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SECTION 1. IDENTIFICATION

Product name	:	Alendronate Solid Formulation			
Manufacturer or supplier's details					
Company name of supplier	:	Organon & Co.			
Address	:	30 Hudson Street, 33nd floor			
		Jersey City, New Jersey, U.S.A 07302			
Telephone	:	1-551-430-6000			
Emergency telephone	:	1-215-631-6999			
E-mail address	:	EHSSTEWARD@organon.com			
Recommended use of the chemical and restrictions on use					
Recommended use	:	Pharmaceutical			

: Not applicable

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with the OSHA Hazard Communication Standard (29 CFR 1910.1200)

Combustible dust

Restrictions on use

Skin irritation	:	Category 2
Serious eye damage	:	Category 1
Reproductive toxicity	:	Category 2
Specific target organ toxicity - single exposure	:	Category 3
Specific target organ toxicity - repeated exposure	:	Category 2 (Bone, Stomach, Kidney)
GHS label elements		
Hazard pictograms	:	
Signal Word	:	Danger
Hazard Statements	:	If small particles are generated during further processing, han- dling or by other means, may form combustible dust concentra- tions in air. H315 Causes skin irritation. H318 Causes serious eye damage. H335 May cause respiratory irritation. H361d Suspected of damaging the unborn child. H373 May cause damage to organs (Bone, Stomach, Kidney) through prolonged or repeated exposure.

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Precau	tionary Statements	P202 Do not h and understoo P260 Do not b P264 Wash sk P271 Use only	reathe dust. in thoroughly after handling. outdoors or in a well-ventilated area. otective gloves, protective clothing, eye protection
		P304 + P340 - and keep com unwell. P305 + P351 - water for seve and easy to do CENTER. P308 + P313 I P332 + P313 I	F ON SKIN: Wash with plenty of soap and water. + P312 IF INHALED: Remove person to fresh air fortable for breathing. Call a doctor if you feel + P338 + P310 IF IN EYES: Rinse cautiously with ral minutes. Remove contact lenses, if present b. Continue rinsing. Immediately call a POISON F exposed or concerned: Get medical attention. f skin irritation occurs: Get medical attention. Fake off contaminated clothing and wash it before
		Storage: P405 Store loo	sked up.
		Disposal:	of contents and container to an approved waste
Other None k	hazards nown.		
ECTION 3	. COMPOSITION/IN	IFORMATION ON INC	GREDIENTS
Substa	nce / Mixture	: Mixture	

Components

Chemical name	CAS-No.	Concentration (% w/w)	
Cellulose	9004-34-6	>= 30 - < 50	
Alendronate	121268-17-5	>= 20 - < 30	
Actual concentration is withheld as a trade socrat			

Actual concentration is withheld as a trade secret

SECTION 4. FIRST AID MEASURES

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.

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If inhaled		: If inhaled, remove to fresh Get medical attention.	If inhaled, remove to fresh air. Get medical attention.		
In case of skin contact		for at least 15 minutes wh and shoes. Get medical attention. Wash clothing before reus			
In case of eye contact		: In case of contact, immed for at least 15 minutes. If easy to do, remove con Get medical attention imm			
If swallowed		: If swallowed, DO NOT inc Get medical attention. Rinse mouth thoroughly w	-		
and	t important symptoms effects, both acute and lyed		tation.		
Prot	ection of first-aiders	and use the recommende	ld pay attention to self-protection, d personal protective equipment osure exists (see section 8).		
Note	es to physician	: Treat symptomatically and	d supportively.		

SECTION 5. FIRE-FIGHTING MEASURES

Suitable extinguishing media	:	Water spray Alcohol-resistant foam Carbon dioxide (CO2) Dry chemical
Unsuitable extinguishing media	:	None known.
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) Phosphorus compounds Metal oxides
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.
Special protective equipment for fire-fighters	:	

