

Version 3.6	Revision Date: 09.04.2021	SDS Number: 16722-00019	Date of last issue: 16.10.2020 Date of first issue: 29.09.2014
SECTIC	ON 1: Identification of	f the substance	mixture and of the company/undertaking
1.1 Prod	luct identifier		
Trac	de name	: Etoricoxib G	Granulation Formulation
Pro	duct code	: ETORICOX	IB GRANULATION
1.2 Rele	vant identified uses of	the substance or	mixture and uses advised against
	e of the Sub- nce/Mixture	: Pharmaceu	tical
1.3 Deta	ils of the supplier of th	e safety data she	et
	npany	: Organon & 30 Hudson	
Tele	ephone	: 551-430-60	00
	ail address of person consible for the SDS	: EHSSTEW	ARD@organon.com
	rgency telephone num -631-6999	ber	

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008)

Reproductive toxicity, Category 2 Specific target organ toxicity - repeated exposure, Category 2 Long-term (chronic) aquatic hazard, Category 2 H361d: Suspected of damaging the unborn child. H373: May cause damage to organs through prolonged or repeated exposure.

H411: Toxic to aquatic life with long lasting effects.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

: 🔨

Hazard pictograms

Signal word	:	Warning
Hazard statements	:	H361d Suspected of damaging the unborn child.H373 May cause damage to organs through prolonged or repeated exposure.H411 Toxic to aquatic life with long lasting effects.



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Preca	utionary statements	P260 Do not br P273 Avoid rele	becial instructions before use. eathe dust. ease to the environment. tective gloves/ protective clothing/ eye protec- on.
		Response: P308 + P313 IF attention. P391 Collect sp	exposed or concerned: Get medical advice/

Hazardous components which must be listed on the label: Etoricoxib

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.

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)
Etoricoxib	202409-33-4	Acute Tox. 4; H302 Repr. 2; H361d STOT RE 2; H373 (Kidney, Liver, Gas- trointestinal tract) Aquatic Chronic 2; H411	>= 25 - < 30

For explanation of abbreviations see section 16.

SECTION 4: First aid measures

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).



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lf i	nhaled	:	If inhaled, remove Get medical atter				
In case of skin contact		:	of water. Remove contamin Get medical atter Wash clothing be				
In	case of eye contact	:	If in eyes, rinse w Get medical atter	ell with water. ition if irritation develops and persists.			
lf s	swallowed	:	Get medical atter	NOT induce vomiting. htion. oughly with water.			
4.2 Mo	st important symptoms a	nd e	effects. both acute	e and delaved			
	Risks		Suspected of dan	naging the unborn child. ge to organs through prolonged or repeated			
			the skin.	can cause mechanical irritation or drying of the eyes can lead to mechanical irritation.			
4 3 Ind	ication of any immediate	mo	dical attention and	d special treatment needed			
	eatment	:		cally and supportively.			
SECTI	ON 5: Firefighting mea	sur	es				
5.1 Ext	inguishing media						
	itable extinguishing media	:	Water spray Alcohol-resistant Carbon dioxide (0 Dry chemical				
	nsuitable extinguishing edia	:	None known.				
5 2 Sn4	5.2 Special hazards arising from the substance or mixture						
Sp	becific hazards during fire- hting	:	Avoid generating concentrations, a potential dust exp	dust; fine dust dispersed in air in sufficient nd in the presence of an ignition source is a			
Ha uc	azardous combustion prod- ts	:	Carbon oxides Metal oxides Oxides of phosphorus Nitrogen oxides (NOx)				



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				Sulphur oxides Chlorine compour	nds	
5.3	5.3 Advice for firefighters					
	Special protective equipment for firefighters		:		e, wear self-contained breathing apparatus. tective equipment.	
	Specific extinguishing meth- ods		:	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, protect Personal precautions		e equipment and emergency procedures 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.
6.3 Methods and material for co	ntai	nment and cleaning up
Methods for cleaning 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. 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.

