

Commission Regulation (EU) 2020/878

Amprolium Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 06.07.2024
3.1	28.09.2024	10859059-00007	Date of first issue: 30.09.2022

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

1.1	Product identifier Trade name	:	Amprolium Solid Formulation
1.2	Relevant identified uses of th	ne s	ubstance or mixture and uses advised against
	Use of the Sub- stance/Mixture	:	Veterinary product
	Recommended restrictions on use	:	Not applicable
1.3	Details of the supplier of the	saf	ety 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)

Skin corrosion, Category 1 Serious eye damage, Category 1 Reproductive toxicity, Category 2

Specific target organ toxicity - repeated exposure, Category 1 Long-term (chronic) aquatic hazard, Category 3 H314: Causes severe skin burns and eye damage.
H318: Causes serious eye damage.
H361: Suspected of damaging fertility or the unborn child.
H372: Causes damage to organs through prolonged or repeated exposure.
H412: Harmful to aquatic life with long lasting effects.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008) Hazard pictograms :



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



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Signa	l word	:	Danger	
Hazar	d statements	:	H361 Suspected H372 Causes da peated exposure.	evere skin burns and eye damage. I of damaging fertility or the unborn child. amage to organs through prolonged or re- aquatic life with long lasting effects.
Preca	utionary statements	:	P260 Do not bre P273 Avoid relea	ase to the environment. ective gloves/ protective clothing/ eye protec-
			immediately all con shower. Immediate P305 + P351 + P3 with water for seve	53 + P310 IF ON SKIN (or hair): Take off ntaminated clothing. Rinse skin with water or ely call a POISON CENTER/ doctor. 38 + P310 IF IN EYES: Rinse cautiously eral minutes. Remove contact lenses, if pre- to. Continue rinsing. Immediately call a d/ doctor.

Hazardous components which must be listed on the label: Amprolium

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.

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		

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Ampro	olium	121-25-5 204-458-4	Repr. 2; H361 STOT RE 1; H372 (Central nervous system) Aquatic Chronic 3; H412	>= 50 - < 70

For explanation of abbreviations see section 16.

SECTION 4: First aid measures

4.1 Description of first aid me	
General advice	 In the case of accident or if you feel unwell, seek medical advice 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. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention immediately.
In case of skin contact	 In case of contact, immediately flush skin with plenty of water for at least 15 minutes while removing contaminated clothing and shoes. Get medical attention immediately. Wash clothing before reuse. Thoroughly clean shoes before reuse.
In case of eye contact	 In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. If easy to do, remove contact lens, if worn. Get medical attention immediately.
If swallowed	 If swallowed, DO NOT induce vomiting. If vomiting occurs have person lean forward. Call a physician or poison control centre immediately. Rinse mouth thoroughly with water. Never give anything by mouth to an unconscious person.
1 2 Most important symptoms	

4.2 Most important symptoms and effects, both acute and delayed

Risks	:	Causes serious eye damage. Suspected of damaging fertility or the unborn child. Causes damage to organs through prolonged or repeated exposure.
		Causes severe burns.



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				Causes digestive	tract burns.
	-	mmediate r	ned		special treatment needed
Т	reatment		:	Treat symptomati	cally and supportively.
SECT	FION 5: Firefigh	ting meas	sure	es	
5.1 Ex	ctinguishing mec	lia			
S	Suitable extinguish	iing media	:	Water spray Alcohol-resistant Carbon dioxide (C Dry chemical	
	Insuitable extingu nedia	ishing	:	None known.	
5.2 Sp	oecial hazards ar	ising from	the	substance or mi	xture
	Specific hazards d ghting	uring fire-	:	concentrations, an potential dust exp	dust; fine dust dispersed in air in sufficient nd in the presence of an ignition source is a losion hazard. Dustion products may be a hazard to health.
	lazardous combus	stion prod-	:	Carbon oxides	
5.3 Ac	dvice for firefight	ters			
	Special protective or firefighters	equipment	:		e, wear self-contained breathing apparatus. rective equipment.
	Specific extinguish ds	ing meth-	:	cumstances and t Use water spray t	measures that are appropriate to local cir- he surrounding environment. o cool unopened containers. ged containers from fire area if it is safe to do

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

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

Environmental precautions	: Avoid release to the environment.
	Prevent further leakage or spillage if safe to do so.
	Retain and dispose of contaminated wash water.
	Local authorities should be advised if significant spillages



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		cannot be conta	ined.
6.3 Metho	ods and material for c	ontainment and clear	ning up
Meth	ods for cleaning up	tainer for dispos Avoid dispersal with compresse Dust deposits s es, as these ma leased into the Local or nationa posal of this ma employed in the mine which regu	of dust in the air (i.e., clearing dust surfaces

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.
		Do not get in eyes.
		Wash skin thoroughly after handling.
		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. Do not eat, drink or smoke when using this product.
		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,



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				wning and decontamination procedures, monitoring, medical surveillance and the tive controls.
7.2 Condit	ions for safe storage,	inc	luding any incom	patibilities
	rements for storage and containers	:		labelled containers. Store locked up. Keep ore in accordance with the particular national
Advice	e on common storage	:	Strong oxidizing	stances and mixtures
•	c end use(s) ic use(s)	:	No data available	

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

-	
Occupational Exposure Limits	6
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
Amprolium	121-25-5	TWA	40 ug/m3 (OEB 3)	Internal
	Further information: DSEN			
		Wipe limit	140 ug/100cm2	Internal

8.2 Exposure controls

Engineering measures

All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.

Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of the compound to uncontrolled areas (e.g., open-face containment devices).

Minimize open handling.

Personal protective equipment

Eye/face protection : Wear safety glasses with side shields or goggles.

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		mists or aeros Wear a faces	vironment or activity involves dusty conditions, sols, wear the appropriate goggles. hield or other full face protection if there is a irect contact to the face with dusts, mists, or
nanu	protection		
Material		: Chemical-resi	stant gloves
Remarks Skin and body protection		Additional boo being perform suits) to avoid	or laboratory coat. ly garments should be used based upon the task ed (e.g., sleevelets, apron, gauntlets, disposable exposed skin surfaces. te degowning techniques to remove potentially
Respiratory protection Filter type		: If adequate loo sure assessm ommended gu	cal exhaust ventilation is not available or expo- ent demonstrates exposures outside the rec- udelines, use respiratory protection. ould conform to NS EN 143

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Physical state	:	powder
Colour	:	light yellow
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)	:	Not applicable
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Flash point	:	Not applicable

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	Auto-ię	gnition temperature	:	No data available	e
	Decon	nposition temperature	:	No data available	e
	рН		:	2,0 - 3,0	
	Viscos Vis	ity cosity, kinematic	:	Not applicable	
		lity(ies) ter solubility	:	No data available	e
		on coefficient: n- ol/water	:	Not applicable	
	Vapou	r pressure	:	Not applicable	
	Relativ	ve density	:	No data available	e
	Densit	у	:	No data available	e
	Relativ	ve vapour density	:	Not applicable	
		e characteristics ticle size	:	No data available	e
9.2	Other i	nformation			
	Explos	sives	:	Not explosive	
	Oxidiz	ing properties	:	The substance o	r mixture is not classified as oxidizing.
	Evapo	ration rate	:	Not applicable	
	Molec	ular 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



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Condi	tions to avoid		eat, flames a void dust forr	
0.5 Incor	npatible materials			
Mater	ials to avoid	: 0	xidizing agen	ts
	rdous decompositio	-		
	I 11: Toxicologica	•		
		i ini orina		
				egulation (EC) No 1272/2008
expos	nation on likely routes sure		alation in contact	
			jestion	
		Ey	e contact	
	e toxicity assified based on av	ailable info	rmation.	
Comp	oonents:			
Ampr	olium:			
Acute	oral toxicity	: LD	50 (Mouse):	3.980 mg/kg
		LD	50 (Rat): 4.0	00 - 4.890 mg/kg
		LD	50 (Dog): > 5	500 mg/kg
Acute	dermal toxicity	: LD	50 (Rat): > 2	.000 mg/kg
-	corrosion/irritation			
Comp	oonents:			
Ampr	olium:			
Speci			bbit	
Resul	t	: No	skin irritatior	1
	us eye damage/eye			
	es serious eye dama	ge.		
Comp	oonents:			
Ampr Speci		_	bbit	

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Respiratory or skin sensitisation

Skin sensitisation

Not classified based on available information.

Respiratory sensitisation

Not classified based on available information.

Components:

Test Type	:	Local lymph node assay (LLNA)
Exposure routes	:	Dermal
Species	:	Mouse
Result	:	Sensitiser

Germ cell mutagenicity

Not classified based on available information.

Components:

Amprolium:	
Genotoxicity in vitro :	Test Type: Bacterial reverse mutation assay (AMES) Result: negative
	Test Type: Chromosomal aberration Test system: Chinese hamster ovary cells Result: positive
	Test Type: in vitro micronucleus test Result: positive
Genotoxicity in vivo :	Test Type: Micronucleus test Species: Mouse Cell type: Bone marrow Result: negative
	Test Type: unscheduled DNA synthesis assay Species: Rat Cell type: Liver cells Result: negative
Germ cell mutagenicity- As- : sessment	Weight of evidence does not support classification as a germ cell mutagen.
Carcinogenicity	
Not classified based on available	e information.