SECTION 6. ACCIDENTAL RELEASE MEASURES

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	tive equ	al precautions, protec- upment and emer- procedures	:		ective equipment. ng advice (see section 7) and personal ent recommendations (see section 8).
	Environ	mental precautions	:	Retain and dispos	akage or spillage if safe to do so. e of contaminated wash water. hould be advised if significant spillages
Methods and materials for containment and cleaning up		:	over the area to m Add excess liquid Soak up with inert Avoid dispersal of with compressed a Dust deposits sho surfaces, as these released into the a Clean up remainin absorbent. Local or national r disposal of this ma employed in the cl determine which r Sections 13 and 1	a absorbents and place a damp covering inimize entry of the material into the air. to allow the material to enter into solution. absorbent material. dust in the air (i.e., clearing dust surfaces air). uld not be allowed to accumulate on a may form an explosive mixture if they are atmosphere in sufficient concentration. og materials from spill with suitable egulations may apply to releases and aterial, as well as those materials and items eanup of releases. You will need to egulations are applicable. 5 of this SDS provide information regarding tional requirements.	

SECTION 7. HANDLING AND STORAGE

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 assessment Keep container tightly closed. Already sensitized individuals, and those susceptible to asthma, allergies, chronic or recurrent respiratory disease, should consult their physician regarding working with respiratory irritants or sensitizers. 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.

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Conditions for safe storage		 Take care to prevent spills, waste and minimize release to the environment. Keep in properly labeled containers. Store locked up. Keep tightly closed. 		
Materials to avoid		Store in accord	well-ventilated place. ance with the particular national regulations. th the following product types: g agents	

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

ingreatents with workplace control parameters		
inert o	r nuisance dust	50 Million particles per cubic foot Value type (Form of exposure): TWA (total dust) Basis: OSHA Z-3
		15 mg/m³ Value type (Form of exposure): TWA (total dust) Basis: OSHA Z-3
		5 mg/m ³ Value type (Form of exposure): TWA (respirable fraction) Basis: OSHA Z-3
		15 Million particles per cubic foot Value type (Form of exposure): TWA (respirable fraction) Basis: OSHA Z-3
Dust, r ticulate	nuisance dust and par- es	10 mg/m³ Value type (Form of exposure): PEL (Total dust) Basis: CAL PEL
		5 mg/m³ Value type (Form of exposure): PEL (respirable dust fraction) Basis: CAL PEL

Components	CAS-No.	Value type (Form of exposure)	Control parame- ters / Permissible concentration	Basis
Cellulose	9004-34-6	TWA	10 mg/m ³	ACGIH
		TWA (Res- pirable)	5 mg/m³	NIOSH REL
		TWA (total)	10 mg/m ³	NIOSH REL
		TWA (total dust)	15 mg/m³	OSHA Z-1
		TWA (respir- able fraction)	5 mg/m³	OSHA Z-1
Alendronate	121268-17-5	TWA	20 µg/m3 (OEB 3)	Internal
		Wipe limit	200 µg/100 cm ²	Internal

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Engineering measures		:	design and operat protect products, Containment tech are required to co	
Pe	ersonal protective equipme	ent		
	espiratory protection	:	maintain vapor ex concentrations are unknown, appropri Follow OSHA resp use NIOSH/MSHA by air purifying res hazardous chemic supplied respirato release, exposure	exhaust ventilation is recommended to posures below recommended limits. Where a above recommended limits or are iate respiratory protection should be worn. birator regulations (29 CFR 1910.134) and a approved respirators. Protection provided spirators against exposure to any cal is limited. Use a positive pressure air r if there is any potential for uncontrolled levels are unknown, or any other re air purifying respirators may not provide on.
Ha	and protection			
	Material	:	Chemical-resistan	t gloves
Ey	Remarks /e protection	:	If the work enviror mists or aerosols, Wear a faceshield	loving. es with side shields or goggles. ment or activity involves dusty conditions, wear the appropriate goggles. or other full face protection if there is a contact to the face with dusts, mists, or
Sł	kin and body protection	 aerosols. Work uniform or laboratory coat. Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets disposable suits) to avoid exposed skin surfaces. Use appropriate degowning techniques to remove poten contaminated clothing. 		arments should be used based upon the ned (e.g., sleevelets, apron, gauntlets, to avoid exposed skin surfaces. egowning techniques to remove potentially
Hy	ygiene measures	:	If exposure to che eye flushing syste working place. When using do no Wash contaminate The effective oper engineering contro appropriate degow	mical is likely during typical use, provide ms and safety showers close to the et eat, drink or smoke. ed clothing before re-use. ration of a facility should include review of ols, proper personal protective equipment, vning and decontamination procedures, monitoring, medical surveillance and the