:



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Local/Total ventilation Advice on safe handling Hygiene measures		and bo : Use of Do no Do no Avoid Avoid Handle practic sessm Minim Keep of Take p Take of enviro : If expo	Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres. Use only with adequate ventilation. Do not breathe dust. Do not swallow. Avoid contact with eyes. Avoid prolonged or repeated contact with skin. Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure as- sessment 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. If exposure to chemical is likely during typical use, provide eye		
			ng systems and safety showers close to the working When using do not eat, drink or smoke. Wash contami- clothing before re-use.		
7.2 Condi	tions for safe storage,	including	any incompatibilities		
	irements for storage and containers		in properly labelled containers. Store locked up. Store in dance with the particular national regulations.		
Advic	e on common storage		t store with the following product types: g oxidizing agents		
7.3 Specif	fic end use(s)				
Spec	ific use(s)	: No da	ta available		
		No da	ta available		

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational Exposure Limits

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
Cellulose	9004-34-6	TWA OEL-RL (Respirable dust)	5 mg/m3	ZA OEL
	Further inform	nation: Recommende	ed Limit	
	TWA OEL-RL 10 mg/m3		10 mg/m3	ZA OEL
		(inhalable dust)	-	
	Further information: Recommended Limit			
		STEL OEL-RL (Dust)	20 mg/m3	ZA OEL
	Further information: Recommended Limit			
Etoricoxib	202409-33- 4	TWA	400 ug/m3 (OEB 2)	Internal



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8.2 Exposure controls

Engineering measures

Ensure adequate ventilation, especially in confined areas. Minimize workplace exposure concentrations. Apply measures to prevent dust explosions. Ensure that dust-bandling systems (such as exhaust ducts, dust collectors,)

Ensure that dust-handling systems (such as exhaust ducts, dust collectors, vessels, and processing equipment) are designed in a manner to prevent the escape of dust into the work area (i.e., there is no leakage from the equipment).

Personal protective equipmentEye protection:Hand protection		Wear the following personal protective equipment: Safety goggles
Material	:	Chemical-resistant gloves
Remarks	:	Choose gloves to protect hands against chemicals depending on the concentration and quantity of the hazardous sub- stance and specific to place of work. Breakthrough time is not determined for the product. Change gloves often! For special applications, we recommend clarifying the resistance to chemicals of the aforementioned protective gloves with the glove manufacturer. Wash hands before breaks and at the end of workday.
Skin and body protection	:	
Respiratory protection	:	If adequate local exhaust ventilation is not available or expo- sure assessment demonstrates exposures outside the rec- ommended guidelines, use respiratory protection.
Filter type	:	Particulates type (P)

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance Colour Odour Odour Threshold	::	powder No data available No data available No data available
рН	:	No data available
Melting point/freezing point	:	No data available
Initial boiling point and boiling	:	No data available
range Flash point	:	No data available
Evaporation rate	:	No data available
Flammability (solid, gas)	:	May form explosive dust-air mixture during processing, han- dling or other means.

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Upper explosion limit / Upper flammability limit	: No data available
Lower explosion limit / Lower flammability limit	: No data available
Vapour pressure	: No data available
Relative vapour density	: No data available
Relative density	: No data available
Density	: 1 g/cm ³
Solubility(ies) Water solubility Partition coefficient: n- octanol/water	No data availableNo data available
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
Viscosity Viscosity, dynamic	: No data available
Viscosity, kinematic	: No data available
Explosive properties	: Not explosive
Oxidizing properties	: The substance or mixture is not classified as oxidizing.
9.2 Other information Flammability (liquids)	: No data available
Molecular weight	: No data available
Particle size	: No data available

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



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Condi	tions to avoid	:	Heat, flames a Avoid dust for	
0.5 Incon	npatible materials			
Mater	ials to avoid	:	Oxidizing age	nts
	dous decomposition			
	zardous decomposition			ז.
SECTION	11: Toxicological in	itor	mation	
	nation on toxicologica			
Inform expos	nation on likely routes of ure	:	Inhalation Skin contact Ingestion Eye contact	
Acute	toxicity		,	
Not cl	assified based on availa	ble	information.	
<u>Produ</u>	<u>ict:</u>			
Acute	oral toxicity	:	Acute toxicity e Method: Calcu	estimate: > 2.000 mg/kg lation method
Comp	oonents:			
Etoric	oxib:			
Acute	oral toxicity	:	LD50 (Rat): 1.4	499 mg/kg
			LD50 (Mouse)	: 1.499 mg/kg
	toxicity (other routes of istration)	:		88 mg/kg ute: Intraperitoneal
			LD50 (Mouse) Application Ro	: 599 mg/kg ute: Intraperitoneal
-	corrosion/irritation			
Not cl	assified based on availa	ble	information.	
<u>Comp</u>	oonents:			
Etoric				
Speci Resul		:	Rabbit No skin irritatic	n
	us eye damage/eye irri assified based on availa			
	oonents:			



