

Version	Revision Date:	SDS Number:	Date of last issue: 06.04.2024
2.3	28.09.2024	5447429-00010	Date of first issue: 20.02.2020

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

<b>1.1 Product identifier</b> Trade name	: Serum Gonadotrophin Formulation
1.2 Relevant identified uses of	f the substance or mixture and uses advised against
Use of the Sub- stance/Mixture	: Veterinary product
Recommended restrictions on use	s : Not applicable
1.3 Details of the supplier of t	he safety data sheet
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)

Reproductive toxicity, Category 1B

H360Fd: May damage fertility. Suspected of damaging the unborn child.

#### 2.2 Label elements

Signal word

## Labelling (REGULATION (EC) No 1272/2008)

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Hazard pictograms



Hazard statements : H360Fd May damage fertility. Suspected of damaging the unborn child.

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

## Serum Gonadotrophin Formulation

Version 2.3	Revision Date: 28.09.2024	SDS Number: 5447429-00010	Date of last issue: 06.04.2024 Date of first issue: 20.02.2020		
Preca	utionary statements	•	pecial instructions before use. tective gloves/ protective clothing/ eye protec- on.		
		<b>Response:</b> P308 + P313 If attention.	exposed or concerned: Get medical advice/		
		<b>Storage:</b> P405 Store locl	ked up.		
Hazardous components which must be listed on the label:					

Gonadotropin, pregnant mare serum

## 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.

Dust contact with the eyes can lead to mechanical irritation. Contact with dust can cause mechanical irritation or drying of the skin. May form explosive dust-air mixture during processing, handling or other means.

## **SECTION 3: Composition/information on ingredients**

## 3.2 Mixtures

#### Components

Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
Gonadotropin, pregnant mare serum	9002-70-4 232-663-9	Repr. 1B; H360Fd 	>= 30 - < 50

For explanation of abbreviations see section 16.



Version	Revision Date:	SDS Number:	Date of last issue: 06.04.2024
2.3	28.09.2024	5447429-00010	Date of first issue: 20.02.2020

## **SECTION 4: First aid measures**

4.1 Description of first aid meas	sures	6
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	:	If in eyes, rinse well with water. Get medical attention if irritation develops and persists.
If swallowed	:	If swallowed, DO NOT induce vomiting. Get medical attention. Rinse mouth thoroughly with water.
4.2 Most important symptoms a	and e	ffects, both acute and delayed
Risks	:	May damage fertility. Suspected of damaging the unborn child.
		Contact with dust can cause mechanical irritation or drying of the skin. Dust contact with the eyes can lead to mechanical irritation.
4.3 Indication of any immediate	e mec	lical attention and special treatment needed
Treatment	:	Treat symptomatically and supportively.
SECTION 5: Firefighting mea	asur	es

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



Vers 2.3	ion	Revision Date: 28.09.2024		9S Number: 47429-00010	Date of last issue: 06.04.2024 Date of first issue: 20.02.2020	
	media					
5.2 \$	Special	hazards arising from	the	substance or mix	xture	
		:	Avoid generating dust; fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard. Exposure to combustion products may be a hazard to health.			
	Hazardous combustion prod- ucts		:	Carbon oxides Metal oxides Oxides of phosphorus		
5.3 A	Advice	for firefighters				
	Special protective equipment for firefighters		:	In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.		
	Specific ods	c extinguishing meth-	:	: Use extinguishing measures that are appropriate to loca cumstances and the surrounding environment. Use water spray to cool unopened containers. Remove undamaged containers from fire area if it is saf so. Evacuate area.		

## **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. Retain and dispose of contaminated wash water. Local authorities should be advised if significant spillages cannot be contained
	cannot be contained.

## 6.3 Methods and material for containment and cleaning up

Methods for cleani	ing up :	Sweep up or vacuum up spillage and collect in suitable con- tainer for disposal. Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air). Dust deposits should not be allowed to accumulate on surfac- es, as these may form an explosive mixture if they are re- leased into the atmosphere in sufficient concentration. Local or national regulations may apply to releases and dis- posal of this material, as well as those materials and items employed in the cleanup of releases. You will need to deter- mine which regulations are applicable.
		mine which regulations are applicable.