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance

: powder

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	Color		:	white	
	Odor		:	odorless	
	Odor Th	nreshold	:	No data available)
	рН		:	No data available)
	Melting	point/freezing point	:	No data available)
	Initial bo range	oiling point and boiling	:	No data available	
	Flash p	oint	:	Not applicable	
	Evapora	ation rate	:	Not applicable	
	Flamma	ability (solid, gas)	:	May form explosi handling or other	ve dust-air mixture during processing, means.
	Flamma	ability (liquids)	:	No data available	
		explosion limit / Upper bility limit	:	No data available	
		explosion limit / Lower bility limit	:	No data available	
	Vapor p	pressure	:	No data available	9
	Relative	e vapor density	:	Not applicable	
	Relative	e density	:	No data available	
	Density		:	1 g/cm ³	
	Solubilit Wate	ty(ies) er solubility	:	No data available	9
	Partitior octanol	n coefficient: n-	:	Not applicable	
		ition temperature	:	No data available	
	Decom	position temperature	:	No data available	
	Viscosit Visc	ty osity, kinematic	:	Not applicable	
	Explosiv	ve properties	:	Not explosive	
	Oxidizir	ng properties	:	The substance or	r mixture is not classified as oxidizing.
	Particle	size	:	No data available	3

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SECTION 10. STABILITY AND REACTIVITY

Reactivity Chemical stability Possibility of hazardous reac- tions	: :	Not classified as a reactivity hazard. Stable under normal conditions. May form explosive dust-air mixture during processing, handling or other means. Can react with strong oxidizing agents.
Conditions to avoid	:	Heat, flames and sparks. Avoid dust formation.
Incompatible materials Hazardous decomposition products	:	Oxidizing agents

SECTION 11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

Inhalation						
Skin contact						
Ingestion						
Eye contact						

Acute toxicity

Not classified based on available information.

Product:

Acute oral toxicity	:	Acute toxicity estimate: 2,115 mg/kg Method: Calculation method
Components:		
Cellulose:		
Acute oral toxicity	:	LD50 (Rat): > 5,000 mg/kg
Acute inhalation toxicity	:	LC50 (Rat): > 5.8 mg/l Exposure time: 4 h

Test atmosphere: dust/mistAcute dermal toxicity: LD50 (Rabbit): > 2,000 mg/kg

Alendronate:

Acute oral toxicity	:	LD50 (Rat): 552 - 626 mg/kg
		LD50 (Mouse): 966 - 1,280 mg/kg
Acute inhalation toxicity	:	Remarks: No data available
Acute dermal toxicity	:	Remarks: No data available

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Skin	corrosion/irritation			
Caus	es skin irritation.			
Com	ponents:			
Alen	dronate:			
Spec Rema		:	Rabbit Severe skin irrit	ation
	ous eye damage/eye es serious eye damag		on	
	ponents:	,		
Alen	dronate:			
Spec Resu		:	Rabbit Severe irritation	
Resp	iratory or skin sens	itizatio	'n	
-	sensitization lassified based on ava	ailable	information.	
-	iratory sensitization		information.	
Com	ponents:			
Alen	dronate:			
Rema	arks	:	No data availab	e
	n cell mutagenicity lassified based on ava	ailable	information.	
<u>Com</u>	ponents:			
Cellu	lose:			
Geno	toxicity in vitro	:	Test Type: Bact Result: negative	erial reverse mutation assay (AMES)
			Test Type: In vit Result: negative	ro mammalian cell gene mutation test
Geno	toxicity in vivo	:	Test Type: Man cytogenetic ass Species: Mouse Application Rou Result: negative	te: Ingestion
Alene	dronate:			
Geno	toxicity in vitro	:	Test Type: Alka Test system: rat	ine elution assay hepatocytes

