

Revision Date: 10/10/2020	-		Date of last issue: 03/23/2020 Date of first issue: 11/22/2019			
1. IDENTIFICATION						
ct name	:	Pancrelipase (H	ligh / Low Lipase) Formulation			
facturer or supplier's	deta	ails				
	:	30 Hudson Stre	Organon & Co. 30 Hudson Street, 33nd floor Jersey City, New Jersey, U.S.A 07302			
gency telephone	:	: 551-430-6000 : 215-631-6999 : EHSSTEWARD@organon.com				
mmended use of the	chen	nical and restric	tions on use			
nmended use	:	Pharmaceutical				
2. HAZARDS IDENTIF		ΓΙΟΝ				
1200)	rdan	ce with the OSH	A Hazard Communication Standard (29 CFF			
rritation	:	Category 2				
ritation	:	Category 2A				
ratory sensitization	:	: Category 1				
label elements						
d pictograms	:					
l Word	:	Danger				
d Statements	:	H315 Causes s H319 Causes s H334 May caus	erious eye irritation. e allergy or asthma symptoms or breathing			
utionary Statements	:	P264 Wash skir P280 Wear prot tion.	athing dust, fume, gas, mist, vapors or spray. In thoroughly after handling. Sective gloves, eye protection and face protec- inadequate ventilation wear respiratory protec			
	10/10/2020 1. IDENTIFICATION Intername facturer or supplier's any name of supplier any name of supplier iss hone gency telephone I address mmended use of the mmended use 2. HAZARDS IDENTIF	10/10/2020 53 1. IDENTIFICATION	10/10/2020 5322088-00003 1. IDENTIFICATION ict name : Pancrelipase (H facturer or supplier's details iany name of supplier : Organon & Co. iss : : Organon & Co. iss : : Organon & Co. iss : : : inny name of supplier : Organon & Co. iss : : : inny name of supplier : : : iss : : : iss : : : : iss : : : : inderess : : : : inderess : Pharmaceutical : 2. HAZARDS IDENTIFICATION : : Category 2 citation : : Category 2 iritation : : Category 1 iabel elements : : Category 1 iabel elements : Danger :			



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		for several minu to do. Continue P332 + P313 If P337 + P313 If P342 + P311 If tor.	P338 IF IN EYES: Rinse cautiously with water utes. Remove contact lenses, if present and easy rinsing. skin irritation occurs: Get medical attention. eye irritation persists: Get medical attention. experiencing respiratory symptoms: Call a doc- ake off contaminated clothing and wash it before
		Disposal: P501 Dispose o disposal plant.	of contents and container to an approved waste
••	r hazards known.		
SECTION	3. COMPOSITION/I	NFORMATION ON ING	REDIENTS
Subs	tance / Mixture	: Mixture	
Com	ponents		

Chemical name	CAS-No.	Concentration (% w/w)
Pancrelipase	53608-75-6	72
Talc	14807-96-6	8.6
Starch	9005-25-8	2.9
Sucrose	57-50-1	2.9
Diethyl phthalate	84-66-2	2.1

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. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention.
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. 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.
If swallowed :	If swallowed, DO NOT induce vomiting. Get medical attention if symptoms occur. Rinse mouth thoroughly with water.
Most important symptoms :	Causes skin irritation.



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	and effects, both acute and delayed		ties if inhaled. Excessive exposition other respiratory	y or asthma symptoms or breathing difficul- ure may aggravate preexisting asthma and disorders (e.g. emphysema, bronchitis, reac-	
Prote	ection of first-aiders	:	tive airways dysfunction syndrome). 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).		
Note	s to physician	:		cally and supportively.	
SECTION	5. FIRE-FIGHTING ME	ASU	IRES		
Suita	ble extinguishing media	:	Water spray Alcohol-resistant Carbon dioxide (C Dry chemical		
Unsu medi	itable extinguishing a	:	High volume water jet		
Spec fightii	ific hazards during fire ng	:	 Avoid generating dust; fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is potential dust explosion hazard. Do not use a solid water stream as it may scatter and sprea fire. Exposure to combustion products may be a hazard to healt 		
Haza ucts	rdous combustion prod-	:	: Carbon oxides Nitrogen oxides (NOx) Sulfur oxides		
Spec ods	ific extinguishing meth-	:	 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 so. Evacuate area. 		
	ial protective equipment e-fighters				

Personal precautions, protec- tive equipment and emer- gency procedures	:	Use personal protective equipment. Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).
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 cannot be contained.
Methods and materials for containment and cleaning up	:	Sweep up or vacuum up spillage and collect in suitable container for disposal. Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air).



