

Version	Revision Date:	SDS Number:	Date of last issue: 06.07.2024
5.1	28.09.2024	9373157-00009	Date of first issue: 27.08.2021

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

1.1	Product identifier Trade name	:	Amoxicillin Trihydrate Solid Formulation
1.2	Relevant identified uses of th	ne s	substance 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 Walton Manor, Walton MK7 7AJ Milton Keynes - United Kingdom
	Telephone	:	+1-908-740-4000
	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) as amended by GB-CLP Regulation, UK SI 2019/720, and UK SI 2020/1567)

Respiratory sensitisation, Category 1	H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled.
Short-term (acute) aquatic hazard, Cate- gory 1	H400: Very toxic to aquatic life.
Long-term (chronic) aquatic hazard, Cat- egory 1	H410: Very toxic to aquatic life with long lasting effects.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008) as amended by GB-CLP Regulation, UK SI 2019/720, and UK SI 2020/1567)

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



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Hazard pictograms		:		¥2
Signa	al word	:	Danger	•
Hazard statements		:	H334	May cause allergy or asthma symptoms or breath- ing difficulties if inhaled.
			H410	Very toxic to aquatic life with long lasting effects.
Preca	autionary statements	:	Prevention:	
				Avoid breathing dust. Avoid release to the environment.
			P284	Wear respiratory protection.
			Response:	
			P304 + P340) IF INHALED: Remove person to fresh air and keep comfortable for breathing.
			P342 + P311	
			P391	Collect spillage.

Hazardous components which must be listed on the label: Amoxicillin Trihydrate

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)
Amoxicillin Trihydrate	61336-70-7	Resp. Sens. 1A; H334 Aquatic Acute 1; H400 Aquatic Chronic 1; H410 M-Factor (Acute aquatic toxicity):	>= 70 - < 90

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			100 M-Factor (Chronic aquatic toxicity): 1	

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).
If inhaled	:	If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention.
In case of skin contact	:	Wash with water and soap. Get medical attention if symptoms occur.
In case of eye contact	:	If in eyes, rinse well with water. Get medical attention if irritation develops and persists.
If swallowed	:	If swallowed, DO NOT induce vomiting. Get medical attention if symptoms occur. Rinse mouth thoroughly with water.
4.2 Most important symptoms	and e	effects, both acute and delayed
Risks	:	May cause allergy or asthma symptoms or breathing difficul- ties if inhaled.
		Excessive exposure may aggravate preexisting asthma and other respiratory disorders (e.g. emphysema, bronchitis, reac- tive airways dysfunction syndrome). Contact with dust can cause mechanical irritation or drying of the skin.
4.0 Indication of succession in the		Dust contact with the eyes can lead to mechanical irritation.
a z indication at any immediat	~ m ~	NIANI AMANNAN ANA ANANANI TRAATMANT NAAAAA

4.3 Indication of any immediate medical attention and special treatment needed

Treatment

: Treat symptomatically and supportively.



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SECTION 5: Firefighting measures

5.1 Extinguishing media

media

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

5.2 Special hazards arising from the substance or mixture

5.2 Special hazards arising from	h 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 Nitrogen oxides (NOx) Metal oxides
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	:	Use extinguishing measures that are appropriate to local cir- cumstances and the surrounding environment. Use water spray to cool unopened containers. Remove undamaged containers from fire area if it is safe to do so.

Evacuate area.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions	:	Use personal protective equipment. Follow safe handling advice (see section 7) and personal pro- tective equipment recommendations (see section 8).
6.2 Environmental precautions		
Environmental precautions	:	Avoid release to the environment. Prevent further leakage or spillage if safe to do so. Retain and dispose of contaminated wash water. If spillage enters rivers or watercourses, inform the Environ- ment Agency (emergency telephone number 0800 807060).