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			acterial reverse mutation assay (AMES) ivation: with and without metabolic activation ive			
		Test Type: In Result: negat	vitro mammalian cell gene mutation test ive			
			hromosomal aberration Chinese hamster ovary cells ocal			
Geno	toxicity in vivo	: Test Type: C Species: Mou Result: negat				
	nogenicity assified based on av	ailable information.				
Comp	oonents:					
Cellu	lose:					
Speci		: Rat				
	cation Route sure time	: Ingestion : 72 weeks				
Resul		: negative				
Alenc	Ironate:					
Speci		: Rat, male				
	cation Route	: Oral				
Expos	sure time	: 2 Years : 1 mg/kg body	^v weight			
_		: 3.75 mg/kg b				
Targe Rema	t Organs Irks	: Thyroid : The mechani mans.	sm or mode of action may not be relevant in hu			
IARC			esent at levels greater than or equal to 0.1% is or confirmed human carcinogen by IARC.			
OSHA		No component of this product present at levels greater than or equal to 0.1% is on OSHA's list of regulated carcinogens.				
NTP		No ingredient of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.				
	oductive toxicity ected of damaging th	e unborn child.				
	oonents:					
Cellu	lose:					
	s on fertility	: Test Type: O	ne-generation reproduction toxicity study			

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			Species: Rat Application Route Result: negative	: Ingestion
Effec	ets on fetal development	:	Test Type: Fertilit Species: Rat Application Route Result: negative	y/early embryonic development
Alen	dronate:			
Effec	cts on fertility	:		e and female
Effec	ets on fetal development	:	Symptoms: Redu body weight, Ske	ale : Oral oxicity: LOAEL: 1 - 15 mg/kg body weight ced number of viable fetuses., Reduced letal malformations. xic effects and adverse effects on the tected.
			Species: Rabbit, Application Route	emale :: Oral oxicity: NOAEL: 40 mg/kg body weight
•	oductive toxicity - As- ment	:	Some evidence o animal experimer	f adverse effects on development, based on its.
	T-single exposure cause respiratory irritation	on.		
Com	ponents:			
-	dronate: essment	:	May cause respir	atory irritation.
	T-repeated exposure	e (Br	one Stomach Kidr	ney) through prolonged or repeated exposure.
	ponents:			ior anough profonged of repeated exposule.
	dronate:			
Targ	et Organs essment	:	Bone, Stomach, I May cause dama exposure.	Kidney ge to organs through prolonged or repeated

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Repe	ated dose toxicity			
Com	ponents:			
Cellu	lose:			
Spec	ies	:	Rat	
NOAI		:	>= 9,000 mg/kg	
	cation Route	:	Ingestion	
Expo	sure time	:	90 Days	
Alen	dronate:			
Spec	ies	:	Rat	
NOAI		:	2.5 mg/kg	
LOAE	EL	:	> 2.5 mg/kg	
	cation Route	:	Intravenous	
	sure time	:	53 Weeks	
Targe	et Organs	:	Stomach	
Spec		:	Dog	
LOAE		:	0.01 mg/kg	
	cation Route	:	Intravenous	
	sure time	:	3 y	
Targe	et Organs	:	Stomach, Bone, I	Kidney
Spec		:	Dog	
NOAI		:	2 mg/kg	
LOAE		:	4 mg/kg	
	cation Route	:	Oral	
	sure time	:	53 Weeks	
rarge	et Organs	•	Kidney	
Asnii	ration toxicity			
-	lassified based on ava	ailabla	information	
INULC	lassilleu baseu on ava	allable	iniomation.	

Components:

Alendronate:

Not applicable

Experience with human exposure

Components:

Alendronate:

Inhalation	:	Symptoms: respiratory tract irritation
Skin contact	:	Symptoms: Severe irritation, skin blistering
Eye contact	:	Symptoms: Severe irritation
Ingestion	:	Symptoms: Gastrointestinal disturbance, musculoskeletal pain

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CTION	12. ECOLOGICAL INFO	DRN	IATION		
Ecoto	oxicity				
<u>Comp</u>	oonents:				
Cellul Toxici	l ose: ty to fish	:	Exposure time: 48	ipes (Japanese medaka)): > 100 mg/l 3 h on data from similar materials	
Alend	Ironate:				
Toxici	ty to fish	:	LC50 (Pimephale Exposure time: 96 Method: OECD To		
			LC50 (Oncorhync Exposure time: 96 Method: FDA 4.17		
	ty to daphnia and other ic invertebrates	:	EC50 (Daphnia m Exposure time: 48 Method: OECD Te		
Toxici plants	ty to algae/aquatic	:	ErC50 (Pseudokir mg/l Exposure time: 72 Method: OECD Te		
			NOEC (Pseudokin Exposure time: 72 Method: OECD Te		
Toxici icity)	ty to fish (Chronic tox-	:	NOEC (Pimephale Exposure time: 32 Method: OECD Te		
			LOEC (Pimephale Exposure time: 32 Method: OECD Te		
	ty to daphnia and other ic invertebrates (Chron- city)	:	NOEC (Daphnia r Exposure time: 21 Method: OECD Te		
Persis	stence and degradabili	ty			
<u>Comp</u>	oonents:				
Cellul Biode	l ose: gradability	:	Result: Readily bi	odegradable.	