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		Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration. Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable. Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.		
SECTIO	N 7. HANDLING AND ST	ORAGE		
Teo	chnical measures	causing an ex Provide adeq	ity may accumulate and ignite suspended dust plosion. uate precautions, such as electrical grounding or inert atmospheres.	
	al/Total ventilation vice on safe handling	 Use only with Do not get on Avoid breathi Do not swallo Do not get in Wash skin the Handle in according practice, base assessment Keep contain Already sension regarding wo Minimize dus Keep contain Keep away fr Take precaut Take care to 	adequate ventilation. skin or clothing. ng dust, fume, gas, mist, vapors or spray. w.	
	nditions for safe storage terials to avoid	Keep tightly of Store in acco	rdance with the particular national regulations.	
IVIA		: Do not store Strong oxidiz	with the following product types: ing agents	

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

<u> </u>	•			
Components	CAS-No.	Value type	Control parame-	Basis
		(Form of	ters / Permissible	
		exposure)	concentration	
Pancrelipase	53608-75-6	TWA	OEB 3 (>= 10 <	Internal
			100 µg/m3)	
Talc	14807-96-6	TWA (Dust)	20 Million	OSHA Z-3
			particles per cubic	
			foot	
		TWA (Res-	2 mg/m ³	NIOSH REL

Ingredients with workplace control parameters



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		pirable)		
		TWA (Res-	2 mg/m ³	ACGIH
		pirable par-		
		ticulate mat-		
		ter)		
Starch	9005-25-8	TWA	10 mg/m ³	ACGIH
		TWA (Res- pirable)	5 mg/m³	NIOSH REL
		TWA (total)	10 mg/m ³	NIOSH REL
		TWA (total	15 mg/m ³	OSHA Z-1
		dust)		
		TWA (respir-	5 mg/m³	OSHA Z-1
		able fraction)		
Sucrose	57-50-1	TWA	10 mg/m ³	ACGIH
		TWA (Res-	5 mg/m³	NIOSH REL
		pirable)		
		TWA (total)	10 mg/m ³	NIOSH REL
		TWA (total	15 mg/m³	OSHA Z-1
		dust)		
		TWA (respir-	5 mg/m³	OSHA Z-1
		able fraction)		
Diethyl phthalate	84-66-2	TWA	5 mg/m ³	ACGIH
		TWA	5 mg/m ³	NIOSH REL

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

Respiratory protection	:	General and local exhaust ventilation is recommended to maintain vapor exposures below recommended limits. Where concentrations are above recommended limits or are unknown, appropriate respiratory protection should be worn. Follow OSHA respirator regulations (29 CFR 1910.134) and use NIOSH/MSHA approved respirators. Protection provided by air purifying respirators against exposure to any hazardous chemical is limited. Use a positive pressure air supplied respirator if there is any potential for uncontrolled release, exposure levels are unknown, or any other circumstance where air purifying respirators may not provide adequate protection.
Material	:	Chemical-resistant gloves
Remarks Eye protection	:	Consider double gloving. Wear safety glasses with side shields or goggles. If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles.



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Skin a	and body protection	 Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, o 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 potent contaminated clothing. 			
Hygie	ene measures	: If exposure to cl eye flushing sys working place. When using do Wash contamina The effective op engineering con appropriate deg	nemical is likely during typical use, provide tems and safety showers close to the not eat, drink or smoke. ated clothing before re-use. teration of a facility should include review of trols, proper personal protective equipment, owning and decontamination procedures, ne monitoring, medical surveillance and the		

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	:	solid
Color	:	No data available
Odor	:	No data available
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
Evaporation rate	:	Not applicable
Flammability (solid, gas)	:	May form combustible dust concentrations in air.
Flammability (liquids)	:	Not applicable
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Vapor pressure	:	Not applicable
Relative vapor density	:	Not applicable



