					
Carcinogenicity - Assess- : Limited evidence of carcinogenicity in animal studies ment Estradiol: Species : Mouse Application Route : Ingestion Exposure time : 24 Months LOAEL : 100 µg/kg Result : positive Target Organs : female reproductive organs Species : Rat Application Route : Subcutaneous Exposure time : 13 weeks LOAEL : 20 mg/kg body weight Result : positive Target Organs : Endocrine system Carcinogenicity - Assess- : Positive evidence from human epidemiological studies ment Reproductive toxicity May damage the unborn child. Components: 17β-hydroxyestra-4,9,11-trien-3-one 17-acetate: 17/acetate:					
ment Estradiol: Species : Mouse Application Route : Ingestion Exposure time : 24 Months LOAEL : 100 µg/kg Result : positive Target Organs : female reproductive organs Species : Rat Application Route : Subcutaneous Exposure time : 13 weeks LOAEL : 20 mg/kg body weight Result : positive Target Organs : Endocrine system Carcinogenicity - Assess- : Positive evidence from human epidemiological studies ment Reproductive toxicity May damage fertility. May damage the unborn child. Components: 17β-hydroxyestra-4,9,11-trien-3-one 17-acetate: 17-acetate:	Taiye	et Organs	. го	ancieas	
Species : Mouse Application Route : Ingestion Exposure time : 24 Months LOAEL : 100 µg/kg Result : positive Target Organs : female reproductive organs Species : Rat Application Route : Subcutaneous Exposure time : 13 weeks LOAEL : 20 mg/kg body weight Result : positive Target Organs : Endocrine system Carcinogenicity - Assess- : Positive evidence from human epidemiological studies ment Reproductive toxicity May damage the unborn child. Components: 17β-hydroxyestra-4,9,11-trien-3-one 17-acetate:		nogenicity - Assess-	: Li	mited evider	ce of carcinogenicity in animal studies
Application Route : Ingestion Exposure time : 24 Months LOAEL : 100 µg/kg Result : positive Target Organs : female reproductive organs Species : Rat Application Route : Subcutaneous Exposure time : 13 weeks LOAEL : 20 mg/kg body weight Result : positive Target Organs : Endocrine system Carcinogenicity - Assess- : Positive evidence from human epidemiological studies ment Reproductive toxicity May damage fertility. May damage the unborn child. Components: 17β-hydroxyestra-4,9,11-trien-3-one 17-acetate:	Estra	diol:			
Exposure time : 24 Months LOAEL : 100 μg/kg Result : positive Target Organs : female reproductive organs Species : Rat Application Route : Subcutaneous Exposure time : 13 weeks LOAEL : 20 mg/kg body weight Result : positive Target Organs : Endocrine system Carcinogenicity - Assess- : Positive evidence from human epidemiological studies ment Reproductive toxicity May damage fertility. May damage the unborn child. Components: 17β-hydroxyestra-4,9,11-trien-3-one 17-acetate:	Speci	ies	: M	ouse	
LOAEL : 100 μg/kg Result : positive Target Organs : female reproductive organs Species : Rat Application Route : Subcutaneous Exposure time : 13 weeks LOAEL : 20 mg/kg body weight Result : positive Target Organs : Endocrine system Carcinogenicity - Assess- ment : Positive evidence from human epidemiological studies Reproductive toxicity May damage fertility. May damage the unborn child. Components: 17β-hydroxyestra-4,9,11-trien-3-one 17-acetate:	_		: In	gestion	
