

according to Regulation (EC) No. 1907/2006

Mirtazapine Solid Formulation

Version	Revision Date: 23.03.2020	SDS Number:	Date of last issue: 13.09.2019
4.3		51095-00015	Date of first issue: 23.01.2015

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

1.1 Product identifier

Trade name : Mirtazapine Solid Formulation

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

Use of the Substance/Mixture : Pharmaceutical

1.3 Details of the supplier of the safety data sheet

Company	:	Organon & Co. 30 Hudson Street, 33nd floor 07302 Jersey City, New Jersey, U.S.A
Telephone	:	551-430-6000
E-mail address of person responsible for the SDS	:	EHSSTEWARD@organon.com

1.4 Emergency telephone number

215-631-6999

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008)

Reproductive toxicity, Category 2	H361fd: Suspected of damaging fertility. Suspected
Charific torget orgen tovicity reported	of damaging the unborn child.
Specific target organ toxicity - repeated	H373: May cause damage to organs through pro-
exposure, Category 2	longed or repeated exposure.
Long-term (chronic) aquatic hazard, Cat-	H412: Harmful to aquatic life with long lasting ef-
egory 3	fects.
2.2 Label elements	

Labelling (REGULATION (EC) No 1272/2008)

Hazard pictograms

Signal word :	Warning
Hazard statements :	 H361fd Suspected of damaging fertility. Suspected of damaging the unborn child. H373 May cause damage to organs through prolonged or repeated exposure. H412 Harmful to aquatic life with long lasting effects.

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Preca	autionary statements	P260 Do not b P273 Avoid re	special instructions before use. breathe dust. lease to the environment. otective gloves/ protective clothing/ eye protec- tion.
		Response: P308 + P313 attention.	IF exposed or concerned: Get medical advice/
		Storage: P405 Store loo	cked up.

Hazardous components which must be listed on the label:

(+/-)-1,2,3,4,10,14b-Hexahydro-2-methylpyrazino[2,1-a]pyrido[2,3-c][2]benzazepine

2.3 Other hazards

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.	Classification	Concentration (% w/w)
	Registration number		
(+/-)-1,2,3,4,10,14b-Hexahydro-2-	85650-52-8	Acute Tox. 4; H302	>= 10 - < 20
methylpyrazino[2,1-a]pyrido[2,3-	288-060-6	Repr. 2; H361fd	
c][2]benzazepine		STOT RE 2; H373	
		Aquatic Chronic 2;	
		H411	

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, se vice immediately. When symptoms persist or in all cases of doul advice.	
Protection of first-aiders	First Aid responders should pay attention to see and use the recommended personal protective when the potential for exposure exists (see se	e equipment
If inhaled	If inhaled, remove to fresh air.	



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		Get medical att	ention.
In c	ase of skin contact	of water. Remove contar Get medical att Wash clothing	
In c	ase of eye contact		well with water.
lf sv	vallowed	Get medical att	O NOT induce vomiting. ention. oroughly with water.
4.2 Most	important symptoms a	Ind effects, both act	ute and delayed
Risks		unborn child.	amaging fertility. Suspected of damaging the nage to organs through prolonged or repeated
		the skin.	ust can cause mechanical irritation or drying of ith the eyes can lead to mechanical irritation.
4.3 Indic	ation of any immediate	medical attention a	ind special treatment needed
Trea	atment	: Treat symptom	atically 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.
5.2 Special hazards arising from	the	e substance or mixture
Specific hazards during fire- fighting	:	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 Silicon oxides

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	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- the 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

••••••••••••••••••••••••••••••••••••••	e eduipinen and energenes presentee
Personal precautions	: Use personal protective equipment. Follow safe handling advice and personal protective equip- ment recommendations.
6.2 Environmental precautions	
Environmental precautions	 Discharge into the environment must be avoided. 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 cont	ainment and cleaning up
Methods for cleaning up	 Sweep up or vacuum up spillage and collect in suitable container 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 surfaces, 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 disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to deter-

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.

mine which regulations are applicable.

certain local or national requirements.

