

Version 4.1	Revision Date: 30.09.2023	SDS Number:Date of last issue: 04.04.20239791115-00010Date of first issue: 08.10.2021	
SECTIO	N 1. IDENTIFICATION		
Pro	duct name	: Sulfadiazine (41%) / Trimethoprim (8%) Solid For	nulation
	nufacturer or supplier's	etails : MSD	
Ado	Iress	: Talcahuano 750, 6th floor, Ciudad Autonoma Buenos Aires, Argentina C1013AAP	
Tel	ephone	: 908-740-4000	
Em	ergency telephone	: 1-908-423-6000	
E-n	nail address	: EHSDATASTEWARD@msd.com	
Red	commended use of the	nemical and restrictions on use	
	commended use strictions on use	: Veterinary product: Not applicable	

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification		
Acute toxicity (Oral)	:	Category 5
Skin corrosion/irritation	:	Category 2
Serious eye damage/eye irritation	:	Category 2B
Respiratory sensitization	:	Category 1
Reproductive toxicity	:	Category 2
Specific target organ toxicity - single exposure	:	Category 3
Specific target organ toxicity - repeated exposure	:	Category 2 (Bone marrow)
Short-term (acute) aquatic hazard	:	Category 1
Long-term (chronic) aquatic hazard	:	Category 1

GHS label elements



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Haza	rd pictograms		!
Signa	ll Word	: Danger	
Haza	rd Statements	H315 + H320 (H334 May cau difficulties if inh H335 May cau H361d Suspec H373 May cau prolonged or re	narmful if swallowed. Causes skin and eye irritation. se allergy or asthma symptoms or breathing haled. se respiratory irritation. eted of damaging the unborn child. se damage to organs (Bone marrow) through epeated exposure. ic to aquatic life with long lasting effects.
Preca	autionary Statements	P202 Do not h and understoo P260 Do not b P264 Wash sk P271 Use only P273 Avoid rel P280 Wear pro- tion/ face prote	reathe dust. in thoroughly after handling. outdoors or in a well-ventilated area. ease to the environment. otective gloves/ protective clothing/ eye protec-
		P304 + P340 + and keep comf doctor if you fe P305 + P351 + for several min easy to do. Co P332 + P313 h tion. P337 + P313 h tention. P342 + P311 h POISON CEN P362 + P364 T reuse. P391 Collect s Storage: P405 Store loc Disposal:	- P338 IF IN EYES: Rinse cautiously with water iutes. Remove contact lenses, if present and ntinue rinsing. f skin irritation occurs: Get medical advice/ atten- f eye irritation persists: Get medical advice/ at- f experiencing respiratory symptoms: Call a TER/ doctor. Take off contaminated clothing and wash it before pillage.
		P501 Dispose disposal plant.	of contents/ container to an approved waste



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Other hazards which do not result in classification

May form explosive dust-air mixture during processing, handling or other means.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)
sulfadiazine	68-35-9	41,67
Trimethoprim	738-70-5	8,33

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 eye contact	:	o ,
If swallowed	:	If swallowed, DO NOT induce vomiting. Get medical attention. Rinse mouth thoroughly with water.
Most important symptoms and effects, both acute and delayed	:	
Protection of first-aiders	:	
Notes to physician	:	Treat symptomatically and supportively.



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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
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	:	In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.

SECTION 6. ACCIDENTAL RELEASE MEASURES

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	:	Surround spill with absorbents and place a damp covering over the area to minimize entry of the material into the air. Add excess liquid to allow the material to enter into solution. Soak up with inert absorbent material. Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air). 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. Clean up remaining materials from spill with suitable absorbent. 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.



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SECTION 7. HANDLING AND STORAGE

Technical measures	Static electricity may accumulate and ignite su	spended dust
	causing an explosion.	
	Provide adequate precautions, such as electric	al grounding
	and bonding, or inert atmospheres.	
Local/Total ventilation	If sufficient ventilation is unavailable, use with I	ocal exhaust
Advice on acts bandling	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.	
		and addate
	Handle in accordance with good industrial hygi practice, based on the results of the workplace	
	assessment	exposure
	Keep container tightly closed.	
	Already sensitized individuals, and those susce	ntiblo
	to asthma, allergies, chronic or recurrent respir	
	should consult their physician regarding working	
	respiratory irritants or sensitizers.	g with
	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 dis	charges
	Do not eat, drink or smoke when using this pro	
	Take care to prevent spills, waste and minimize	
	environment.	
Conditions for safe storage	Keep in properly labeled containers.	
Conditions for sale storage	Store locked up.	
	Keep tightly closed.	
	Keep in a cool, well-ventilated place.	
	Store in accordance with the particular nationa	regulations
Materials to avoid	Do not store with the following product types:	rogulationo.
	Strong oxidizing agents	
	Self-reactive substances and mixtures	
	Organic peroxides	
	Explosives	
	Gases	