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	pecies esult	:	Rabbit Mild eye irritation	
R	espiratory or skin sensitis	atic	on	
-	kin sensitisation ot classified based on availa	able	information.	
	espiratory sensitisation ot classified based on availa	able	information.	
<u>C</u>	omponents:			
Te E: Si A:	t oricoxib: est Type xposure routes pecies ssessment esult		Local lymph node Skin contact Mouse Did not cause ser negative	assay (LLNA) sitisation on laboratory animals.
	erm cell mutagenicity ot classified based on availa	able	information.	
<u>C</u>	omponents:			
	toricoxib: enotoxicity in vitro	:	Test Type: revers Result: negative	e mutation assay
				mammalian cell gene mutation test an lymphoblastoid cells
				osomal aberration ese hamster ovary cells
			Test Type: Alkalin Result: negative	e elution assay
G	enotoxicity in vivo	:	Test Type: Chrom Species: Rat Cell type: Bone m Application Route Result: negative	
			Test Type: Alkalin Species: Rat Application Route Result: negative	-

Carcinogenicity

Not classified based on available information.



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<u>Comp</u>	oonents:		
Etoric	coxib:		
	ation Route sure time	: Rat, male and : oral (gavage) : 2 Years : positive	
	ation Route	: Mouse, male : oral (gavage) : 2 Years : negative	
-	oductive toxicity ected of damaging the	unborn child.	
Comp	oonents:		
Etoric	oxib:		
Effect	s on fertility	Species: Rat Application R	oute: Oral city - Parent: NOAEL: 10 mg/kg body weight
		Test Type: Fo Species: Rat Application R Result: negat	oute: Oral
Effect ment	s on foetal develop-	: Species: Rat Application R Result: positi	oute: Oral
		Species: Rab Application R Result: positi	oute: Oral
Repro	ductive toxicity - As-	: Some eviden animal exper	ce of adverse effects on development, based o

STOT - single exposure

Not classified based on available information.

STOT - repeated exposure

May cause damage to organs through prolonged or repeated exposure.

Components:

Etoricoxib:	
Exposure routes : Target Organs : Assessment :	Ingestion Kidney, Liver, Gastrointestinal tract May cause damage to organs through prolonged or repeated exposure.



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	Repea	ted dose toxicity			
	Comp	onents:			
	Etoric	oxib:			
	Exposi		:	Rat 30 mg/kg oral (gavage) 27 Weeks Gastrointestinal t	ract, Kidney
	Exposi		:	Rat 30 mg/kg oral (gavage) 53 Weeks Liver	
	Exposi		:	Dog 50 mg/kg oral (gavage) 53 Weeks Liver	
	Exposi			Dog 200 mg/kg oral (gavage) 14 Weeks Gastrointestinal t	ract, Kidney
	-	ation toxicity assified based on avai	lable	information.	
	Experi	ience with human ex	posi	ure	
	<u>Comp</u>	onents:			
	Etoric	oxib:			
	Ingesti	on	:	tension, Diarrhoe heartburn, Nause	r respiratory tract infection, Headache, hyper- a, urinary tract infection, flu-like symptoms, a, bronchitis, Dizziness, asthenia, Rash, n, Abdominal pain, pharyngitis, Oedema

SECTION 12: Ecological information

12.1 Toxicity

Components:		
Etoricoxib:		
Toxicity to fish	:	LC50 (Pimephales promelas (fathead minnow)): > 30 mg/l Exposure time: 96 h Method: OECD Test Guideline 203
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia magna (Water flea)): > 30 mg/l Exposure time: 48 h



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			Method: OECD 1	Fest Guideline 202
Toxi plan	city to algae/aquatic ts	:	mg/l Exposure time: 7	rchneriella subcapitata (green algae)): > 10 2 h Fest Guideline 201
Тохі	Toxicity to microorganisms		EC50 : > 1.000 n Exposure time: 3 Test Type: Resp Method: OECD 1	5 ĥ
			NOEC : 1.000 m Exposure time: 3 Test Type: Resp Method: OECD T	h
Toxi icity)	city to fish (Chronic tox-	:		
aqua	city to daphnia and other atic invertebrates (Chron- xicity)	:		
12.2 Per	sistence and degradabili	ity		
<u>Con</u>	<u>iponents:</u>			
	Etoricoxib: Biodegradability		Result: not rapidly degradable Biodegradation: 0,2 % Exposure time: 28 d	
12.3 Bio	accumulative potential			
<u>Con</u>	nponents:			
Part	icoxib: ition coefficient: n- nol/water	:	log Pow: 2,3	
	bility in soil lata available			
	ults of PBT and vPvB as	se	ssment	
Pro	duct:			
	essment	:	to be either persi	nixture contains no components considered stent, bioaccumulative and toxic (PBT), or nd very bioaccumulative (vPvB) at levels of