Components:

Amprolium:

Species	:	Rat
Exposure time	:	2 Years

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Res	sult	: negative	
-	productive toxicity spected of damaging fertili	ty or the unborn chil	d.
Co	mponents:		
	prolium: ects on fertility	Species: Mous Application Ro Fertility: NOAE Result: Effects	
Effe	ects on foetal develop- nt		it
	productive toxicity - As- ssment		e of adverse effects on sexual function and on development, based on animal experiments.
	OT - single exposure t classified based on availa	able information.	
ST	OT - repeated exposure		
Cau	uses damage to organs th	rough prolonged or	epeated exposure.
<u>Co</u>	mponents:		
Am	prolium:		
	oosure routes get Organs	: Oral : Central nervou	s system

Target Organs	: Central nervous system
Assessment	: Causes damage to organs through prolonged or repeated
	exposure.

Repeated dose toxicity

Components:

Amprolium:

Species NOAEL Application Route Exposure time	:	Rat 20 mg/kg Oral 2 yr
Symptoms	:	Reduced body weight
Species NOAEL Application Route	:	Dog 100 mg/kg Oral

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Targe Symp Specie NOAE Applic Expos	es EL cation Route sure time t Organs	2 yr Central nervous Dilatation of the p Dog 100 mg/kg Oral 59 Weeks Central nervous ataxia, Convulsio	oupil, paralysis

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:

Amprolium:	
Inhalation :	Target Organs: Skin
	Symptoms: Allergic reactions
Eye contact :	Target Organs: Lungs
	Symptoms: Allergic reactions, Asthma
Ingestion :	Target Organs: Central nervous system
	Symptoms: Neurological disorders

SECTION 12: Ecological information

12.1 Toxicity

Components:		
Amprolium:		
Toxicity to fish	:	LC50 (Pimephales promelas (fathead minnow)): > 100 mg/l Exposure time: 96 h Method: OECD Test Guideline 203
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia magna (Water flea)): 110 mg/l Exposure time: 48 h Method: OECD Test Guideline 202



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Toxic plants	ity to algae/aquatic	 EC50 (Pseudokirchneriella subcapitata (green algae)): 100 mg/l Exposure time: 72 h Method: OECD Test Guideline 201 	
	stence and degradab	ity	
12.3 Bioad	ccumulative potential		
<u>Com</u>	oonents:		
Partiti	r olium: on coefficient: n- ol/water	: log Pow: -1,12 pH: 7	
12.4 Mobi No da	lity in soil ita available		
12.5 Resu	Its of PBT and vPvB a	sessment	
<u>Produ</u> Asses	uct: ssment	: 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 Endo	crine disrupting prop	rties	
Produ	uct:		
Asses	ssment	: 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 a levels of 0.1% or higher.	
12.7 Othe	r adverse effects		

12.7 Other adverse effects

No data available

SECTION 13: Disposal considerations

13.1 Waste treatment methods

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

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If not otherwise specified: Dispose of as unused product.

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
14.2 UN proper shipping name		
ADN	:	Not regulated as a dangerous good
ADR	:	Not regulated as a dangerous good
RID	:	Not regulated as a dangerous good
IMDG	:	Not regulated as a dangerous good
ΙΑΤΑ	:	Not regulated as a dangerous good
14.3 Transport hazard class(es)		
ADN	:	Not regulated as a dangerous good
ADR	:	Not regulated as a dangerous good
RID	:	Not regulated as a dangerous good
IMDG	:	Not regulated as a dangerous good
ΙΑΤΑ	:	Not regulated as a dangerous good
14.4 Packing group		
ADN	:	Not regulated as a dangerous good
ADR	:	Not regulated as a dangerous good
RID	:	Not regulated as a dangerous good
IMDG	:	Not regulated as a dangerous good
IATA (Cargo)	:	Not regulated as a dangerous good
IATA (Passenger)	:	Not regulated as a dangerous good
14.5 Environmental hazards Not regulated as a dangerous	go	od

14.6 Special precautions for user

Not applicable

14.7 Maritime transport in bulk according to IMO instruments

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

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances,	:	Not applicable
mixtures and articles (Annex XVII)		
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
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 Parliar	nent	t and of the Council o
•		

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		
H361	:	Suspected of damaging fertility or the unborn child.
H372	:	Causes damage to organs through prolonged or repeated exposure if swallowed.
H412	:	Harmful to aquatic life with long lasting effects.

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Full text of other abbreviations

Aquatic Chronic	: Long-term (chronic) aquatic hazard
Repr.	: Reproductive toxicity
STOT RE	: Specific target organ toxicity - repeated exposur
FOR-2011-12-06-1358	: Norway. Occupational Exposure limits
FOR-2011-12-06-1358 /	: Long term exposure limit
TWA	

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by Road; AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA -European Chemicals Agency; EC-Number - European Community number; ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association: IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of very high concern; TCSI - Taiwan Chemical Substance Inventory; TECI -Thailand Existing Chemicals Inventory; 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	e mixture:	Classification procedure:
Skin Corr. 1	H314	Based on product data or assessment
Eye Dam. 1	H318	Based on product data or assessment
Repr. 2	H361	Calculation method



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STOT	RE 1	H372	Calculation method	
Aquat	ic Chronic 3	H412	Calculation method	

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