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Alend	dronate:		
Biode	gradability		idily biodegradable. tion: 70.3 % me: 7 d
Stabil	ity in water		n half life (DT50): 375 d ECD Test Guideline 111
Bioad	cumulative potentia	I	
<u>Com</u>	oonents:		
Alend	dronate:		
	ion coefficient: n- ol/water	: log Pow: -1	.73
Mobi	lity in soil		
No da	ata available		
Othe	r adverse effects		
No da	ata available		

Disposal methods	
Waste from residues	 Dispose of in accordance with local regulations. Do not dispose of waste into sewer.
Contaminated packaging	 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 INFORMATION

International Regulations

UNRTDG

Not regulated as a dangerous good

IATA-DGR

Not regulated as a dangerous good

IMDG-Code

Not regulated as a dangerous good

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

Domestic regulation

49 CFR

Not regulated as a dangerous good

Special precautions for user

Not applicable

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SECTION 15. REGULATORY INFORMATION

CERCLA Reportable Quantity

This material does not contain any components with a CERCLA RQ.

SARA 304 Extremely Hazardous Substances Reportable Quantity

This material does not contain any components with a section 304 EHS RQ.

SARA 302 Extremely Hazardous Substances Threshold Planning Quantity

This material does not contain any components with a section 302 EHS TPQ.

SARA 311/312 Hazards	Combustible dust Reproductive toxicity Specific target organ toxicity (single o Skin corrosion or irritation Serious eye damage or eye irritation	r repeated exposure)		
SARA 313	This material does not contain any ch known CAS numbers that exceed the reporting levels established by SARA	threshold (De Minimis)		
US State Regulations				
Pennsylvania Right To Know				
Cellulose		9004-34-6		
Lactose Alendronate		63-42-3 121268-17-5		
California Permissible Exposure Limits for Chemical Contaminants				
Cellulose		9004-34-6		
The ingredients of this product are reported in the following inventories:				
AICS	not determined			
DSL :	not determined			
IECSC	not determined			

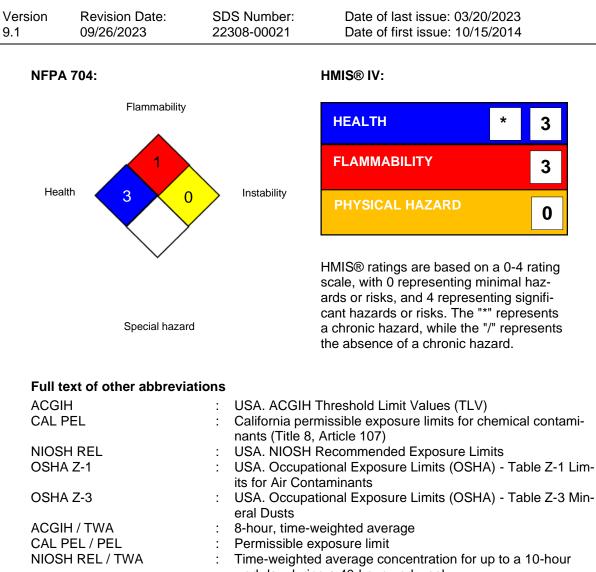
SECTION 16. OTHER INFORMATION

Further information





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 OSHA Z-1 / TWA
 :
 8-hour time weighted average

 OSHA Z-3 / TWA
 :
 8-hour time weighted average

 AllC - Australian Inventory of Industrial Chemicals: ASTM - American Socie

AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; 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; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; HMIS - Hazardous Materials Identification System; 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 Pre-



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vention of Pollution from Ships; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NTP - National Toxicology Program; 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; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; 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

Sources of key data used to compile the Material Safety Data Sheet	:	Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agen- cy, http://echa.europa.eu/

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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.

US / Z8