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F	Relative	e density	:	No data available	9
C	Density	,	:	No data available	9
S	Solubili Wat	ty(ies) er solubility	:	No data available	9
-	Partition	n coefficient: n-	:	Not applicable	
		ition temperature	:	No data available	9
C	Decom	position temperature	:	No data available	9
V	√iscosi Visc	ty osity, kinematic	:	Not applicable	
E	Explosi	ve properties	:	Not explosive	
C	Oxidizir	ng properties	:	The substance o	r mixture is not classified as oxidizing.
Ν	Molecu	lar weight	:	No data available	9
F	Particle	size	:	No data available	9

SECTION 10. STABILITY AND REACTIVITY

Reactivity Chemical stability Possibility of hazardous reac- tions	:	Stable under normal conditions.
Conditions to avoid	:	Heat, flames and sparks. Avoid dust formation.
Incompatible materials Hazardous decomposition	:	
products	•	

SECTION 11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure Inhalation

Skin contact Ingestion Eye contact

Acute toxicity

Not classified based on available information.

Components:

Pancrelipase:

Acute oral toxicity

: LD50 (Rat): > 10,000 mg/kg



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	Talc: Acute	oral toxicity	:	LD50 (Rat): > 5,0 Remarks: Based)00 mg/kg on data from similar materials
	Starch Acute	n: oral toxicity	:	LD50 (Rat): > 5,0)00 mg/kg
	Acute	dermal toxicity	:	LD50 (Rabbit): >	2,000 mg/kg
	Sucro Acute	se: oral toxicity	:	LD50 (Rat): 29,7	00 mg/kg
	-	/l phthalate: oral toxicity	:	LD50 (Rat): > 5,0	000 mg/kg
	Acute	inhalation toxicity	:	LC50 (Rat): > 4.6 Exposure time: 6 Test atmosphere	h
	Acute	dermal toxicity	:	LD50 (Rat): > 11	,181 mg/kg
	Cause	orrosion/irritation s skin irritation. onents:			
	-				
	Specie Methoo Result Remar	d	:	Rabbit OECD Test Guid Skin irritation Based on data fre	eline 404 om similar materials
	Talc:				
	Specie Result		:	Rabbit No skin irritation	
	Diethy	l phthalate:			
	Specie Result	es	:	Rabbit No skin irritation	
		is eye damage/eye irr s serious eye irritation.		on	
		onents:			
	Pancr Result Remar		:		reversing within 21 days om similar materials



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Talc:			
Specie	S	: Rabbit	
Result		: No eye irritat	ion
Starch	:		
Specie	S	: Rabbit	
Result		: No eye irritat	ion
Diethy	l phthalate:		
Species	S	: Rabbit	
Result		: No eye irritat	
Remarl	KS	: Based on da	ta from similar materials
Respir	atory or skin sensit	ization	
-	ensitization		
		ilable information	
	ssified based on ava	liable information.	
-	atory sensitization use allergy or asthm	a symptoms or brea	thing difficulties if inhaled.
-	onents:	,	5
Pancre	elipase:		
	of exposure	: Inhalation	
Specie		: Humans	
Result	-	: positive	
Remarl	ks		ta from similar materials
Assess	ment	: May cause s	ensitization by inhalation.
Talc:			
	of exposure	: Skin contact	
Species		: Humans	
Result		: negative	
_			
Starch		.	
Test Ty		: Maximization	n Test
Routes Species	of exposure	: Skin contact	
Result	5	: Guinea pig : negative	
Rooult		. nogativo	
Diethy	l phthalate:		
Test Ty		: Buehler Test	
	of exposure	: Skin contact	
Species	S	: Guinea pig	
Result		: negative	
C a max	cell mutagenicity		

Germ cell mutagenicity

Not classified based on available information.