Commission Regulation (EU) 2020/878

## **Serum Gonadotrophin Formulation**

Version	Revision Date: 28.09.2024	SDS Number:	Date of last issue: 06.04.2024
2.3		5447429-00010	Date of first issue: 20.02.2020
		Sections 13 and	d 15 of this SDS provide information regardin

Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

## 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	:	Static electricity may accumulate and ignite suspended dust causing an explosion. Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.
	Local/Total ventilation	:	If sufficient ventilation is unavailable, use with local exhaust ventilation.
	Advice on safe handling	:	Do not get on skin or clothing. Do not breathe dust. Do not swallow. Avoid contact with eyes. Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure as- sessment Keep container tightly closed. Minimize dust generation and accumulation. Keep container closed when not in use. Keep away from heat and sources of ignition. Take precautionary measures against static discharges. Take care to prevent spills, waste and minimize release to the environment.
	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, in	Iclu	uding 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:

ce on common storage : Do not store with the following product type Strong oxidizing agents Self-reactive substances and mixtures Organic peroxides Explosives Gases



## Serum Gonadotrophin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 06.04.2024
2.3	28.09.2024	5447429-00010	Date of first issue: 20.02.2020

## 7.3 Specific end use(s)

Specific use(s)

: No data available

## **SECTION 8: Exposure controls/personal protection**

#### 8.1 Control parameters

#### **Occupational Exposure Limits**

Dust

5 mg/m3 Value type (Form of exposure): TWA (respirable dust) Basis: FOR-2011-12-06-1358

10 mg/m3 Value type (Form of exposure): TWA (total dust) Basis: FOR-2011-12-06-1358

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
Gonadotropin, pregnant mare serum	opin, 9002-70-4 TWA		4 µg/m3 (OEB 4) Inter	
		Wipe limit	40 μg/100 cm2	Internal

## 8.2 Exposure controls

## Engineering measures

Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of the compound to uncontrolled areas (e.g., vacuum conveying from a closed system, packout head with inflatable seal from stationary container, ventilated enclosure, etc.).

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.

#### 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, disposable suits) to avoid exposed skin surfaces.



## Serum Gonadotrophin Formulation

Version 2.3			Date of last issue: 06.04.2024 Date of first issue: 20.02.2020
Respi	ratory protection	contaminate : If adequate sure assess ommended	iate degowning techniques to remove potentially d clothing. local exhaust ventilation is not available or expo- ment demonstrates exposures outside the rec- guidelines, use respiratory protection. should conform to NS EN 143
Filter type		: Particulates	

## **SECTION 9: Physical and chemical properties**

## 9.1 Information on basic physical and chemical properties

Physical state	:	powder
Colour	:	white
Odour	:	No data available
Odour Threshold	:	No data available
Melting point/freezing point	:	No data available
Initial boiling point and boiling range	:	No data available
Flammability (solid, gas)	:	May form explosive dust-air mixture during processing, han- dling or other means.
Flammability (liquids)	:	No data available
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Flash point	:	Not applicable
Auto-ignition temperature	:	No data available
Decomposition temperature	:	No data available
рН	:	No data available
Viscosity Viscosity, kinematic	:	Not applicable
Solubility(ies) Water solubility	:	No data available

Commission Regulation (EU) 2020/878



## Serum Gonadotrophin Formulation

Versi 2.3	ion	Revision Date: 28.09.2024		S Number: 47429-00010	Date of last issue: 06.04.2024 Date of first issue: 20.02.2020
-	Partition coefficient: n- octanol/water		:	Not applicable	
Ň	Vapour	pressure	:	Not applicable	
I	Relative	e density	:	No data available	9
[	Density		:	No data available	9
I	Relative vapour density		:	Not applicable	
I		characteristics icle size	:	No data available	e
9.2 O	Other in	formation			
I	Explosi	ves	:	Not explosive	
(	Oxidizir	ng properties	:	The substance o	r mixture is not classified as oxidizing.
I	Evapor	ation rate	:	Not applicable	
ſ	Molecu	lar weight	:	No data available	e

## **SECTION 10: Stability and reactivity**

#### 10.1 Reactivity

Not classified as a reactivity hazard.