6.3 Methods and material for containment and cleaning up

Methods for cleaning up :	Surround spill with a	absorbents and place a	damp covering
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		Add excess liqui Soak up with ine Avoid dispersal of with compressed Dust deposits sh es, as these may leased into the a Clean up remain bent. Local or national posal of this mat employed in the mine which regu	minimise entry of the material into the air. d to allow the material to enter into solution. ert absorbent material. of dust in the air (i.e., clearing dust surfaces d air). nould not be allowed to accumulate on surfac- y form an explosive mixture if they are re- tatmosphere in sufficient concentration. hing materials from spill with suitable absor- l regulations may apply to releases and dis- terial, as well as those materials and items cleanup of releases. You will need to deter- lations are applicable. 15 of this SDS provide information regarding mational 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

Techaicel accounter		
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	: Use only with adequate ventilation.	
Advice on safe handling	: Do not breathe dust.	
, and of on oard namaning	Do not swallow.	
	Avoid contact with eyes.	
	Avoid prolonged or repeated contact with skin.	
	Handle in accordance with good industrial hygiene and safety	v
	practice, based on the results of the workplace exposure as-	
	sessment	
	Keep container tightly closed.	
	Already sensitised individuals, and those susceptible	
	to asthma, allergies, chronic or recurrent respiratory disease,	,
	should consult their physician regarding working with respira-	-
	tory irritants or sensitisers.	
	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.	е
Hygiene measures	: If exposure to chemical is likely during typical use, provide ey	/e
	flushing systems and safety showers close to the working	
	place. When using do not eat, drink or smoke. Wash contami	i-
	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, e monitoring, medical surveillance and the tive controls.
7.2 Conditions for safe storage, including any incompatibilities				
Requirements for storage areas and containers		:		labelled containers. Keep tightly closed. nce with the particular national regulations.
Advic	e on common storage	:	Do not store with Strong oxidizing a	the following product types: agents
•	ic end use(s)		No data available	
Speci	fic use(s)	:	No data available	

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational Exposure Limits

dust of any kind 10 mg/m3 Value type (Form of exposure): TWA (Inhalable) Basis: GB EH40

4 mg/m3 Value type (Form of exposure): TWA (Respirable fraction) Basis: GB EH40

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
Amoxicillin Trihy- drate	61336-70-7	TWA	1 mg/m3 (OEB 1)	Internal
	Further information: RSEN			

8.2 Exposure controls

Engineering measures

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

Personal protective equipme		
Eye/face protection	,	Wear safety glasses with side shields or goggles. If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles. Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.
Hand protection Material	:	Chemical-resistant gloves

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Skin and body protection Respiratory protection Filter type		: :	· · · · · · · · · · · · · · · · · · ·			
SEC	SECTION 9: Physical and chemical properties					
9.1	Informatio Appearan Colour Odour Odour Th pH		al an : : :	powder white characteristic No data available 5.5 - 7.5		
	Melting po	pint/freezing point	:	(as aqueous solu No data available		
	Initial boili range Flash poir	ing point and boiling nt	:	No data available Not applicable		
	Evaporati	on rate	:	Not applicable		
	Flammabi	ility (solid, gas)	:	May form explosi dling or other me	ve dust-air mixture during processing, han- ans.	
	Upper exp flammabil	olosion limit / Upper ity limit	:	No data available		
	Lower exp flammabil	olosion limit / Lower ity limit	:	No data available		
	Vapour pr	ressure	:	Not applicable		
	Relative v	apour density	:	Not applicable		
	Relative c	lensity	:	No data available		
	Density		:	No data available		
	Partition of octanol/w	solubility coefficient: n-	:	1.43 g/l Not applicable No data available	9	
	Decompo	sition temperature	:	No data available	9	
	Viscosity					

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	Viscosity, kinematic	:	Not applicable	
Explosive properties		:	Not explosive	
Oxidizing properties		:	The substance o	r mixture is not classified as oxidizing.
9.2 Other information			No data available	
Γle	ammability (liquids)	•	NU Udla avallable	÷
M	olecular weight	:	No data available	9
Pa	article size	:	No data available	9

SECTION 10: Stability and reactivity

10.1 Reactivity

Not classified as a reactivity hazard.

10.2 Chemical stability

Stable under normal conditions.

10.3 Possibility of hazardous reactions

Hazardous reactions	: May form explosive dust-air mixture during processing, han- dling or other means. Can react with strong oxidizing agents.
10.4 Conditions to avoid	
Conditions to avoid	: Heat, flames and sparks. Avoid dust formation.
40 E Incompetible metoriale	

10.5 Incompatible materials

Materials to avoid : Oxidizing agents

10.6 Hazardous decomposition products

No hazardous decomposition products are known.

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Information on likely routes of : Inhalation exposure Skin contact Ingestion Eye contact

Acute toxicity

Not classified based on available information.