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Com	ponents:		
Panc	relipase:		
Genc	otoxicity in vitro	Method: OE Result: neg	Bacterial reverse mutation assay (AMES) CD Test Guideline 471 ative ased on data from similar materials
		Method: OE Result: neg	n vitro mammalian cell gene mutation test CD Test Guideline 476 ative ased on data from similar materials
		Method: OE Result: neg	Chromosome aberration test in vitro CD Test Guideline 473 ative ased on data from similar materials
Talc:			
Geno	otoxicity in vitro		DNA damage and repair, unscheduled DNA syn- mmalian cells (in vitro) ative
Genc	otoxicity in vivo	Species: Ra	Route: Ingestion
Stard	ch:		
Genc	otoxicity in vitro	: Test Type: I Result: neg	Bacterial reverse mutation assay (AMES) ative
Sucr	ose:		
Genc	otoxicity in vitro	: Test Type: I Result: neg	n vitro mammalian cell gene mutation test ative
Dieth	yl phthalate:		
Genc	otoxicity in vitro		Bacterial reverse mutation assay (AMES) CD Test Guideline 471 ative
			n vitro mammalian cell gene mutation test CD Test Guideline 476 ative
			Chromosome aberration test in vitro CD Test Guideline 473 ative

Carcinogenicity

Not classified based on available information.



ersion 2	Revision Date: 10/10/2020		9S Number: 22088-00003	Date of last issue: 03/23/2020 Date of first issue: 11/22/2019
<u>Comp</u>	oonents:			
	ation Route sure time	:	Mouse inhalation (dust/m 2 Years negative	nist/fume)
Dieth	yl phthalate:			
	ation Route sure time	:	Rat Skin contact 103 weeks negative	
IARC				t at levels greater than or equal to 0.1% is onfirmed human carcinogen by IARC.
OSHA			this product prese regulated carcino	nt at levels greater than or equal to 0.1% is gens.
NTP				t at levels greater than or equal to 0.1% is carcinogen by NTP.
<u>Comp</u> Pancr	assified based on avail ponents: relipase: s on fertility	:	Test Type: Two-g	eneration reproduction toxicity study
Effects	s on fertility	:	Test Type: Two-g Species: Rat Application Route Result: negative	
				on data from similar materials
Effects	s on fetal development	:	Species: Rat Application Route Result: negative	vo-fetal development e: Ingestion on data from similar materials
Talc: Effects	s on fetal development	:	Test Type: Embry Species: Rat Application Route Result: negative	vo-fetal development e: Ingestion
-	yl phthalate: s on fertility	:	Species: Rat Application Route	eneration reproduction toxicity study e: Ingestion est Guideline 416



rsion	Revision Date: 10/10/2020		DS Number: 22088-00003	Date of last issue: 03/23/2020 Date of first issue: 11/22/2019
			Result: negative	
Effect	s on fetal development	:	Test Type: Embry Species: Rat Application Route Result: negative	vo-fetal development e: Ingestion
			Test Type: Embry Species: Rabbit Application Route Result: negative	vo-fetal development e: Skin contact
	-single exposure assified based on availa	able	information.	
	-repeated exposure assified based on availa	able	information.	
Repe	ated dose toxicity			
Comp	oonents:			
Panci	elipase:			
	EL cation Route sure time od		Rat > 100 mg/kg Ingestion 13 Weeks OECD Test Guide Based on data fro	eline 408 om similar materials
Starc	h:			
	EL cation Route sure time		Rat >= 2,000 mg/kg Skin contact 28 Days OECD Test Guide	eline 410
Dieth	yl phthalate:			
		:	Rat 150 mg/kg Ingestion 16 Weeks	
Aspir	ation toxicity			
Not cl	assified based on availa	able	information.	

Ecotoxicity

Components:

Pancrelipase:



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Τοχία	city to fish	:	Exposure time: 96 Method: OECD Te	
	city to daphnia and other tic invertebrates	:	Exposure time: 48 Method: OECD Te	
Toxic plant	city to algae/aquatic s	:	10 mg/l Exposure time: 72 Method: OECD Te	
			Exposure time: 72 Method: OECD Te	
Talc	:			
Τοχία	city to fish	:	LC50 (Brachydan Exposure time: 24	o rerio (zebrafish)): > 100,000 mg/l h
Dietł	hyl phthalate:			
	city to fish	:	LC50 (Oncorhync Exposure time: 96	hus mykiss (rainbow trout)): 12 mg/l i h
	city to daphnia and other tic invertebrates	:	LC50 (Daphnia m Exposure time: 48	agna (Water flea)): 90 mg/l h
Toxic plant	city to algae/aquatic s	:	ErC50 (Desmodes Exposure time: 72	smus subspicatus (green algae)): 45 mg/l ! h
			EC10 (Desmodes Exposure time: 72	mus subspicatus (green algae)): 9 mg/l ! h
Toxic icity)	city to fish (Chronic tox-	:	NOEC (Cyprinus o Exposure time: 28	carpio (Carp)): 5 mg/l s d
aqua	city to daphnia and other tic invertebrates (Chron- kicity)	:	NOEC (Daphnia r Exposure time: 21	nagna (Water flea)): 25 mg/l d
Pers	istence and degradabili	ity		
Com	ponents:			
	crelipase:			
	egradability	:	Result: Readily bi	odegradable.
Dieth	hyl phthalate:			



