

according to the OSHA Hazard Communication Standard

Phenylbutazone Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/06/2024
12.0	07/06/2024	666683-00023	Date of first issue: 05/12/2016

SECTION 1. IDENTIFICATION

Product name	:	Phenylbutazone Formulation			
Manufacturer or supplier's o	deta	ails			
Company name of supplier Address		Merck & Co., Inc 126 E. Lincoln Avenue Rahway, New Jersey U.S.A. 07065			
Telephone Emergency telephone E-mail address	:	908-740-4000 1-908-423-6000 EHSDATASTEWARD@merck.com			
Recommended use of the chemical and restrictions on use					
Recommended use Restrictions on use	:	Veterinary product Not applicable			

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with the OSHA Hazard Communication Standard (29 CFR 1910.1200) Combustible dust				
Acute toxicity (Oral)	:	Category 4		
Eye irritation	:	Category 2A		
GHS label elements Hazard pictograms	:			
Signal Word	:	Warning		
Hazard Statements	:	If small particles are generated during further processing, han- dling or by other means, may form combustible dust concentra- tions in air. H302 Harmful if swallowed. H319 Causes serious eye irritation.		
Precautionary Statements	:	Prevention: P264 Wash skin thoroughly after handling. P270 Do not eat, drink or smoke when using this product. P280 Wear eye protection and face protection.		
		Response: P301 + P312 + P330 IF SWALLOWED: Call a doctor if you feel unwell. Rinse mouth. P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.		

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P337 + P313 If eye irritation persists: Get medical attention.

Disposal:

P501 Dispose of contents and container to an approved waste disposal plant.

Other hazards

Contact with dust can cause mechanical irritation or drying of the skin.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture	:	Mixture
---------------------	---	---------

Components

CAS-No.	Concentration (% w/w)
8008-74-0	>= 70 - < 90
50-33-9	>= 20 - < 30
112945-52-5	>= 5 - < 10
50-81-7	>= 1 - < 5
	8008-74-0 50-33-9 112945-52-5

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.
If inhaled	:	If inhaled, remove to fresh air. Get medical attention if symptoms occur.
In case of skin contact	:	Wash with water and soap. Get medical attention if symptoms occur.
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.
If swallowed	:	If swallowed, DO NOT induce vomiting unless directed to do so by medical personnel. Get medical attention. Rinse mouth thoroughly with water.
Most important symptoms	:	Never give anything by mouth to an unconscious person. Harmful if swallowed.
and effects, both acute and delayed		Causes serious eye irritation. Contact with dust can cause mechanical irritation or drying of the skin.
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).
Notes to physician	:	Treat symptomatically and supportively.

SECTION 5. FIRE-FIGHTING MEASURES

Suitable extinguishing media :

Water spray Alcohol-resistant foam



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Unsuitable extinguishing media Specific hazards during fire		:	Carbon dioxide (O Dry chemical None known. Exposure to comb	CO2) Dustion products may be a hazard to health.
fightin Hazar ucts	g dous combustion prod-	:	Carbon oxides Nitrogen oxides (I	NOx)
Specif ods	Specific extinguishing meth- ods		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
	al protective equipment -fighters	:	In the event of fire	e, wear self-contained breathing apparatus. rective equipment.
SECTION	6. ACCIDENTAL RELE	AS	E MEASURES	
tive ec	nal precautions, protec- quipment and emer- procedures	:	Follow safe handl	ective equipment. ing advice (see section 7) and personal ent recommendations (see section 8).
Enviro	nmental 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 cannot be contained.		akage or spillage if safe to do so. se of contaminated wash water. should be advised if significant spillages
	Methods and materials for containment and cleaning up		container for disp Avoid dispersal of with compressed Dust deposits sho surfaces, as these released into the Local or national disposal of this m employed in the of determine which the Sections 13 and	dust in the air (i.e., clearing dust surfaces