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ritat	LD50 (Rat): > 8,0 LD50 (Mouse): > LD50 (Dog): > 3, information.	10,000 mg/kg
able ritat able	LD50 (Mouse): > LD50 (Dog): > 3,	10,000 mg/kg
able ritat able	LD50 (Mouse): > LD50 (Dog): > 3,	10,000 mg/kg
r itat able	LD50 (Dog): > 3,	
r itat able		000 mg/kg
r itat able	information	
r itat able		
able		
	information.	
able	information.	
syn	nptoms or breathin	g difficulties if inhaled.
:	Sensitiser	
:		tisation by inhalation. human evidence
abla	information.	
able	inionnation.	
	Toot Turo: Pooto	rial reverse mutation appay (AMES)
:	Result: negative	rial reverse mutation assay (AMES)
:	Test Type: Micro	nucleus test
	Species: Mouse Result: negative	
	-	
	Test Type: Rode Species: Mouse Result: negative	nt dominant lethal test (germ cell) (in vi
	able	Species: Mouse

Reproductive toxicity

Not classified based on available information.



ersion 1	Revision Date: 28.09.2024	SDS Number: 9373157-00009	Date of last issue: 06.07.2024 Date of first issue: 27.08.2021
Com	ponents:		
Amoxicillin Trihydrate: Effects on fertility		Result: Reduce Remarks: Not c Test Type: Fert	ute: Oral L: 200 mg/kg body weight d fertility classified due to inconclusive data.
		Result: Reduce	.: 500 mg/kg body weight
Effec ment	ts on foetal develop-	•	
		Result: Some e based on anima	e ute: Oral Toxicity: LOAEL: 200 mg/kg body weight vidence of adverse effects on development,
		Result: Reduce weight gain	
	T - single exposure classified based on avai	lable information.	
	F - repeated exposure classified based on avai		
Com	ponents:		
Amo	xicillin Trihydrate:		

Amoxicillin Trihydrate:

Remarks

: Not classified due to inconclusive data.

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Repe	ated dose toxicity		
Com	ponents:		
Amo	xicillin Trihydrate:		
	cation Route sure time	: Rat : Oral : 6 Months : No significant a	dverse effects were reported
	cation Route sure time	: Dog : Oral : 6 Months : No significant a	dverse effects were reported
Aspi	ration toxicity		
Not c	lassified based on ava	ilable information.	
Expe	rience with human e	xposure	
Com	ponents:		
Amo	xicillin Trihydrate:		
Inges	stion	flatulence, skin	usea, Vomiting, Abdominal pain, Diarrhoea, rash, Breathing difficulties produce an allergic reaction.
SECTION	N 12: Ecological inf	ormation	
12.1 Toxic	city		

Components:		
Amoxicillin Trihydrate:		
Toxicity to fish	:	LC50 (Carassius auratus (goldfish)): 0.035 mg/l Exposure time: 96 h Method: OECD Test Guideline 203
Toxicity to algae/aquatic plants	:	NOEC (green algae): 530 mg/l Exposure time: 72 h
		EC50 (Synechococcus leopoliensis (blue-green algae)): 0.0022 mg/l Exposure time: 96 h
		NOEC (blue-green algae): 0.0057 mg/l Exposure time: 72 h
M-Factor (Acute aquatic tox- icity)	:	100
M-Factor (Chronic aquatic toxicity)	:	1

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12.2 Persistence and degradability

Components:

Amoxicillin Trihydrate:

Biodegradability	:	Result: Readily biodegradable.
		Biodegradation: 88 %
		Exposure time: 28 d
		Method: OECD Test Guideline 301B

12.3 Bioaccumulative potential

С	0	r	n	р	0	n	e	r	It	s	:	

Amoxicillin Trihydrate:

Bioaccumulation	:	Remarks: Bioaccumulation is unlikely.
Partition coefficient: n- octanol/water	:	log Pow: -0.124 Method: OECD Test Guideline 107

12.4 Mobility in soil

No data available

12.5 Results of PBT and vPvB assessment

Assessment :		This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.
Components:		
Amoxicillin Trihydrate:		
Assessment	:	Substance is not persistent, bioaccumulative, and toxic (PBT) Product does not contain substances which are very persistent and very bioaccumulative (vPvB) at levels of 0.1%

or higher.