Sections 13 and 15 of this SDS provide information regarding

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Local/Total ventilation Advice on safe handling Hygiene measures		 Do not breat Do not swall Avoid contact Avoid prolon Handle in act practice, bas sessment Minimize dus Keep contain Keep away f Take precau Take care to environment If exposure t flushing syst place. When 	ow. ct with eyes. ged or repeated contact with skin. cordance with good industrial hygiene and safety sed on the results of the workplace exposure as- st generation and accumulation. her closed when not in use. rom heat and sources of ignition. tionary measures against static discharges. prevent spills, waste and minimize release to the
7.2 Co	nditions for safe storage,	including any in	compatibilities
	equirements for storage eas and containers		perly labelled containers. Store locked up. Store in with the particular national regulations.
Ad	dvice on common storage	: Do not store Strong oxidiz	with the following product types: zing agents
•	ecific end use(s) becific use(s)	: No data ava	ilable

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational Exposure Limits

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
Starch	9005-25-8	OELV - 8 hrs (TWA) (Respira- ble dust)	4 mg/m3	IE OEL
	Further inform	nation: Where no spe	cific short-term exposure lim	it is listed, a
			posure limit value should be	
		OELV - 8 hrs (TWA) (inhalable dust)	10 mg/m3	IE OEL
(+/-)- 1,2,3,4,10,14b- Hexahydro-2- methylpyra- zino[2,1- a]pyrido[2,3- c][2]benzazepine	85650-52-8	TWA	25 μg/m3	Internal
		Wipe limit	250 μg/100 cm ²	Internal



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	Silica		71187-19-4	OELV - 8 hrs (TWA) (Respira- ble dust)	2.4 mg/m3 (Silica)	IE OEL
					pecific short-term exposure line exposure limit value should be	
				OELV - 8 hrs (TWA) (inhalable dust)	6 mg/m3 (Silica)	IE OEL

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-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 equipment Wear the following personal protective equipment: Eye protection : Safety goggles Equipment should conform to I.S. EN 166 Hand protection Material Chemical-resistant gloves : Remarks Choose gloves to protect hands against chemicals depending : on the concentration and quantity of the hazardous substance 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 Select appropriate protective clothing based on chemical resistance data and an assessment of the local exposure potential. Skin contact must be avoided by using impervious protective clothing (gloves, aprons, boots, etc). Respiratory protection If adequate local exhaust ventilation is not available or expo-: sure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection. Equipment should conform to I.S. EN 143 Filter type Particulates type (P) :

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance	: powder
Colour	: No data available
Odour	: No data available
Odour Threshold	: No data available

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	рН		:	No data available	9
	Melting	point/freezing point	:	No data available	9
		oiling point and boiling	:	No data available	9
	range Flash p	oint	:	Not applicable	
	Evapor	ation rate	:	No data available	9
	Flamma	ability (solid, gas)	:	May form explos dling or other me	ive dust-air mixture during processing, han- ans.
		explosion limit / Upper bility limit	:	No data available	9
		explosion limit / Lower bility limit	:	No data available	9
	Vapour	pressure	:	No data available	9
	Relative	e vapour density	:	No data available	9
	Relative	e density	:	No data available	9
	Density	,	:	No data available	9
		er solubility n coefficient: n-	:	No data available No data available	
		nition temperature	:	No data available	9
	Decom	position temperature	:	No data available	9
	Viscosi [.] Visc	ty osity, dynamic	:	No data available	9
	Visc	osity, kinematic	:	No data available	9
	Explosi	ve properties	:	Not explosive	
	Oxidizir	ng properties	:	The substance o	r mixture is not classified as oxidizing.
9.2	9.2 Other information				
	Flamma	ability (liquids)	:	No data available	9
	Molecu	lar weight	:	No data available	9
	Particle	size	:	No data available	9



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SECTION	۱ 10: Stability and ۱	reactiv	vity	
10.1 Reac	•			
	lassified as a reactivity	y nazai	ſ ɑ .	
	n ical stability e under normal conditi	iono		
	ibility of hazardous	reactio		
Haza	rdous reactions	:	dling or othe	plosive dust-air mixture during processing, han- r means. th strong oxidizing agents.
10.4 Cond	litions to avoid			
Cond	itions to avoid	:	Heat, flames Avoid dust fo	
10.5 Incor	npatible materials			
Mater	ials to avoid	:	Oxidizing ag	ents
10.6 Haza	rdous decompositio	n prod	lucts	
	azardous decompositio	-		<i>i</i> n.
SECTION	11: Toxicological	infor	mation	
11.1 Infor	mation on toxicologi	ical eff	ects	
	nation on likely routes		Inhalation Skin contact Ingestion Eye contact	

Acute toxicity

Not classified based on available information.

Product:

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

Components:

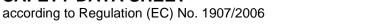
(+/-)-1,2,3,4,10,14b-Hexahyd	ro-2	2-methylpyrazino[2,1-a]pyrido[2,3-c][2]benzazepine:
Acute oral toxicity	:	LD50 (Rat): 320 - 490 mg/kg

Skin corrosion/irritation

Not classified based on available information.