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parame- ters / Permissible concentration	Basis
sulfadiazine	68-35-9	TŴA	2 mg/m3 (OEB 1)	Internal
Trimethoprim	738-70-5	TWA	400 µg/m3 (OEB 2)	Internal



Sulfadiazine (41%) / Trimethoprim (8%) Solid Formulation

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Engi	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. 				
Pers	onal protective equip	ment					
Respiratory protection		exposure as	local exhaust ventilation is not available or sessment demonstrates exposures outside the ed guidelines, use respiratory protection. type				
	l protection aterial	: Chemical-re	sistant gloves				
Eye ş	protection	: Wear safety glasses with side shields or goggles. If the work environment or activity involves dusty condition 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, o aerosols.					
	Skin and body protection Hygiene measures		n or laboratory coat. to chemical is likely during typical use, provide systems and safety showers close to the ce. do not eat, drink or smoke. minated clothing before re-use. e operation of a facility should include review of controls, proper personal protective equipment, degowning and decontamination procedures, giene monitoring, medical surveillance and the histrative controls.				

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	:	powder
Color	:	white
Odor	:	No data available
Odor Threshold	:	No data available
рН	:	6,5 - 8,5
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 explosive dust-air mixture during processing,



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				handling or other	means.
	Flamma	ability (liquids)	:	Not applicable	
Upper explosion limit / Upper flammability limit		:	No data available		
		explosion limit / Lower bility limit	:	No data available	
	Vapor p	pressure	:	Not applicable	
	Relative	e vapor density	:	Not applicable	
	Relative	e density	:	No data available)
	Density		:	No data available)
	Solubili Wate	ty(ies) er solubility	:	No data available)
	Partition octanol	n coefficient: n-	:	Not applicable	
		ition temperature	:	No data available)
	Decom	position temperature	:	No data available)
	Viscosit Visc	ty osity, kinematic	:	Not applicable	
	Explosi	ve properties	:	Not explosive	
	Oxidizir	ng properties	:	: The substance or mixture is not classified as oxidizing.	
	Molecu	lar weight	:	No data available)
	Particle	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.
Incompatible materials	:	Oxidizing agents
Hazardous decomposition products	:	No hazardous decomposition products are known.



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ECTION	11. TOXICOLOGICAL I	NFC	ORMATION	
Inform expos	nation on likely routes of sure	:	Inhalation Skin contact Ingestion Eye contact	
	e toxicity be harmful if swallowed.			
Produ	uct:			
Acute	oral toxicity	:	Acute toxicity es Method: Calcula	stimate: 2.251 mg/kg ation method
Comp	oonents:			
sulfac	diazine:			
Acute	oral toxicity	:	LD50 (Mouse):	1.500 mg/kg
Acute	dermal toxicity	:	LD50 (Rat): > 5. Remarks: Based	.000 mg/kg d on data from similar materials
	toxicity (other routes of nistration)	:	LD50 (Rat): 880 Application Rou	
			LD50 (Mouse): Application Rou	
Trime	ethoprim:			
	oral toxicity	:	LD50 (Rat): 1.50	00 - 5.300 mg/kg
			LD50 (Mouse):	1.910 - 7.000 mg/kg
	toxicity (other routes of histration)	:) - 500 mg/kg te: Intraperitoneal
			LD50 (Dog): 90 Application Rou	
			LD50 (Mouse): Application Rou	
Cause	corrosion/irritation es skin irritation.			
	<u>ponents:</u>			
sulfac Resul	diazine: t		Skin irritation	
Rema		:		rom similar materials



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Serious eye damage/eye irritation

Causes eye irritation.

Components:

sulfadiazine:

Species	:	Rabbit
Result	:	Irritation to eyes, reversing within 7 days
Remarks	:	Based on data from similar materials

Respiratory or skin sensitization

Skin sensitization

Not classified based on available information.

Respiratory sensitization

May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Components:

sulfadiazine:

Test Type :	Maximization Test
Species :	Guinea pig
Result :	Not a skin sensitizer.
Remarks :	Based on data from similar materials

Trimethoprim:

Test Type	:	Maximization Test
Routes of exposure	:	Dermal
Species	:	Guinea pig
Result	:	Not a skin sensitizer.

Germ cell mutagenicity

Not classified based on available information.