Result : positive Target Organs : female reproductive organs Species : Rat Application Route : Subcutaneous Exposure time : 13 weeks LOAEL : 20 mg/kg body weight Result : positive Target Organs : Endocrine system Carcinogenicity - Assess- : Positive evidence from human epidemiological studies Reproductive toxicity May damage fertility. May damage the unborn child. Components: 17β-hydroxyestra-4,9,11-trien-3-one 17-acetate:					
Target Organs:female reproductive organsSpecies:RatApplication Route:SubcutaneousExposure time:13 weeksLOAEL:20 mg/kg body weightResult:positiveTarget Organs:Endocrine systemCarcinogenicity - Assess-:Positive evidence from human epidemiological studiesmentReproductive toxicityMay damage fertility. May damage the unborn child.Components:17β-hydroxyestra-4,9,11-trien-3-one 17-acetate:					
Application Route : Subcutaneous Exposure time : 13 weeks LOAEL : 20 mg/kg body weight Result : positive Target Organs : Endocrine system Carcinogenicity - Assess- ment : Positive evidence from human epidemiological studies Reproductive toxicity May damage fertility. May damage the unborn child. Components: 17β-hydroxyestra-4,9,11-trien-3-one 17-acetate: :					uctive organs
Application Route : Subcutaneous Exposure time : 13 weeks LOAEL : 20 mg/kg body weight Result : positive Target Organs : Endocrine system Carcinogenicity - Assess- ment : Positive evidence from human epidemiological studies Reproductive toxicity May damage fertility. May damage the unborn child. Components: 17β-hydroxyestra-4,9,11-trien-3-one 17-acetate: :	Speci	ies	: R	at	
LOAEL : 20 mg/kg body weight Result : positive Target Organs : Endocrine system Carcinogenicity - Assess- : Positive evidence from human epidemiological studies ment Reproductive toxicity May damage fertility. May damage the unborn child. Components: 17β-hydroxyestra-4,9,11-trien-3-one 17-acetate:	Appli	cation Route			
Result : positive Target Organs : Endocrine system Carcinogenicity - Assess- : Positive evidence from human epidemiological studies ment Reproductive toxicity May damage fertility. May damage the unborn child. Components: 17β-hydroxyestra-4,9,11-trien-3-one 17-acetate:					
Target Organs : Endocrine system Carcinogenicity - Assess- : Positive evidence from human epidemiological studies ment Reproductive toxicity May damage fertility. May damage the unborn child. Components: 17β-hydroxyestra-4,9,11-trien-3-one 17-acetate:					/ weight
Carcinogenicity - Assess- : Positive evidence from human epidemiological studies ment Reproductive toxicity May damage fertility. May damage the unborn child. <u>Components:</u> 17β-hydroxyestra-4,9,11-trien-3-one 17-acetate:					tem
ment Reproductive toxicity May damage fertility. May damage the unborn child. Components: 17β-hydroxyestra-4,9,11-trien-3-one 17-acetate:		U		accine sys	
May damage fertility. May damage the unborn child. <u>Components:</u> 17β-hydroxyestra-4,9,11-trien-3-one 17-acetate:		nogenicity - Assess-	: Po	ositive evide	nce from human epidemiological studies
<u>Components:</u> 17β-hydroxyestra-4,9,11-trien-3-one 17-acetate:		-	amage th	ne unborn ch	ild.
17β-hydroxyestra-4,9,11-trien-3-one 17-acetate:	•				
			ion_?_or	na 17-acatat	o.