Serious eye damage/eye irritation

Not classified based on available information.





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Respiratory or skin sensitisation

Skin sensitisation

Not classified based on available information.

Respiratory sensitisation

Not classified based on available information.

Germ cell mutagenicity

Not classified based on available information.

Components:

(+/-)-1,2,3,4,10,14b-Hexahydro-2-methylpyrazino[2,1-a]pyrido[2,3-c][2]benzazepine:

Genotoxicity in vitro :	Test Type: Bacterial reverse mutation assay (AMES) Result: negative
	Test Type: In vitro mammalian cell gene mutation test Test system: Chinese hamster lung cells Result: negative
	Test Type: unscheduled DNA synthesis assay Test system: mammalian cells Result: negative
	Test Type: sister chromatid exchange assay Test system: mammalian cells Result: negative
Genotoxicity in vivo :	Test Type: Micronucleus test Species: Rat Cell type: Bone marrow Application Route: Oral Result: negative

Carcinogenicity

Not classified based on available information.

Components:

(+/-)-1,2,3,4,10,14b-Hexahydro-2-methylpyrazino[2,1-a]pyrido[2,3-c][2]benzazepine:

Species Application Route Exposure time LOAEL Result Target Organs	:	Mouse Oral 18 month(s) 200 mg/kg body weight equivocal Liver
Species Application Route Exposure time LOAEL Result Target Organs	:	Rat Oral 2 Years 20 mg/kg body weight equivocal Liver, Thyroid



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Susp	roductive toxicity bected of damaging fertil	ity. Suspected of da	maging the unborn child.
(+/-)	-1.2.3.4.10.14b-Hexahv	dro-2-methylpyrazi	no[2,1-a]pyrido[2,3-c][2]benzazepine:
	cts on fertility	: Test Type: Fe Species: Rat Application Ro Fertility: LOAE Symptoms: Ef tions Result: Anima	rtility/early embryonic development
Effeo men	cts on foetal develop- t	Result: Embry	oute: Oral Il Toxicity: LOAEL: 100 mg/kg body weight otoxic effects and adverse effects on the off- etected., No teratogenic effects
		Species: Rabb Application Ro Developmenta	bit
	roductive toxicity - As- ment	fertility, based	e of adverse effects on sexual function and on animal experiments., Some evidence of s on development, based on animal experi-

STOT - single exposure

Not classified based on available information.

STOT - repeated exposure

May cause damage to organs through prolonged or repeated exposure.

Components:

(+/-)-1,2,3,4,10,14b-Hexahydro-2-methylpyrazino[2,1-a]pyrido[2,3-c][2]benzazepine:

Exposure routes	:	Ingestion
Target Organs	:	Nervous system
Assessment	:	May cause damage to organs through prolonged or repeated
		exposure.

Repeated dose toxicity

Components:

(+/-)-1,2,3,4,10,14b-Hexahydro-2-methylpyrazino[2,1-a]pyrido[2,3-c][2]benzazepine: Species : Rat

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Expos Targe Specie LOAE Applic Expos	ation Route sure time t Organs es L sation Route sure time t Organs	 120 mg/kg Oral 13 Weeks Nervous system Dog 15 mg/kg Oral 52 Weeks Nervous system Tremors 	
Expos	L ation Route sure time t Organs	: Dog : 20 mg/kg : Oral : 13 Weeks : Nervous system, Testis : Tremors	

Aspiration toxicity

Not classified based on available information.

:

Experience with human exposure

Components:

(+/-)-1,2,3,4,10,14b-Hexahydro-2-methylpyrazino[2,1-a]pyrido[2,3-c][2]benzazepine:

Ingestion

Symptoms: Drowsiness, constipation, dry mouth, asthenia, Dizziness, Disorientation

SECTION 12: Ecological information

12.1 Toxicity

Components:

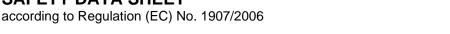
 (+/-)-1,2,3,4,10,14b-Hexahydro-2-methylpyrazino[2,1-a]pyrido[2,3-c][2]benzazepine: Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): 6.92 mg/ Exposure time: 96 h Method: FDA 4.11 			
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia magna (Water flea)): 19.5 mg/l Exposure time: 48 h	
Toxicity to algae/aquatic plants	:	EC50 (Pseudokirchneriella subcapitata (green algae)): 5.7 mg/l Exposure time: 72 h Method: OECD Test Guideline 201	
		NOEC (Pseudokirchneriella subcapitata (green algae)): 3.2 mg/l Exposure time: 72 h Method: OECD Test Guideline 201	

