

Proligestone Formulation

Commission Regulation (EU) 2020/878

Version	Revision Date:	SDS Number:	Date of last issue: 06.04.2024
2.15	28.09.2024	3068874-00017	Date of first issue: 07.08.2018

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1	Product	identifier

Trade name : Proligestone Formulation

Other means of identification : Delvosteron (A004103)

1.2 Relevant identified uses of the substance or mixture and uses advised against

Use of the Sub- stance/Mixture	:	Pharmaceutical			
Recommended restrictions on use	:	Not applicable			
B Details of the supplier of the safety data sheet					

1.3

Company	:	MSD Kilsheelan Clonmel Tipperary, IE
Telephone	:	353-51-601000
E-mail address of person responsible for the SDS	:	EHSDATASTEWARD@msd.com

1.4 Emergency telephone number

1-908-423-6000

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008)

Carcinogenicity, Category 2	
Reproductive toxicity, Category 1B	

H351: Suspected of causing cancer. H360D: May damage the unborn child.

2.2 Label elements

Labelling (REGULATIO	ON (EC) No 1272/2008)
Hazard nictograms	

Hazard pictograms		•	
Signal word	: Danger		
Hazard statements	: H351	Suspected of causing cancer.	

Hazard statements

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



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		H360D	May damage the unborn child.
Preca	utionary statements	: Prevention	:
		P201 P280	Obtain special instructions before use. Wear protective gloves/ protective clothing/ eye protection/ face protection.
		Response:	
		P308 + P31	3 IF exposed or concerned: Get medical advice/ attention.
		Storage:	
		P405	Store locked up.

Hazardous components which must be listed on the label:

Proligestone

2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

Ecological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Toxicological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Components

Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
Proligestone	23873-85-0 245-922-6	Acute Tox. 4; H302 Carc. 2; H351 Repr. 1B; H360D STOT RE 2; H373 (Adrenal gland, Ova- ry, Uterus (including cervix))	>= 1 - < 10

For explanation of abbreviations see section 16.



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SECTION 4: First aid measures

4.1 Description of first aid measu	4.1 Description of 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.				
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).				
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.				
4.2 Most important symptoms and effects, both acute and delayed						
Risks	:	Suspected of causing cancer. May damage the unborn child.				

4.3 Indication of any immediate medical attention and special treatment needed

Treatment

: Treat symptomatically and supportively.

SECTION 5: Firefighting measures

5.1 Extinguishing media		
Suitable extinguishing media		Water spray Alcohol-resistant foam Carbon dioxide (CO2) Dry chemical
Unsuitable extinguishing media	:	None known.



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5.2 S	pecial	hazards arising from	the	e substance or mi	xture
Specific hazards during fire- fighting		:	Exposure to com	pustion products may be a hazard to health.	
	Hazardous combustion prod- ucts		:	Carbon oxides Metal oxides	
5.3 A	dvice	for firefighters			
	Special protective equipment for firefighters		:		e, wear self-contained breathing apparatus. tective equipment.
	Specifi ods	c extinguishing meth-	:	cumstances and t Use water spray t	measures that are appropriate to local cir- he surrounding environment. o cool unopened containers. ged containers from fire area if it is safe to do

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions	:	Use personal protective equipment. Follow safe handling advice (see section 7) and personal pro- tective equipment recommendations (see section 8).
6.2 Environmental precautions		
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.

6.3 Methods and material for containment and cleaning up

Methods for 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. 	

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



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6.4 Reference to other sections

See sections: 7, 8, 11, 12 and 13.