## 10.2 Chemical stability

Stable under normal conditions.

#### 10.3 Possibility of hazardous reactions

Hazardous reactions	:	May form explosive dust-air mixture during processing, han- dling or other means. Can react with strong oxidizing agents.
10.4 Conditions to avoid		
Conditions to avoid	:	Heat, flames and sparks. Avoid dust formation.
<b>10.5 Incompatible materials</b> Materials to avoid	:	Oxidizing agents

## **10.6 Hazardous decomposition products**

No hazardous decomposition products are known.

## **SECTION 11: Toxicological information**

## 11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008



## Serum Gonadotrophin Formulation

ersion 3	Revision Date: 28.09.2024		S Number: 47429-00010	Date of last issue: 06.04.2024 Date of first issue: 20.02.2020			
Inforr expos	nation on likely routes of sure	:	Inhalation Skin contact Ingestion Eye contact				
Not c	e toxicity lassified based on availa ponents:	ble	information.				
	idotropin, pregnant ma	ro 6	orum.				
	e oral toxicity		LD50 (Mouse): 12	20 mg/kg			
Acute	inhalation toxicity	:	Remarks: No data	a available			
Acute	e dermal toxicity	:	Remarks: No data	a available			
	e toxicity (other routes of histration)	:	LD50 (Mouse): > Application Route	0 0			
			LD50 (Mouse): > Application Route				
			LD50 (Rat): 500 n Application Route				
			LD50 (Rat): 500 n Application Route				
-	Skin corrosion/irritation						
	lassified based on availa	ble mormation.					
	Components:						
Rema	<b>idotropin, pregnant ma</b> arks	:	No data available				
<b>C</b> a ria							
	ous eye damage/eye irri lassified based on availa						
<u>Com</u>	ponents:						
Gona	dotropin, pregnant ma	re s	erum:				
Rema	arks	:	No data available				
Resp	iratory or skin sensitis	atory or skin sensitisation					
-	sensitisation lassified based on availa	ble	information.				
Resp	iratory sensitisation lassified based on availa						
			9 / 15				

Commission Regulation (EU) 2020/878



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## Serum Gonadotrophin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 06.04.2024
2.3	28.09.2024	5447429-00010	Date of first issue: 20.02.2020

#### **Components:**

## Gonadotropin, pregnant mare serum: Remarks : No data available

#### Germ cell mutagenicity

Not classified based on available information.

#### **Components:**

#### Gonadotropin, pregnant mare serum:

: Test Type: Cytogenetic assay
Species: Mouse
Application Route: Intraperitoneal injection
Result: positive
Remarks: Not classified due to data which are conclusive although insufficient for classification.

#### Carcinogenicity

Not classified based on available information.

#### **Components:**

#### Gonadotropin, pregnant mare serum:

Carcinogenicity - Assess-	:	No data available
ment		

#### **Reproductive toxicity**

May damage fertility. Suspected of damaging the unborn child.

#### **Components:**

#### Gonadotropin, pregnant mare serum:

Effects on fertility :	Test Type: Fertility Species: Rat Application Route: Subcutaneous Fertility: LOAEL: 10 μg/kg Result: Effects on fertility Remarks: May cause adverse reproductive effects. Based on data from similar materials
Effects on foetal develop- : ment	Remarks: May cause birth defects. Based on data from similar materials
Reproductive toxicity - As- : sessment	Some evidence of adverse effects on development, based animal experiments., Clear evidence of adverse effects on sexual function and fertility, based on animal experiments.

## STOT - single exposure

Not classified based on available information.



## **Serum Gonadotrophin Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 06.04.2024
2.3	28.09.2024	5447429-00010	Date of first issue: 20.02.2020

#### STOT - repeated exposure

Not classified based on available information.

#### **Repeated dose toxicity**

#### Components:

#### Gonadotropin, pregnant mare serum:

Species NOAEL Application Route Exposure time Symptoms	 Rat 1,5 mg/kg Oral 3 Days No adverse effects
Species LOAEL Application Route Exposure time Target Organs	 Rat 10 mg/kg Oral 14 Days Reproductive organs

#### 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:**

#### Gonadotropin, pregnant mare serum:

1 / 1 0	
Inhalation	: Symptoms: Headache, Fatigue, mood swings, altered mental
	status, Oedema, Allergic reactions, Effects on fertility
Skin contact	: Remarks: May produce an allergic reaction.
Ingestion	: Remarks: May be harmful if swallowed.