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 Advice on safe handling		Use only with adequate ventilation. Do not breathe dust.
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		Wash skin th Handle in ac practice, bas assessment Minimize du Keep contai Keep away Take precau Do not eat, o Take care to environment	n eyes. aged or repeated contact with skin. horoughly after handling. cordance with good industrial hygiene and safety sed on the results of the workplace exposure st generation and accumulation. her closed when not in use. from heat and sources of ignition. titionary measures against static discharges. drink or smoke when using this product. o prevent spills, waste and minimize release to the
Condit	tions for safe storage		perly labeled containers. ordance with the particular national regulations.
Materi	als to avoid	: Do not store Strong oxidi	with the following product types: zing agents

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

:

	•			
Components	CAS-No.	Value type (Form of	Control parame- ters / Permissible	Basis
		exposure)	concentration	
Oils, sesame	8008-74-0	TWA (mist - total)	10 mg/m ³	NIOSH REL
		TWA (mist - respirable)	5 mg/m³	NIOSH REL
Phenylbutazone	50-33-9	TWA	30 µg/m3 (OEB 3)	Internal
		Wipe limit	300 µg/100 cm ²	Internal
Silicon, amorphous	112945-52-5	TWA (Dust)	20 Million particles per cubic foot (Silica)	OSHA Z-3
		TWA (Dust)	80 mg/m3 / %SiO2 (Silica)	OSHA Z-3
		TWA	6 mg/m ³ (Silica)	NIOSH REL
Ascorbic acid	50-81-7	TWA	5000 µg/m3 (OEB 1)	Internal

Ingredients with workplace control parameters

Engineering measures

Ensure adequate ventilation, especially in confined areas. Minimize workplace exposure concentrations. Apply measures to prevent dust explosions. Ensure that dust-handling systems (such as exhaust ducts, dust collectors, vessels, and processing equipment) are designed in a manner to prevent the escape of dust into the work area (i.e., there is no leakage from the equipment).

Personal protective equipment

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	Respiratory protection		nd local exhaust ventilation is recommended to apor exposures below recommended limits. Where ions are above recommended limits or are appropriate respiratory protection should be worn. HA respirator regulations (29 CFR 1910.134) and H/MSHA approved respirators. Protection provided ying respirators against exposure to any chemical is limited. Use a positive pressure air espirator if there is any potential for uncontrolled kposure levels are unknown, or any other nee where air purifying respirators may not provide protection.
Hand	I protection		
Μ	aterial	: Chemical-	resistant gloves
R	Remarks		oves to protect hands against chemicals depending centration specific to place of work. Breakthrough determined for the product. Change gloves often! I applications, we recommend clarifying the to chemicals of the aforementioned protective in the glove manufacturer. Wash hands before d at the end of workday.
Eye	Eye protection		ollowing personal protective equipment:
Skin	and body protection	 Safety goggles Select appropriate protective clothing based on chemic resistance data and an assessment of the local exposision potential. Skin contact must be avoided by using impervious pro- clothing (gloves, aprons, boots, etc). 	
Hygie	ene measures	: If exposure eye flushir working pl When usir	e to chemical is likely during typical use, provide of systems and safety showers close to the

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	:	paste
Color	:	white
Odor	:	citrus
Odor Threshold	:	No data available
рН	:	No data available
Melting point/freezing point	:	No data available
Initial boiling point and boiling range	:	No data available
Flash point	:	Not applicable



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	Evapora	ation rate	:	No data available	9
	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	9
		explosion limit / Lower bility limit	:	No data available	
	Vapor p	pressure	:	No data available)
	Relative	e vapor density	:	No data available)
	Density		:	No data available)
	Solubili Wate	ty(ies) er solubility	:	No data available	9
	Partition octanol	n coefficient: n-	:	No data available)
		ition temperature	:	No data available)
	Decom	position temperature	:	No data available)
	Viscosit Visc	ty osity, kinematic	:	No data available	9
	Explosi	ve properties	:	Not explosive	
	Oxidizir	ng properties	:	The substance o	r mixture is not classified as oxidizing.
	Molecu	lar weight	:	No data available	2
	Particle Particle	characteristics size	:	No data available	

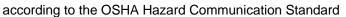
SECTION 10. STABILITY AND REACTIVITY

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.