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Toxicity to microorganisms		:	EC50 (Natural mi Exposure time: 3 Test Type: Respir Method: OECD T	ration inhibition		
			NOEC (Natural m Exposure time: 3 Test Type: Respir Method: OECD Te	ration inhibition		
Toxicity to fish (Chronic tox- icity)		:	NOEC: 3.6 mg/l Exposure time: 3 ⁴ Species: Pimepha Method: OECD To	ales promelas (fathead minnow)		
aquatio	Toxicity to daphnia and other aquatic invertebrates (Chron- ic toxicity)		NOEC: 0.32 mg/l Exposure time: 21 d Species: Daphnia magna (Water flea) Method: OECD Test Guideline 211			
	tence and degradabil a available	ity				
	cumulative potential					
Compo	onents:					
		ro-	2-methylpyrazino[2,1-a]pyrido[2,3-c][2]benzazepine:		
	umulation	:		rnchus mykiss (rainbow trout) factor (BCF): 334		
Partitio octanol	n coefficient: n- /water	:	log Pow: 2.78			
12.4 Mobilit	ty in soil					
Compo	onents:					
(+/-)-1,	2,3,4,10,14b-Hexahyd	ro-	2-methylpyrazino[2,1-a]pyrido[2,3-c][2]benzazepine:		
	ition among environ- compartments	:	log Koc: 4.48			
	s of PBT and vPvB as	sse	ssment			
Not rele						
	adverse effects a available					
SECTION	SECTION 13: Disposal considerations					
13.1 Waste Produc	treatment methods t	:		ordance with local regulations. European Waste Catalogue, Waste Codes		





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Conta	aminated packaging	Waste codes s discussion with Empty contain dling site for re	et specific, but application specific. should be assigned by the user, preferably in h the waste disposal authorities. ers should be taken to an approved waste han- ecycling or disposal. e specified: Dispose of as unused product.

SECTION 14: Transport information

14.1 UN number

Not regulated as a dangerous good

14.2 UN proper shipping name

Not regulated as a dangerous good

14.3 Transport hazard class(es)

Not regulated as a dangerous good

14.4 Packing group

Not regulated as a dangerous good

14.5 Environmental hazards

Not regulated as a dangerous good

14.6 Special precautions for user

Not applicable

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

Remarks

: Not applicable for 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 the market and use of certain dangerous substances, preparations 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) No 1005/2009 on substances that de-	:	Not applicable
plete the ozone layer		
Regulation (EU) 2019/1021 on persistent organic pollu-	:	Not applicable
tants (recast)		
Regulation (EC) 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 Parliar	nen	and of the Council c

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:

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



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Take	re applicable. e note of Directive 94/33/ lations, where applicable		on the protection of	young people at work or stricter national			
The	components of this pro	oduc	t are reported in	the following inventories:			
AICS	6	:	not determined				
DSL		:	not determined				
IECS	IECSC		not determined				
	15.2 Chemical safety assessment A Chemical Safety Assessment has not been carried out.						
SECTIO	N 16: Other informati	on					
Othe	er information	:		nges have been made to the previous version the body of this document by two vertical			
Full	text of H-Statements						
H30	2	:	Harmful if swallov	ved.			
H36	1fd	:	Suspected of dan unborn child.	naging fertility. Suspected of damaging the			
H37	3	:		ge to organs through prolonged or repeated owed.			
H41	1	:	•	fe with long lasting effects.			
Full	text of other abbreviati	ons					
	e Tox.	:	Acute toxicity				
	atic Chronic	:		ic) aquatic hazard			
Rep	r. T RE	:	Reproductive toxi	city gan toxicity - repeated exposure			
510		•	opecine larger org	Jan toxicity - repeated exposure			

STOT RE	: Specific target organ toxicity - repeated expo	sure
IE OEL	: Ireland. List of Chemical Agents and Occupa	tional Exposure
	Limit Values Schedule 1	

IE OEL / OELV - 8 hrs (TWA)	:	Occupational exposure limit value (8-hour reference period)

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; AICS - Australian Inventory of Chemical Substances; 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 Organisa-



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tion 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; 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	:	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 m	ixture:	Classification procedure:
Repr. 2	H361fd	Calculation method
STOT RE 2	H373	Calculation method
Aquatic Chronic 3	H412	Calculation method

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