SECTION 7: Handling and storage

7.1 Precautions for safe 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 breathe mist or vapours. 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 as- sessment Keep container tightly closed. Take care to prevent spills, waste and minimize release to the environment.					
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 contami- nated 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.					
7.2 Conditions for safe storage,	incl	luding any incompatibilities					
Requirements for storage areas and containers	:	Keep in properly labelled containers. Store locked up. Keep tightly closed. Store in accordance with the particular national regulations.					
Advice on common storage	:	Do not store with the following product types: Strong oxidizing agents Self-reactive substances and mixtures Organic peroxides Explosives Gases					
7.3 Specific end use(s)							
Specific use(s)	:	No data available					
		No data available					



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SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational Exposure Limits

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
Proligestone	23873-85-0	TWA	5 ug/m3 (OEB 4)	Internal
		Wipe limit	50 ug/100cm2	Internal

8.2 Exposure controls

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.

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

Eye/face 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.
hand protection		
Material	:	Chemical-resistant gloves
Remarks Skin and body protection	:	Consider double gloving. Work uniform or laboratory coat. Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, dis- posable suits) to avoid exposed skin surfaces. Use appropriate degowning techniques to remove potentially contaminated clothing.
Respiratory protection Filter type	:	If adequate local exhaust ventilation is not available or expo- sure assessment demonstrates exposures outside the rec- ommended guidelines, use respiratory protection. Equipment should conform to I.S. EN 143 Particulates type (P)

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Physical state	: Aqueous solution
Colour	: white to off-white

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	Odour		:	No data available	
	Odour ⁻	Threshold	:	No data available	
	Melting	point/freezing point	:	No data available	
	Initial be range	oiling point and boiling	:	No data available	
	Flamma	ability (solid, gas)	:	Not applicable	
	Flamma	ability (liquids)	:	No data available	
		explosion limit / Upper bility limit	:	No data available	
		explosion limit / Lower bility limit	:	No data available	
	Flash p	oint	:	No data available	
	Auto-ig	nition temperature	:	No data available	
	Decom	position temperature	:	No data available	
	рН		:	No data available	
	Viscosi Visc	ty osity, kinematic	:	No data available	
	Solubili Wat	ty(ies) er solubility	:	soluble	
	Solu	bility in other solvents	:	No data available	
	Partition octanol	n coefficient: n- /water	:	Not applicable	
	Vapour	pressure	:	No data available	
	Relative	e density	:	No data available	
	Density		:	1.035 g/cm ³	
	Relative	e vapour density	:	No data available	
		characteristics icle size	:	Not applicable	



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9.2 Other	information			
Explo	osives	:	Not explosive	
Oxidi	zing properties	:	The substance of	or mixture is not classified as oxidizing.
Evap	oration rate	:	No data availabl	e
SECTION	N 10: Stability and re	eactiv	/ity	
10.1 Reac Not c	tivity lassified as a reactivity	hazar	ď.	
	nical stability e under normal conditio	ons.		
10.3 Poss	bility of hazardous re	eactio	ons	
Haza	rdous reactions	:	Can react with s	trong oxidizing agents.
10.4 Cond	litions to avoid			
Cond	itions to avoid	:	None known.	
10.5 Inco	mpatible materials			
	rials to avoid	:	Oxidizing agents	3
10.6 Haza	rdous decomposition	prod	lucts	
	azardous decompositio	-		
11.1 Infor Inforr expos	nation on likely routes o sure	sses a		gulation (EC) No 1272/2008
	e toxicity lassified based on avai	lahla i	nformation	
Prod		IADIE I		
	e oral toxicity	:	Acute toxicity est Method: Calculat	imate: > 2,000 mg/kg ion method
<u>Com</u>	ponents:			

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	corrosion/irritation assified based on availa	able	information.					
	us eye damage/eye irr assified based on availa							
Respi	Respiratory or skin sensitisation							
	sensitisation assified based on availa	able	information.					
-	ratory sensitisation assified based on availa	able	information.					
	cell mutagenicity assified based on availa	able	information.					
	nogenicity ected of causing cancer							
<u>Comp</u>	onents:							
-	estone: logenicity - Assess-	:	Limited evidence	of carcinogenicity in animal studies				
-	ductive toxicity amage the unborn child	d.						
<u>Comp</u>	onents:							
-	estone: s on fertility	:	Test Type: Fertilit Species: Rat Application Route Fertility: NOAEL: Result: No effects	: Subcutaneous 10 mg/kg body weight				
			Test Type: Fertilit Species: Rabbit Application Route Fertility: LOAEL: Result: Postimpla	: Subcutaneous 10 mg/kg body weight				
Repro sessm	ductive toxicity - As- nent	:	May damage the ty.	unborn child. Suspected of damaging fertili-				

STOT - single exposure

Not classified based on available information.