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	npatible materials rdous decomposition icts	:	Oxidizing a No hazardo	gents us decomposition products are known.
SECTION	11. TOXICOLOGICAL	INF	ORMATION	
Inhala Skin o Inges	contact	s of	exposure	
	e toxicity ful if swallowed.			
Prod	uct:			
Acute	e oral toxicity	:		y estimate: 1,225 mg/kg culation method
Com	ponents:			
Oils,	sesame:			
-	e oral toxicity	:		> 2,000 mg/kg ased on data from similar materials
Acute	e dermal toxicity	:	LD50 (Rabb	it): > 2,000 mg/kg
Phen	ylbutazone:			
	e oral toxicity	:	LD50 (Rat):	245 mg/kg
			LD50 (Mous	e): 238 mg/kg
			LD50 (Dog):	332 mg/kg
Silico	on, amorphous:			
Acute	e oral toxicity	:	Method: OE	> 5,000 mg/kg CD Test Guideline 401 ased on data from similar materials
Acute	inhalation toxicity	:	Assessment tion toxicity	
Acute	e dermal toxicity	:		it): > 5,000 mg/kg ased on data from similar materials
Asco	rbic acid:			
Acute	e oral toxicity	:	LD50 (Rat):	11,900 mg/kg





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Skin corrosion/irritation

Not classified based on available information.

Components:

Oils, sesame:

Species	:	Rabbit
Result	:	No skin irritation

Silicon, amorphous:

Species :	I	Rabbit
Method :	(OECD Test Guideline 404
Result :	I	No skin irritation
Remarks :	I	Based on data from similar materials

Ascorbic acid:

Species	:	Rabbit
Method	:	OECD Test Guideline 404
Result	:	No skin irritation

Serious eye damage/eye irritation

Causes serious eye irritation.

Components:

Oils, sesame:

Species	:	Rabbit
Result	:	No eye irritation

Phenylbutazone:

Species	:	Rabbit
Result	:	Irritation to eyes, reversing within 21 days

Silicon, amorphous:

Species	:	Rabbit
Result	:	No eye irritation
Method	:	OECD Test Guideline 405
Remarks	:	Based on data from similar materials

Ascorbic acid:

Species	:	Rabbit
Result	:	No eye irritation
Method	:	OECD Test Guideline 405

Respiratory or skin sensitization

Skin sensitization

Not classified based on available information.





ersion 2.0	Revision Date: 07/06/2024	SDS Nu 666683		Date of last issue: 04/06/2024 Date of first issue: 05/12/2016
-	iratory sensitizatior lassified based on av		nation.	
Com	ponents:			
Oils,	sesame:			
Test Route Resu	es of exposure	: Skir	nan repeat ins 1 contact ative	sult patch test (HRIPT)
Asco	rbic acid:			
Test Route Speci Resu	es of exposure ies	: Skir : Guir	irer optimisati n contact nea pig ative	on test
	cell mutagenicity lassified based on av	ailable inforr	mation.	
Com	ponents:			
	sesame: toxicity in vitro		t Type: Bacte ult: negative	rial reverse mutation assay (AMES)
			0	
	ylbutazone: toxicity in vitro		t Type: Bacte ult: negative	rial reverse mutation assay (AMES)
			t Type: Chron ult: positive	nosome aberration test in vitro
		mali	t Type: In vitro an cells ult: negative	o sister chromatid exchange assay in mam-
			t Type: Chron ult: negative	nosomal aberration
Geno	toxicity in vivo	cyto Spe App	t Type: Mamn genetic assay cies: Mouse lication Route ult: negative	
		Spe App	cies: Mouse	nt dominant lethal test (germ cell) (in vivo) e: Intraperitoneal injection
			t Type: Micro cies: Mouse	nucleus test



