

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		51099-00015	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 Sub-	:	Pharmaceutical
stance/Mixture		

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
Charlie target argen 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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Precautionary statements		 Prevention: P201 Obtain special instructions before use. P260 Do not breathe dust. P273 Avoid release to the environment. P280 Wear protective gloves/ protective clothing/ eye protection/ face protection. 		
		Response: P308 + P313 IF attention.	exposed or concerned: Get medical advice/	
		Storage: P405 Store lock	ked 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.	Classification	Concentration
	EC-No.		(% w/w)
	Index-No.		
	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 RE2; H373	
		Aquatic Chronic2;	
		H411	

For explanation of abbreviations see section 16.

SECTION 4: First aid measures

4.1 Description of first aid measures

General advice	Ň	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	ä	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.



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In case of skin contact		:	of water. Remove contamin Get medical attent Wash clothing before		
	In case	of eye contact	:	If in eyes, rinse we Get medical attent	ell with water. ion if irritation develops and persists.
	If swalld	owed	:	If swallowed, DO I Get medical attent Rinse mouth thoro	
12	Most im	nortant symptoms an	d o	ffacts both acuta	and delayed
4.2 Most important symptoms and Risks		:	Suspected of damaging fertility. Suspected of damagin unborn child. May cause damage to organs through prolonged or rep exposure.		
				the skin.	can cause mechanical irritation or drying of the eyes can lead to mechanical irritation.
4 2 1		n of only immediate r		ical attention and	
4.3 Indication of any immediate med Treatment :			nea :		special treatment needed
SEC	CTION (5: Firefighting meas	sure	9S	
5.1 E	Extinaui	shing media			
	-	e extinguishing media	:	Water spray Alcohol-resistant for Carbon dioxide (C Dry chemical	
	Unsuita media	ble extinguishing	:	None known.	
5.2 9	Special	hazards arising from	the	substance or mix	ture
	•	hazards during fire-	:	Avoid generating of	dust; fine dust dispersed in air in sufficient In the presence of an ignition source is a

Exposure to combustion products may be a hazard to health.





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5.3 Advice for firefighters Special protective equipment for firefighters		÷	: In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.			
Specific extinguishing meth- ods		:	cumstances and t Use water spray t	g measures that are appropriate to local cir- the surrounding environment. to 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 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 con	tainment 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 determine 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.
Provide adequate precautions, such as electrical grounding
and bonding, or inert atmospheres.

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practice, based on the results sessment Minimize dust generation and Keep container closed when Keep away from heat and so Take precautionary measure Take care to prevent spills, w environment. Hygiene measures : If exposure to chemical is like flushing systems and safety s place. When using do not ear		ist. or eyes. or repeated contact with skin. ance with good industrial hygiene and safety on the results of the workplace exposure as- meration and accumulation. osed when not in use.			
7.2	Conditi	ons for safe storage,	inc	luding any incom	patibilities
		ements for storage and containers	: Keep in properly labelled containers. Store locked accordance with the particular national regulations		
	Advice	on common storage	:	: Do not store with the following product types: Strong oxidizing agents	
7.3	•	c end use(s) ic use(s)	:	No data available	

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

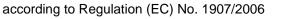
Occupational Exposure Limits

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
(+/-)- 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 cm²	Internal
Silica	71187-19-4	TWA (respirable dust)	1,5 mg/m3 (Silica)	FOR-2011- 12-06-1358

8.2 Exposure controls

Engineering measures

Ensure adequate ventilation, especially in confined areas.





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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

Eye protection	:	Wear the following personal protective equipment: Safety goggles Equipment should conform to NS 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 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	:	Select appropriate protective clothing based on chemical re- sistance data and an assessment of the local exposure poten- tial. 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 rec- ommended guidelines, use respiratory protection. Equipment should conform to NS EN 143
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	:	Not applicable
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	9
Lower explosion limit / Lower flammability limit		:	No data available	
Vapou	r pressure	:	No data available)
Relativ	ve vapour density	:	No data available	9
Relativ	ve density	:	No data available	9
Densit	у	:	No data available)
Wa Partitic octanc	lity(ies) ter solubility on coefficient: n- ol/water gnition temperature	:	No data available No data available No data available	
Decon	nposition temperature	:	No data available)
Viscos Vis	ity cosity, dynamic	:	No data available	9
Vis	cosity, kinematic	:	No data available)
Explos	sive properties	:	Not explosive	
Oxidiz	ing properties	:	The substance o	r mixture is not classified as oxidizing.
	nformation nability (liquids)	:	No data available	9
Molec	ular weight	:	No data available	9
Particl	e 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.