STOT - repeated exposure

Not classified based on available information.

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<u>Co</u> ı	mponents:				
Pro	oligestone:				
Target Organs Assessment		 Adrenal gland, Ovary, Uterus (including cervix) May cause damage to organs through prolonged or reperences 			
Rep	peated dose toxicity				
<u>Co</u>	mponents:				
Pro	ligestone:				
LÖ/ App Exp	ecies AEL Dication Route posure time get Organs	: Dog : 25 mg/kg : Subcutaneous : 90 d : Adrenal gland,	Uterus (including cervix), Ovary		
LÖ/ App Exp	ecies AEL blication Route bosure time get Organs	: Rat : 50 mg/kg : Subcutaneous : 90 d : Adrenal gland,	Uterus (including cervix), Ovary		

Aspiration toxicity

Not classified based on available information.

11.2 Information on other hazards

Endocrine disrupting properties

Product:

Assessment

: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Experience with human exposure

Components:

Proligestone:

General Information Inhalation	:	Remarks: May cause cancer based on animal data. Symptoms: Jaundice, Headache, Dizziness, menstrual irregu-
		larities, changes in libido, bleeding, breast changes



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SECTION 12: Ecological information

12.1 Toxicity

Components:		
Proligestone: Toxicity to fish	:	LC50 (Pimephales promelas (fathead minnow)): > 0.5 mg/l Exposure time: 96 h Method: OECD Test Guideline 203 Remarks: No toxicity at the limit of solubility
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia magna (Water flea)): > 0.5 mg/l Exposure time: 48 h Method: OECD Test Guideline 202 Remarks: No toxicity at the limit of solubility
Toxicity to algae/aquatic plants	:	EC50 (Pseudokirchneriella subcapitata (green algae)): > 1 mg/l Exposure time: 72 h Method: OECD Test Guideline 201 Remarks: No toxicity at the limit of solubility
		NOEC (Pseudokirchneriella subcapitata (green algae)): 1 mg/l Exposure time: 72 h Method: OECD Test Guideline 201 Remarks: No toxicity at the limit of solubility
Toxicity to microorganisms	:	EC50 : > 1,000 mg/l Exposure time: 3 h Test Type: Respiration inhibition Method: OECD Test Guideline 209 Remarks: No toxicity at the limit of solubility
		NOEC : 1,000 mg/l Exposure time: 3 h Test Type: Respiration inhibition Method: OECD Test Guideline 209 Remarks: No toxicity at the limit of solubility
12.2 Persistence and degradabili	ty	

Components: **Proligestone:**

Biodegradability		Result: Not readily biodegradable.		
		Biodegradation: 0 %		
		Exposure time: 28 d		
		Method: OECD Test Guideline 301B		



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12.3 Bioaccumulative potential

No data available

12.4 Mobility in soil

No data available

12.5 Results of PBT and vPvB assessment

Product:

Assessment

: This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

12.6 Endocrine disrupting properties

Product:

Assessment	: The substance/mixture does not contain components consid- ered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.
	· · · · · · · · · · · · · · · · · · ·

12.7 Other adverse effects

No data available

SECTION 13: Disposal considerations

13.1 Waste treatment methods	
Product	 Dispose of in accordance with local regulations. According to the European Waste Catalogue, Waste Codes are not product specific, but application specific. Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities. Do not dispose of waste into sewer.
Contaminated packaging	 Empty containers should be taken to an approved waste han- dling site for recycling or disposal. If not otherwise specified: Dispose of as unused product.