## **SECTION 12: Ecological information**

#### 12.1 Toxicity

No data available

## 12.2 Persistence and degradability

No data available



VersionRevision Date:SDS Number:Date of last issue: 06.04.20242.328.09.20245447429-00010Date of first issue: 20.02.2020	
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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.
	levels of 0.1% or nigner.

## 12.7 Other adverse effects

No data available

## **SECTION 13: Disposal considerations**

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

## **SECTION 14: Transport information**

## 14.1 UN number or ID number

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



Version 2.3	Revision Date: 28.09.2024	SDS Number: 5447429-00010	Date of last issue: 06.04.2024 Date of first issue: 20.02.2020
14.2 UN p	proper shipping name		
ADN		: Not regulated as	s a dangerous good
ADR		: Not regulated as	s a dangerous good
RID		: Not regulated as	s a dangerous good
IMDO	3	: Not regulated as	s a dangerous good
ΙΑΤΑ		: Not regulated as	s a dangerous good
14.3 Tran	sport hazard class(es	)	
ADN		: Not regulated as	s a dangerous good
ADR		: Not regulated as	s a dangerous good
RID		: Not regulated as	s a dangerous good
IMDO	3	: Not regulated as	s a dangerous good
ΙΑΤΑ		: Not regulated as	s a dangerous good
14.4 Pack	king group		
ADN		: Not regulated as	s a dangerous good
ADR		: Not regulated as	s a dangerous good
RID		: Not regulated as	s a dangerous good
IMDO	3	: Not regulated as	s a dangerous good
ΙΑΤΑ	(Cargo)	: Not regulated as	s a dangerous good
ΙΑΤΑ	(Passenger)	: Not regulated as	s a dangerous good
	ronmental hazards	is good	
	egulated as a dangerou cial precautions for us	-	
•	applicable		
	time transport in bulk	-	
Rema			or product as supplied.
SECTION	N 15: Regulatory info	ormation	
15.1 Safe ture	ty, health and environ	mental regulations/le	egislation specific for the substance or mix
REA0 the m mixtu	CH - Restrictions on the narket and use of certai res and articles (Annex CH - Candidate List of \$	n dangerous substance XVII)	es,

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REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII)	:	Not applicable
REACH - Candidate List of Substances of Very High	:	Not applicable
Concern for Authorisation (Article 59). REACH - List of substances subject to authorisation		Not applicable
(Annex XIV)	•	
Regulation (EC) on substances that deplete the ozone	:	Not applicable
layer Regulation (EU) 2019/1021 on persistent organic pollu-		Not applicable
Regulation (EO) 2019/1021 on persistent organic polic-	•	Not applicable



Version	Revision Date:	SDS Number:	Date of last issue: 06.04.2024
2.3	28.09.2024	5447429-00010	Date of first issue: 20.02.2020

tants (recast)

Regulation (EU) No 649/2012 of the European Parlia- : Not applicable ment and the Council concerning the export and import of dangerous chemicals

Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances. Not applicable

Other regulations:

Note the Working Environment Act § 4-1 and § 4-2 on requirements for the employer to protect pregnant employees against discomfort and injury as a result of the work situation and the working environment.

Note the regulation on organization, leadership and participation, chapter 12 on the work of children and young people.

#### 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				
H360Fd	: May damage fertility. Suspected of damaging the unborn child.			
Full text of other abbreviation	ons			
Repr. FOR-2011-12-06-1358 FOR-2011-12-06-1358 / TWA	<ul> <li>Reproductive toxicity</li> <li>Norway. Occupational Exposure limits</li> <li>Long term exposure limit</li> </ul>			

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 Agency



Version	Revision Date:	SDS Number:	Date of last issue: 06.04.2024
2.3	28.09.2024	5447429-00010	Date of first issue: 20.02.2020

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; 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

## 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/

#### Classification of the mixture:

Repr. 1B

H360Fd

Classification procedure:

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. 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.

NO / EN