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		Application Ro Result: positiv	
	cell mutagenicity - ssment	: Weight of evic cell mutagen.	lence does not support classification as a gerr
Silico	on, amorphous:		
	toxicity in vitro	Method: OEC Result: negati	cterial reverse mutation assay (AMES) D Test Guideline 471 ve ed on data from similar materials
Geno	toxicity in vivo	cytogenetic te Species: Rat Application Ro Result: negati	
Asco	rbic acid:		
Geno	toxicity in vitro	: Test Type: Ba Result: negati	cterial reverse mutation assay (AMES) ve
		Test Type: In Result: negati	vitro mammalian cell gene mutation test ve
		Test Type: Ch Result: negati	romosome aberration test in vitro ve
Geno	toxicity in vivo	cytogenetic as Species: Mous	se function
	nogenicity		
	assified based on ava	ilable information.	
	oonents:		
	ylbutazone:	. Det	
Speci Applio	es cation Route	: Rat : Ingestion	
	sure time	: 103 weeks	
Resu		: positive	
Speci		: Mouse	
	cation Route	: Ingestion	
Expos	sure time	: 103 weeks : positive	
D	T		
Resu	it i	. positive	



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r	nent				cinogen	
S A E F	Species Applicat	tion Rou re time		:	Rat Ingestion 103 weeks negative Based on data fro	m similar materials
S A E F	Species Applicat	ic acid s tion Rou re time	ute No ingredient			at levels greater than or equal to 0.1% is offirmed human carcinogen by IARC.
C	OSHA		No componen	nt of	•	nt at levels greater than or equal to 0.1% is
١	NTP					at levels greater than or equal to 0.1% is carcinogen by NTP.
١	Not clas	ssified b	toxicity based on availa	ble	information.	
_		onents:				
	•	butazo on fetal	ne: development	:	Species: Rat Application Route	o-fetal development Ingestion ity.: NOAEL: 42 mg/kg body weight
					Test Type: Embry Species: Rabbit Application Route Result: negative	o-fetal development
					Species: Rabbit Application Route	o-fetal development Ingestion ity.: NOAEL: 60 mg/kg body weight
		, amorp on fetal	ohous: development	:	Test Type: Embry Species: Rat Application Route	o-fetal development



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			Result: negative Remarks: Base	e ed on data from similar materials
Asco	bic acid:			
Effect	s on fetal developme	nt :	Test Type: Emb Species: Rat Application Rou Result: negative	
	-single exposure assified based on ava	ailable	information.	
STOT	-repeated exposure	•		
Not cl	assified based on ava	ailable	information.	
Repe	ated dose toxicity			
<u>Comp</u>	oonents:			
Phen	ylbutazone:			
Speci	es	:	Rat	
NOAE	EL	:	50 mg/kg	
LOAE	L	:	100 mg/kg	
	ation Route	:	Ingestion	
	sure time	:	13 Weeks	
	t Organs	:	Kidney	
Rema	rks	:	Significant toxic	city observed in testing
Speci	es	:	Mouse	
NOAE	E	:	150 mg/kg	
	ation Route	:	Ingestion	
Expos	sure time	:	13 Weeks	
Silico	n, amorphous:			
Speci	es	:	Rat	
NOAE		:	1.3 mg/l	
Applic	ation Route	:	inhalation (dust	t/mist/fume)
	sure time	:	13 Weeks	
Rema	rks	:	Based on data	from similar materials
Asco	bic acid:			
Speci	es	:	Rat, male	
NOAE		:	>= 8,100 mg/kg]
Applic	ation Route	:	Ingestion	-
	sure time		13 Weeks	

Not classified based on available information.