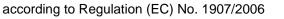
10.4 Conditions to avoid



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Cond	itions to avoid	: Heat, flames Avoid dust fo			
10.5 Incoi	mpatible materials				
Mater	rials to avoid	: Oxidizing age	ents		
No ha	rdous decomposition azardous decompositio	on products are know	n.		
SECTION	N 11: Toxicological	information			
11.1 Infor	mation on toxicologi	cal effects			
	nation on likely routes				
Acute	e toxicity				
	lassified based on ava	ilable information.			
Prod Acute	<u>uct:</u> e oral toxicity		estimate: > 2.000 mg/kg ulation method		
Com	ponents:				
(+/-)-′	1.2.3.4.10.14b-Hexah	/dro-2-methvlpvrazi	no[2,1-a]pyrido[2,3-c][2]benzazepine:		
	e oral toxicity		20 - 490 mg/kg		
-	corrosion/irritation lassified based on ava	ilable information.			
	ous eye damage/eye i lassified based on ava				
Resp	iratory or skin sensit	isation			
-	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.				
Com	ponents:				
. ,	1,2,3,4,10,14b-Hexahy toxicity in vitro		no[2,1-a]pyrido[2,3-c][2]benzazepine: cterial reverse mutation assay (AMES) ve		





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			ro mammalian cell gene mutation test inese hamster lung cells
		Test Type: unsc Test system: ma Result: negative	
		Test Type: siste Test system: ma Result: negative	
Geno	toxicity in vivo	: Test Type: Micro Species: Rat Cell type: Bone Application Rout Result: negative	marrow te: Oral

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

Reproductive toxicity

Suspected of damaging fertility. Suspected of damaging the unborn child.

Components:

Effects on fertility	 Test Type: Fertility/early embryonic development Species: Rat Application Route: Oral Fertility: LOAEL: 15 mg/kg body weight Symptoms: Effect on estrous cycle, Increase of early resorp- tions Result: Animal testing did not show any effects on fertility., Embryotoxic effects and adverse effects on the offspring were detected 	
	detected.	

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Effects on foetal develop- ment		: Test Type: Development Species: Rat Application Route: Oral Developmental Toxicity: LOAEL: 100 mg/kg body weight Result: Embryotoxic effects and adverse effects on the off- spring were detected., No teratogenic effects			
		•	it		
Repro sessn	oductive toxicity - As- nent	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:

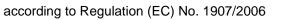
Exposure routes Target Organs Assessment	:	Ingestion Nervous system May cause damage to organs through prolonged or repeated
		exposure.

Repeated dose toxicity

Components:

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

Species LOAEL Application Route Exposure time Target Organs	:	Rat 120 mg/kg Oral 13 Weeks Nervous system
Species LOAEL Application Route Exposure time Target Organs Symptoms	:	Dog 15 mg/kg Oral 52 Weeks Nervous system Tremors
Species LOAEL Application Route	:	Dog 20 mg/kg Oral





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ersion .3	Revision Date: 23.03.2020	SDS Number:Date of last issue: 13.09.201951099-00015Date of first issue: 23.01.2015
	sure time et Organs otoms	 13 Weeks Nervous system, Testis Tremors
Aspir	ration toxicity	
Not c	lassified based on ava	able information.
Expe	rience with human e	oosure
Com	ponents:	
(+/-)-′	1,2,3,4,10,14b-Hexah	dro-2-methylpyrazino[2,1-a]pyrido[2,3-c][2]benzazepine:
Inges	tion	: Symptoms: Drowsiness, constipation, dry mouth, asthenia Dizziness, Disorientation

12.1 Toxicity

Components:

(+/-)-1,2,3,4,10,14b-Hexahydr Toxicity to fish	ro-2	2-methylpyrazino[2,1-a]pyrido[2,3-c][2]benzazepine: LC50 (Pimephales promelas (fathead minnow)): 6,92 mg/l 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
Toxicity to microorganisms	:	EC50 (Natural microorganism): > 1.000 mg/l Exposure time: 3 h Test Type: Respiration inhibition Method: OECD Test Guideline 209
		NOEC (Natural microorganism): < 100 mg/l Exposure time: 3 h Test Type: Respiration inhibition Method: OECD Test Guideline 209
Toxicity to fish (Chronic tox- icity)	:	NOEC: 3,6 mg/l Exposure time: 31 d Species: Pimephales promelas (fathead minnow) Method: OECD Test Guideline 210



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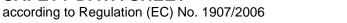
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aqua	city to daphnia and other tic invertebrates (Chron- cicity)		NOEC: 0,32 mg/l Exposure time: 2 Species: Daphnia Method: OECD T	a magna (Water flea)
	istence and degradabil ata available	lity		
12.3 Bioa	ccumulative potential			
<u>Com</u>	ponents:			
	1,2,3,4,10,14b-Hexahyd ccumulation	lro-: :	Species: Oncorhy Bioconcentration	[2,1-a]pyrido[2,3-c][2]benzazepine: /nchus mykiss (rainbow trout) factor (BCF): 334 est Guideline 305
	tion coefficient: n- nol/water	:	log Pow: 2,78	
12.4 Mob	ility in soil			
<u>Com</u>	ponents:			
Distr	1,2,3,4,10,14b-Hexahyd ibution among environ- al compartments			[2,1-a]pyrido[2,3-c][2]benzazepine:
12.5 Res	ults of PBT and vPvB as elevant	sse	ssment	
	er adverse effects ata available			
SECTIO	N 13: Disposal consid	dera	ations	
13.1 Was	te treatment methods			
Prod	uct	:	According to the l are not product sp Waste codes sho	ordance with local regulations. European Waste Catalogue, Waste Codes pecific, but application specific. uld be assigned by the user, preferably in ne waste disposal authorities.
Cont	aminated packaging	:	Empty containers dling site for recy	should be taken to an approved waste han-
SECTIO	N 14: Transport infor	mat	If not otherwise s	

14.1 UN number

Not regulated as a dangerous good

14.2 UN proper shipping name

Not regulated as a dangerous good





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	port hazard class(es) gulated as a dangerous				
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 Concern for Authorisation (Article 59).	:	Not applicable
REACH - List of substances subject to authorisation (Annex XIV)	:	Not applicable
Regulation (EC) No 1005/2009 on substances that deplete the ozone layer	:	Not applicable
Regulation (EU) 2019/1021 on persistent organic pollu- tants (recast)	:	Not applicable
Regulation (EC) No 649/2012 of the European Parlia- ment and the Council concerning the export and import of dangerous chemicals	:	Not applicable

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, where applicable.

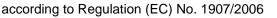
Young people under the age of 18 are not allowed to use or be exposed to the product professionally. Young people above the age of 15 are, however, except from this rule if the product is a necessary part of their education.

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.





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SECTIO	N 16: Other informa	tion			
Othe	er information	:		hanges have been made to the previous version I in the body of this document by two vertical	
Full	text of H-Statements				
H302		:	Harmful if swallowed.		
H36	361fd : Suspected of damaging fertility. Suspected of unborn child.		damaging fertility. Suspected of damaging the		
H37	3	: May cause damage to organs through prolonged or exposure if swallowed.			
H411		:	Toxic to aquatic life with long lasting effects.		
Full	text of other abbrevia	tions			
Acut	e Tox.	:	Acute toxicity		
Aqua	atic Chronic	: Long-term (chronic) aquatic hazard		ronic) aquatic hazard	
Rep		:	: Reproductive toxicity		
	IT RE	:	: Specific target organ toxicity - repeated exposure		
	-2011-12-06-1358	:		pational Exposure limits	
FOR TWA	2-2011-12-06-1358 / A	8 / : Long term exposure limit		osure limit	

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 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;



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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, OEC eChem Portal search results and European Chemicals Age cy, http://echa.europa.eu/	
Classification of the mixture:	Classification procedure:	

Repr. 2	H361fd	Calculation method
STOT RE 2	H373	Calculation method
Aquatic Chronic 3	H412	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