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		Species: Rat Application F	
Effec	ts on foetal develop-	Result: Posti	mplantation loss.
ment	•	Species: Rat Application F Developmen	
Reprosessor	oductive toxicity - As- nent	fertility, base	nce of adverse effects on sexual function and d on animal experiments., Some evidence of cts on development, based on animal experi-
Estra	adiol:		
Effec	ts on fertility	Species: Rat Application F	Route: Ingestion NEL: 0.5 mg/kg body weight
		Species: Rat Duration of S	Single Treatment: 90 d NEL: 0.69 mg/kg body weight
		Species: Mo Application F	Route: Oral \EL: 0.1 mg/kg body weight
Effec ment	ts on foetal develop-	Species: Mo Application F Teratogenici Symptoms: N	imbryo-foetal development use, female Route: Subcutaneous ty: LOAEL: 4 mg/kg body weight Malformations were observed. ive, Teratogenic effects
		Species: Rat Application F Teratogenici Symptoms: F Result: posit	Dne-generation reproduction toxicity study Route: Subcutaneous ty: LOAEL: 2.5 µg/kg body weight Reduced body weight ive, Embryotoxic effects and adverse effects on were detected.
		Test Type: E Species: Rat	mbryo-foetal development



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			Symptoms: Early number of viable Result: Embryoto	e: Subcutaneous oxicity: LOAEL: 0.2 mg/kg body weight Resorptions / resorption rate, Reduced fetuses, Reduced body weight xic effects and adverse effects on the off- cted only at high maternally toxic doses
Reproductive toxicity - As- sessment		:	: May damage fertility. May damage the unborn child.	
Magn	esium stearate:			
Effect	s on fertility	:	reproduction/deve Species: Rat Application Route Method: OECD T Result: negative	ined repeated dose toxicity study with the elopmental toxicity screening test e: Ingestion est Guideline 422 on data from similar materials
Effect ment	s on foetal develop-	:	Species: Rat Application Route Result: negative	vo-foetal development e: Ingestion on data from similar materials
	- single exposure		information	

Not classified based on available information.

STOT - repeated exposure

Causes damage to organs (Liver, Bone, Blood, Endocrine system) through prolonged or repeated exposure.

Causes damage to organs (Endocrine system, Blood) through prolonged or repeated exposure if swallowed.

Components:

17β-hydroxyestra-4,9,11-trien-3-one 17-acetate:

Exposure routes	: Ingestion
Target Organs	: Endocrine system, Blood
Target Organs Assessment	: Causes damage to organs through prolonged or repeated
	exposure.

Estradiol:

• •	Liver, Bone, Blood, Endocrine system Causes damage to organs through prolonged or repeated exposure.
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Repeated dose toxicity

Components:

17β-hydroxyestra-4,9,11-trien-3-one 17-acetate:



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	ΞL	: Pig : 0.004 mg/kg : 0.08 mg/kg : 14 Weeks : Testis, Ovary,	Liver, Uterus (including cervix)	
Expos	ΞL	: Rat : 0.04 mg/kg : 3.6 mg/kg : Oral : 23 Weeks : Blood		
Expo	ΞL	: Monkey, fema : 0.01 mg/kg : 0.04 mg/kg : Oral : 122 Days : female reprode		
Expos	ΞL	: Monkey, male : 0.002 mg/kg : 0.04 mg/kg : Oral : 30 Days : male reproduc		
Expo	ΞL	: Rat : 0.05 mg/kg : 0.1 mg/kg : Oral : 3 Months : male reproduc	tive organs, Ovary, Uterus (including cervix)	
Expo	es		nd, Ovary, Uterus (including cervix), Liver, Bone tem, Blood, Testis	
Speci NOAE Applic	EL cation Route sure time	: Rat : > 100 mg/kg : Ingestion : 90 Days : Based on data	a from similar materials	



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Aspiration toxicity

Not classified based on available information.

Experience with human exposure

Components:

Ingestion	:	Symptoms: male reproductive effects, gynecomastia, changes in libido
Estradiol:		
Inhalation	:	Symptoms: tingling, Nose bleeding
Skin contact	:	Symptoms: Skin irritation, Redness, pruritis
Ingestion	:	Symptoms: Headache, Gastrointestinal disturbance, Dizzi- ness, Vomiting, Diarrhoea, water retention, liver function change, changes in libido, breast tenderness, menstrual irreg- ularities

12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

17β-hydroxyestra-4,9,11-trien-3-one 17-acetate:

Toxicity to fish (Chronic tox- icity)	:	NOEC (Pimephales promelas (fathead minnow)): 0.000035 mg/l Exposure time: 21 d Method: OECD Test Guideline 229 Remarks: Based on data from similar materials
M-Factor (Chronic aquatic toxicity)	:	1,000
Estradiol:		
Toxicity to fish	:	LC50 (Oryzias latipes (Japanese medaka)): 3.9 mg/l Exposure time: 96 h
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia magna (Water flea)): 2.7 mg/l Exposure time: 48 h
Toxicity to algae/aquatic plants	:	NOEC (Pseudokirchneriella subcapitata (green algae)): 1.7 mg/l Exposure time: 72 h Method: OECD Test Guideline 201
		EC50 (Pseudokirchneriella subcapitata (green algae)): > 1.7 mg/l



rsion .0	Revision Date: 2024/09/28		S Number: 111-00023	Date of last issue: 2023/11/16 Date of first issue: 2014/10/28
п			Exposure time: 7	2 h
			Exposure time: 7 Method: OECD T	est Guideline 201
Toxicity)	y to fish (Chronic tox-	:	Exposure time: 1	atipes (Japanese medaka)): 0.000003 mg/l 60 d ⁻ est Guideline 210
	y to daphnia and other c invertebrates (Chron-	:	NOEC (Daphnia Exposure time: 2	magna (Water flea)): 0.2 mg/l 1 d
	tor (Chronic aquatic	:	1,000	
	y to microorganisms	:	EC50: > 100 mg/ Exposure time: 3 Test Type: Respi Method: OECD T	h
			NOEC: 100 mg/l Exposure time: 3 Test Type: Respi Method: OECD T	
Magne	esium stearate:			
Toxicit	y to fish	:	Exposure time: 4 Method: DIN 384	
	y to daphnia and other c invertebrates	:	Exposure time: 4 Test substance: Method: Directive	Water Accommodated Fraction e 67/548/EEC, Annex V, C.2. on data from similar materials
Toxicit plants	y to algae/aquatic	:	mg/l Exposure time: 7 Test substance: ¹ Method: OECD 1	Water Accommodated Fraction Fest Guideline 201 on data from similar materials
			mg/l Exposure time: 7 Test substance: Method: OECD 1	kirchneriella subcapitata (green algae)): > 1 2 h Water Accommodated Fraction ⁻ est Guideline 201 on data from similar materials
Toxicit	y to microorganisms	:	EC10 (Pseudome Exposure time: 1	onas putida): > 100 mg/l 6 h



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			Tost substans	e: Water Accommodated Fraction
				ed on data from similar materials
Persi	stence and degradabil	lity		
Com	oonents:			
Estra	diol:			
Biode	gradability	:	Result: rapidly Biodegradatio Exposure time	n: 84 %
Magn	esium stearate:			
Biode	gradability	:	Result: Not bio Remarks: Bas	odegradable ed on data from similar materials
Bioad	ccumulative potential			
<u>Com</u>	oonents:			
17β-h	nydroxyestra-4,9,11-tri	en-3	one 17-acetat	e:
	ion coefficient: n- ol/water	:	log Pow: 3.77	
Estra				
	ion coefficient: n- ol/water	:	log Pow: 4.01	
Magn	esium stearate:			
	ion coefficient: n- ol/water	:	log Pow: > 4	
Mobi	lity in soil			
<u>Comp</u>	ponents:			
Estra	diol:			
	bution among environ- al compartments	:	log Koc: 3.81	
	rdous to the ozone lay pplicable	er		
	r adverse effects ata available			
DISPO	SAL CONSIDERATION	NS		

Waste from residues	:	Dispose of in accordance with local regulations.
		Do not dispose of waste into sewer.
Contaminated packaging	:	Empty containers should be taken to an approved waste han-