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CTION 12. ECOLOGICAL INFO	ORN	I ATION
Ecotoxicity		
Components:		
Phenylbutazone:		
Ecotoxicology Assessment		
Acute aquatic toxicity	:	Toxic effects cannot be excluded
Chronic aquatic toxicity	:	Toxic effects cannot be excluded
Silicon, amorphous:		
Toxicity to fish	:	LC50 (Danio rerio (zebra fish)): > 10,000 mg/l Exposure time: 96 h Method: OECD Test Guideline 203 Remarks: Based on data from similar materials
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia magna (Water flea)): > 1,000 mg/l Exposure time: 24 h Method: OECD Test Guideline 202 Remarks: Based on data from similar materials
Toxicity to algae/aquatic plants	:	EC50 (Desmodesmus subspicatus (green algae)): > 10,00 mg/l Exposure time: 72 h Method: OECD Test Guideline 201 Remarks: Based on data from similar materials
		NOEC (Desmodesmus subspicatus (green algae)): 10,000 mg/l Exposure time: 72 h Method: OECD Test Guideline 201 Remarks: Based on data from similar materials
Ascorbic acid:		
Toxicity to fish	:	LC50 (Oncorhynchus mykiss (rainbow trout)): 1,020 mg/l Exposure time: 96 h Method: OECD Test Guideline 203
Toxicity to microorganisms	:	EC50: 140 mg/l Exposure time: 16 h Method: DIN 38 412 Part 8
Persistence and degradabili	ity	
Components:		
Oils, sesame:		
Biodegradability	:	Result: Readily biodegradable.
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	orbic acid: egradability	Biodegradatic Exposure time		
Bioa	accumulative potential			
Com	ponents:			
Parti	nylbutazone: tion coefficient: n- nol/water	: log Pow: 3.16		
Parti	orbic acid: tion coefficient: n- nol/water	: log Pow: -1.8	5	
	ility in soil lata available			
•	er adverse effects lata available			
SECTION	13 DISPOSAL CONS			

SECTION 13. DISPOSAL CONSIDERATIONS

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

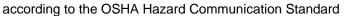
Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

Domestic regulation

49 CFR

Not regulated as a dangerous good





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Special precautions for user

Not applicable

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 Acute toxicity (any route of exposure) Serious eye damage or eye irritation
SARA 313	:	This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

US State Regulations

Pennsylvania Right To	Know					
Oils, sesame Phenylbutazo Silicon, amorr		8008-74-0 50-33-9 112945-52-5				
California Permissible Exposure Limits for Chemical Contaminants						
Oils, sesame Silicon, amorr	bhous	8008-74-0 112945-52-5				
The ingredients of this	product are reported in the following	inventories:				
AICS	: not determined					
DSL	: not determined					
IECSC	: not determined					

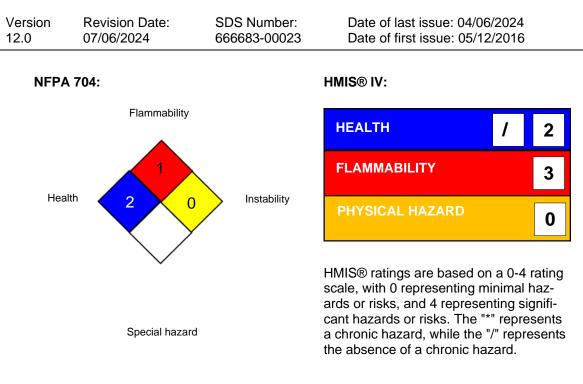
SECTION 16. OTHER INFORMATION

Further information



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Full text of other abbreviations

NIOSH REL OSHA Z-3		USA. NIOSH Recommended Exposure Limits USA. Occupational Exposure Limits (OSHA) - Table Z-3 Min- eral Dusts
NIOSH REL / TWA	:	Time-weighted average concentration for up to a 10-hour workday during a 40-hour workweek
OSHA Z-3 / TWA	:	8-hour time weighted average

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 Prevention 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;



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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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Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

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