SECTION 14: Transport information

14.1 UN number or ID number

: Not regulated as a dangerous good
: Not regulated as a dangerous good
: Not regulated as a dangerous good
: Not regulated as a dangerous good
: Not regulated as a dangerous good

14.2 UN proper shipping name

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ADN		:	Not regulated as	a dangerous good		
ADR		:	Not regulated as	a dangerous good		
RID		:	Not regulated as	a dangerous good		
IMDG		:	Not regulated as	a dangerous good		
ΙΑΤΑ		:	Not regulated as	a dangerous good		
14.3 Trans	sport hazard class(es))				
ADN		:	Not regulated as	a dangerous good		
ADR		:	Not regulated as	a dangerous good		
RID		:	Not regulated as	a dangerous good		
IMDG		:	Not regulated as	a dangerous good		
ΙΑΤΑ		:	Not regulated as	a dangerous good		
14.4 Packing group						
ADN		:	Not regulated as	a dangerous good		
ADR		:	Not regulated as	a dangerous good		
RID		:	Not regulated as	a dangerous good		
IMDG		:	Not regulated as	a dangerous good		
ΙΑΤΑ	(Cargo)	:	Not regulated as	a dangerous good		
ΙΑΤΑ	(Passenger)	:	Not regulated as	a dangerous good		
14.5 Envir	onmental hazards					
Not re	gulated as a dangerou	s go	od			
-	14.6 Special precautions for user Not applicable					
14.7 Maritime transport in bulk according to IMO instruments						
Rema	rks	:	Not applicable for	r product as supplied.		

SECTION 15: Regulatory information

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

REACH - Restrictions on the manufacture, placing on	:	Conditions of restriction for the fol-
the market and use of certain dangerous substances,		lowing entries should be considered:
mixtures and articles (Annex XVII)		Number on list 3

Substance(s) or mixture(s) are listed here according to their appearance in the regulation, irrespective of their use/purpose or the conditions of the restriction. Please refer to the condi-

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				tions in corresponding Regulation to determine whether an entry is appli- cable to the placing on the market or not.
	EACH - Candidate List of	ו :	Not applicable	
	oncern for Authorisation (egulation (EC) on substar		ne :	Not applicable
	/er			Net en l'achte
	egulation (EU) 2019/1021 nts (recast)	on persistent organic po	oliu- :	Not applicable
R m	egulation (EU) No 649/20 ent and the Council conce dangerous chemicals	•		Not applicable
R	EACH - List of substances	s subject to authorisation		Not applicable
· · ·	,	8/EU of the European Pa	arliame	nt and of the Council on the control of

major-accident hazards involving dangerous substances.

Not applicable

Other regulations:

Take note of Directive 92/85/EEC regarding maternity protection or stricter national regulations, where applicable.

Take note of Directive 94/33/EC on the protection of young people at work or stricter national regulations, where applicable.

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

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

15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

Other information : Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

Full text of H-Statements

H302	:	Harmful if swallowed.
H351	:	Suspected of causing cancer.
H360D	:	May damage the unborn child.
H373	:	May cause damage to organs through prolonged or repeated
		exposure.

Full text of other abbreviations

Acute Tox.	:	Acute toxicity
Carc.	:	Carcinogenicity

🔁 MSD 🧥 Public

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Repr.		: Reproductive	toxicity
STOT RE		: Specific targe	t organ toxicity - repeated exposure

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by Road; AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA -European Chemicals Agency; EC-Number - European Community number; 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; 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; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of Very High Concern; TCSI - Taiwan Chemical Substance Inventory; TECI -Thailand Existing Chemicals Inventory; TRGS - Technical Rule for Hazardous Substances; TSCA - Toxic Substances Control Act (United States); UN - United Nations; vPvB - Very Persistent and Very Bioaccumulative

Further information

Sources of key data used to compile the Safety Data	:	Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agen-
Sheet		cy, http://echa.europa.eu/

Classification of the mixture:

Classification of the mixtur	Classification procedure:	
Carc. 2	H351	Calculation method
Repr. 1B	H360D	Calculation method

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.

IE / EN