12.6 Other adverse effects

Product:

Endocrine disrupting poten- : tial	This substance/mixture does not contain components consid- ered to have endocrine disrupting properties for environment according to UK REACH Article 57(f).
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SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product

: Dispose of in accordance with local regulations.



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Contaminated packaging	 According to the European Waste Catalogue, Waste Codes are not product specific, but application specific. 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. If not otherwise specified: Dispose of as unused product. 				
SECTION 14: Transport infor	rmation				
14.1 UN number					
ADN	: UN 3077				
ADR	: UN 3077				
RID	: UN 3077				
IMDG	: UN 3077				
ΙΑΤΑ	: UN 3077				
14.2 UN proper shipping name					
ADN	: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Amoxicillin Trihydrate)				
ADR	: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Amoxicillin Trihydrate)				
RID	: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Amoxicillin Trihydrate)				
IMDG	: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Amoxicillin Trihydrate)				
ΙΑΤΑ	: Environmentally hazardous substance, solid, n.o.s. (Amoxicillin Trihydrate)				
14.3 Transport hazard class(es)					
	Class Subsidiary risks				
ADN	: 9				
ADR	: 9				
RID	: 9				
IMDG	: 9				
ΙΑΤΑ	: 9				
14.4 Packing group					
ADN					

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C F		group cation Code Identification Number	: : :	III M7 90 9	
P C F L	lazard .abels	group cation Code Identification Number restriction code	: : : : : : : : : : : : : : : : : : : :	III M7 90 9 (-)	
P C H		group cation Code Identification Number	: :	III M7 90 9	
P L	MDG Packing abels EmS Co		:	III 9 F-A, S-F	
P a P P	ircraft)	instruction (cargo instruction (LQ)	: : : :	956 Y956 III Miscellaneous	
P g P P	Packing Jer airci	instruction (LQ)	:	956 Y956 III Miscellaneous	
		nmental hazards			
E	ADR	mentally hazardous	:	yes	
R	RID	mentally hazardous mentally hazardous	:	yes yes	
	MDG /larine	pollutant	:	yes	
		Passenger) mentally hazardous	:	yes	
I/	ATA (C	-	:	yes	



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14.6 Special precautions for user

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.

SECTION 15: Regulatory information

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

Relevant EU provisions transposed through retained EU law

UK REACH List of restrictions (A	nnex 17)	:	Not applicable	
UK REACH Candidate list of sub	, ,	:	Not applicable	
concern (SVHC) for Authorisatio The Persistent Organic Pollutant Regulation (EU) 2019/1021 as a	ts Regulations (retained	:	Not applicable	
ain) Regulation (EC) on substances t layer	that deplete the ozone	:	Not applicable	
UK REACH List of substances s (Annex XIV)	ubject to authorisation	:	Not applicable	
GB Export and import of hazardo Informed Consent (PIC) Regulat		:	Not applicable	
Control of Major Accident Hazar	ds Regulations 2015 (CC	OMA	.H)	
			Quantity 1	Quantity 2
E1	ENVIRONMENTAL HAZARDS		100 t	200 t

Other regulations:

Take note of The Management of Health and Safety at Work Regulations 1999 (requirements relating to protection of young people at work contained in Regulation 19) and of Directive 94/33/EC on the protection of young people at work.

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 :

GB EH40 / TWA

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			are highlighted in lines.	the body of this document by two vertical			
Full te	xt of H-Statements						
H334		:	May cause allergy or asthma symptoms or breathing difficul- ties if inhaled.				
H400		:	Very toxic to aquatic life.				
H410		:	Very toxic to aquatic life with long lasting effects.				
Full text of other abbreviations							
Aquatio	Aquatic Acute		Short-term (acute) aquatic hazard			
Aquatic Chronic		:		ic) aquatic hazard			
Resp. Sens.		:	Respiratory sensi	tisation			
GB EH40		:	UK. EH40 WEL -	Workplace Exposure Limits			

Long-term exposure limit (8-hour TWA reference period)

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 : compile the Safety Data

Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agen-



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Sheet cy, http://echa.europa.eu/						
Classi	fication of the mixt	ure:	Classification procedure:			
Resp. Sens. 1		H334	Calculation method			
Aquatic Acute 1		H400	Calculation method			
Aquatic Chronic 1		H410	Calculation method			

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