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			dling site for recyc If not otherwise sp	cling or disposal. becified: Dispose of as unused product.
14. TRAN	SPORT INFORMATION			
Interr	national Regulations			
	r DG umber er shipping name	:	N.O.S.	ALLY HAZARDOUS SUBSTANCE, SOLID,
Label	ng group	: :	9 III 9 yes	vdroxyestra-4,9,11-trien-3-one 17-acetate)
IATA - UN/ID Prope		:		azardous substance, solid, n.o.s.
Label Packi	ng group s ng instruction (cargo	::	9 III Miscellaneous 956	vdroxyestra-4,9,11-trien-3-one 17-acetate)
ger ai	ng instruction (passen- rcraft)	:	956	
IMDG UN nu	onmentally hazardous - Code umber er shipping name	:	N.O.S.	ALLY HAZARDOUS SUBSTANCE, SOLID,
Label EmS	ng group s	:	(Estradiol, 17β-hy 9 III 9 F-A, S-F yes	droxyestra-4,9,11-trien-3-one 17-acetate)
Packi Label EmS Marin	ng group s Code e pollutant	: : : :	III 9 F-A, S-F yes	OI 73/78 and the IBC Code

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

: 171

Not applicable for product as supplied.

National Regulations

Refer to section 15 for specific national regulation.

Special precautions for user

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

ERG Code
ERG Code



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15. REGULATORY INFORMATION

Related Regulations

Fire Service Law

Not applicable to dangerous materials / designated flammables.

Chemical Substance Control Law

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

Industrial Safety and Health Law

Harmful Substances Prohibited from Manufacture

Not applicable

Harmful Substances Required Permission for Manufacture

Not applicable

Substances Prevented From Impairment of Health

Not applicable

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

Not applicable

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

Not applicable

Substances Subject to be Notified Names

Article 57-2 (Enforcement Order Table 9)

Chemical name	Concentration (%)	Remarks
Magnesium stearate	>=1 - <10	-

Substances Subject to be Indicated Names

Article 57 (Enforcement Order Article 18)

Chemical name	Remarks
Magnesium stearate	-

Skin and Eye Damage Substances for PPE Requirements (ISHL MO Art. 594-2) Not applicable

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

Not applicable

Ordinance on Prevention of Hazards Due to Specified Chemical Substances

Not applicable

Ordinance on Prevention of Lead Poisoning

Not applicable

Ordinance on Prevention of Tetraalkyl Lead Poisoning

Not applicable



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	ance on Prevention	n of Organic Solvent	Poisoning	
Subs	tances)	e Industrial Safety ar	nd Health Law - Attached table 1 (Dangerou	
Poisc	oplicable onous and Deleteric oplicable	ous Substances Cont	rol Law	
Act o viron	n Confirmation, etc		s of Specific Chemical Substances in the E o the Management Thereof	
-	Pressure Gas Safet	y Act		
	sive Control Law			
Not a	oplicable			
Vess	el Safety Law			
		substances and article nd its Attached Table	es (Article 2 and 3 of rules on shipping and sto 1)	
Misce	ion Law Ilaneous dangerous aw and its Attached		es (Article 194 of The Enforcement Rules of A	
Marin	e Pollution and Sea	a Disaster Prevention	etc Law	
Bulk t	ransportation	: Not classified	as noxious liquid substance	
	transportation		narine pollutant	
Narco	otics and Psychotro	pics Control Act		
		Raw Material (Export / I	Import Permission)	
Not applicable Specific Narcotic or Psychotropic Raw Material (Export / Import permission) Not applicable				
	e Disposal and Pub trial waste	lic Cleansing Law		
The c	omponents of this	product are reported	in the following inventories:	
AICS		: not determine	d	
DSL		: not determine	d	
IECS	0	: not determine	d	
	R INFORMATION			

In this SDS, if the concentration of substances subject to notification under the Industrial Safety and Health Law is indicated as a range, it includes cases where it is a trade secret.



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Further information

Sources of key data used to	:	Internal technical data, data from raw material SDSs, OECD
compile the Safety Data		eChem Portal search results and European Chemicals Agen-
Sheet		cy, 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)		
ACGIH / TWA	:	8-hour, time-weighted average		

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

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text.



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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