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Biode	egradability	:	Result: Readily b Biodegradation: Exposure time: 2	94.6 %
Bioa	ccumulative potential			
Com	ponents:			
Partit	relipase: ion coefficient: n- ol/water	:	log Pow: < 4	
	ose: ion coefficient: n- ol/water	:	Pow: < 1	
Partit	yl phthalate: ion coefficient: n- ol/water	:	log Pow: 2.2	
	lity in soil ata available			
••	r adverse effects ata available			

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal n	nethods
------------	---------

Waste from residues	:	Dispose of in accordance with local regulations.
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

UN/ID/NA number	:	UN 3077
Proper shipping name	:	Environmentally hazardous substance, solid, n.o.s.
		(Diethyl phthalate)
Class	:	9



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Label ERG	Code e pollutant	SIZES WHER	NFORMATION ONLY APPLIES TO PACKAGE E THE HAZARDOUS SUBSTANCE MEETS ABLE QUANTITY.

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.

SECTION 15. REGULATORY INFORMATION

CERCLA Reportable Quantity

Components	CAS-No.	Component RQ (lbs)	Calculated product RQ (lbs)
Diethyl phthalate	84-66-2	1000	47619

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 Respiratory or skin sensitization Skin corrosion or irritation 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.

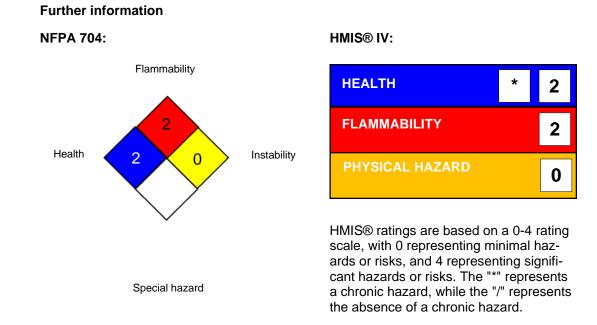
US State Regulations

Pennsylvania Right To Know				
Pancrelipase	53608-75-6			
Cellacefate	9004-38-0			
Talc	14807-96-6			
Sucrose	57-50-1			
Starch	9005-25-8			
Diethyl phthalate	84-66-2			
California List of Hazardous Substances				
Talc	14807-96-6			
Diethyl phthalate	84-66-2			
Polyvinyl pyrrolidone	9003-39-8			
California Permissible Exposure Limits for Chemical Contaminants				
Talc	14807-96-6			
Sucrose	57-50-1			
Starch	9005-25-8			



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	Diethyl phthalate			84-66-2
	ngredients of this pro		-	e following inventories:
AICS			determined	
DSL	_		determined	
IECS	C	: not	determined	

SECTION 16. OTHER INFORMATION



Full text of other abbreviations

ACGIH NIOSH REL OSHA Z-1	:	USA. ACGIH Threshold Limit Values (TLV) USA. NIOSH Recommended Exposure Limits USA. Occupational Exposure Limits (OSHA) - Table Z-1 Lim- its for Air Contaminants
OSHA Z-3	:	USA. Occupational Exposure Limits (OSHA) - Table Z-3 Mineral Dusts
ACGIH / TWA	:	8-hour, time-weighted average
NIOSH REL / TWA	:	Time-weighted average concentration for up to a 10-hour workday during a 40-hour workweek
OSHA Z-1 / TWA OSHA Z-3 / TWA		8-hour time weighted average 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



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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; 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; 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 SheetInternal technical data, data fre eChem Portal search results a cy, http://echa.europa.eu/	om raw material SDSs, OECD and European Chemicals Agen-
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