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12.6 Oth	er adverse effects			
Proc	luct:			
Endo tial	ocrine disrupting poten-	:	ered to have end REACH Article 57	ixture does not contain components consid- ocrine disrupting properties according to 7(f) or Commission Delegated regulation or Commission Regulation (EU) 2018/605 at higher.
SECTIO	N 13: Disposal consi	dera	ations	
13.1 Was	ste treatment methods			
Proc	luct taminated packaging	:	According to the are not product s Waste codes sho discussion with th Empty containers dling site for recy	ordance with local regulations. European Waste Catalogue, Waste Codes pecific, but application specific. uld be assigned by the user, preferably in the waste disposal authorities. I should be taken to an approved waste han- cling or disposal. pecified: Dispose of as unused product.
14.1 UN	number			
ADN	I	:	UN 3077	
ADR	1	:	UN 3077	
RID		:	UN 3077	
IMD	G	:	UN 3077	
ΙΑΤΑ	A	:	UN 3077	
14.2 UN	proper shipping name			
ADN	I	:	ENVIRONMENT/ N.O.S. (Etoricoxib)	ALLY HAZARDOUS SUBSTANCE, SOLID,
ADR	2	:	ENVIRONMENT/ N.O.S. (Etoricoxib)	ALLY HAZARDOUS SUBSTANCE, SOLID,
RID		:	ENVIRONMENT/ N.O.S. (Etoricoxib)	ALLY HAZARDOUS SUBSTANCE, SOLID,
IMD	G	:	ENVIRONMENT/ N.O.S. (Etoricoxib)	ALLY HAZARDOUS SUBSTANCE, SOLID,
IATA	A	:	Environmentally I (Etoricoxib)	nazardous substance, solid, n.o.s.

14.3 Transport hazard class(es)

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ADN		:	9	
ADR		:	9	
RID		:	9	
IMDO	6	:	9	
ΙΑΤΑ		:	9	
14.4 Pack	ing group			
Class Haza Label ADR Packi Class Haza Label	ing group sification Code rd Identification Number		III M7 90 9 III M7 90 9 9 (-)	
Class	ing group sification Code rd Identification Number Is	:	III M7 90 9	
Label	ing group	:	III 9 F-A, S-F	
Packi aircra Packi	ing instruction (LQ) ing group	:	956 Y956 III Miscellaneous	
Packi ger a Packi	(Passenger) ing instruction (passen- ircraft) ing instruction (LQ) ing group	:	956 Y956 III Miscellaneous	
	ronmental hazards			
ADN Envir	onmentally hazardous	:	yes	
ADR Envir	onmentally hazardous	:	yes	
RID Envir IMDG	onmentally hazardous	:	yes	



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Marine	pollutant	: yes	
IATA (Passenger) Environmentally hazardous		: yes	
•	Cargo) nmentally hazardous	: yes	
•	al precautions for use		or informational purposes only and solely

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.

14.7 Transport in bulk according to Annex II of Marpol and the IBC Code

Remarks	:	Not applicable for product as supplied.
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SECTION 15: Regulatory information

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

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.
H361d	:	Suspected of damaging the unborn child.
H373	:	May cause damage to organs through prolonged or repeated exposure if swallowed.
H411	:	Toxic to aquatic life with long lasting effects.
Full text of other abbreviations		
Acute Tox.	:	Acute toxicity
Aquatic Chronic	:	Long-term (chronic) aquatic hazard
Repr.	:	Reproductive toxicity
STOT RE	:	Specific target organ toxicity - repeated exposure
ZA OEL	:	South Africa. Hazardous Chemical Substances Regulations, Occupational Exposure Limits
ZA OEL / TWA OEL-RL ZA OEL / STEL OEL-RL	:	Long term occupational exposure limits - recommended limit Short term occupational exposure limits - recommended limit



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ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - European 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; 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 : compile the Safety Data Sheet

Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, http://echa.europa.eu/

Classification of the mix	Classification procedure:	
Repr. 2	H361d	Calculation method
STOT RE 2	H373	Calculation method
Aquatic Chronic 2	H411	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.



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ZA / EN