Components:

sulfadiazine:	
Genotoxicity in vitro	: Test Type: Bacterial reverse mutation assay (AMES) Result: negative Remarks: Based on data from similar materials
	Test Type: Chromosomal aberration Test system: Chinese hamster ovary cells Result: negative Remarks: Based on data from similar materials
Trimethoprim:	
Genotoxicity in vitro	: Test Type: Bacterial reverse mutation assay (AMES) Result: negative
	Test Type: Chromosomal charaction

Test Type: Chromosomal aberration



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			Result: negative	
			Test Type: In vitro Result: negative	o mammalian cell gene mutation test
			Test Type: DNA c thesis in mammal Result: negative	damage and repair, unscheduled DNA syn- lian cells (in vitro)
Geno	toxicity in vivo	:	Test Type: Micror Species: Rat Result: negative	nucleus test
			Test Type: Chrom Species: Humans Result: negative	nosomal aberration
Carci	nogenicity			
Not c	lassified based on availa	able	information.	
-	oductive toxicity ected of damaging the u	nbo	rn child.	
Com	oonents:			
sulfa	diazine:			
	ts on fetal development	:	Result: Embryoto	
Trime	ethoprim:			
Effect	ts on fertility	:	Test Type: Fertilit Species: Rat Application Route Fertility: NOAEL: Result: No effects	e: Oral 70 mg/kg body weight
Effect	ts on fetal development	:	Result: Effects on	e: Oral oxicity: LOAEL: 70 mg/kg body weight
			Result: Embryoto	e: Oral oxicity: LOAEL: 70 mg/kg body weight



			ster
			pit
Reprod sessme	luctive toxicity - As-	: Suspected of	damaging the unborn child.
May ca	single exposure use respiratory irritati onents:	on.	
sulfadi Assess		: May cause rea	spiratory irritation.
	repeated exposure	- (David and an and a share) the	
-	onents:	s (bone marrow) im	ough prolonged or repeated exposure.
Trimet	hoprim:		
Target Assess	Organs ment	 Bone marrow Causes dama exposure. 	ge to organs through prolonged or repeated
Repeat	ted dose toxicity		
Compo	onents:		
Trimet	hoprim:		
Exposu	-	: Rat : 100 mg/kg : 300 mg/kg : Oral : 6 Months : Bone marrow,	Liver, Pituitary gland, Thyroid
	S	: Rat	



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Expo	cation Route sure time et Organs	: Oral : 3 Months : Bone marrow	1
Expo	EL	: Dog : 2,5 mg/kg : 45 mg/kg : Oral : 3 Months : Blood, Thyro	id
-	ration toxicity lassified based on ava	ilable information.	
Expe	rience with human e	xposure	
Com	ponents:		
	diazine: eral Information	: May cause e	ye, skin, and respiratory tract irritation.
Trime	ethoprim:		
Inges	ition	Symptoms: A	ns: Bone marrow Abdominal pain, Nausea, Vomiting, skin rash, eadache, mental depression, confusion

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity	
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Components:		
sulfadiazine:		
Toxicity to fish	:	LC50 (Pimephales promelas (fathead minnow)): > 100 mg/l Exposure time: 96 h Method: OECD Test Guideline 203
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia magna (Water flea)): > 100 mg/l Exposure time: 48 h
		Method: OECD Test Guideline 202
Toxicity to algae/aquatic plants	:	EC50 (Anabaena flos-aquae): 17 mg/l Exposure time: 72 h
		Method: OECD Test Guideline 201
		NOEC (Anabaena flos-aquae): 3,9 mg/l Exposure time: 72 h
		Method: OECD Test Guideline 201
		EC50 (Pseudokirchneriella subcapitata (green algae)): > 1 mg/l
		Exposure time: 72 h Method: OECD Test Guideline 201



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		mg/l Exposure time: 7	irchneriella subcapitata (green algae)): 0,13 2 h Fest Guideline 201
		EC50 (Microcysti Exposure time: 7 Method: ISO 869	
M-Factor (Acute aquatic to icity))X- :	1	
Toxicity to daphnia and oth aquatic invertebrates (Chro ic toxicity)		Exposure time: 2	magna (Water flea)): 6,2 mg/l 1 d Fest Guideline 211
M-Factor (Chronic aquatic toxicity)	:	1	
Toxicity to microorganisms	3 :	EC50: > 1.000 m Exposure time: 3 Test Type: Respi Method: OECD 1	ĥ
		NOEC: 1.000 mg Exposure time: 3 Test Type: Respi Method: OECD T	h
Trimethoprim:			
Toxicity to fish	:	LC50 (Pimephale Exposure time: 9	es promelas (fathead minnow)): 100 mg/l 6 h
Toxicity to daphnia and oth aquatic invertebrates	ner :	EC50 (Daphnia r Exposure time: 4	nagna Straus (Water flea)): 92 mg/l 8 h
Toxicity to algae/aquatic plants	:	EC50 (Pseudokir mg/l Exposure time: 7	rchneriella subcapitata (microalgae)): 80,3 ′2 h
		NOEC (Pseudok mg/l Exposure time: 7	irchneriella subcapitata (green algae)): 16 '2 h
		EC50 (Anabaena Exposure time: 7	a flos-aquae): 253 mg/l 2 h
		EC10 (Anabaena Exposure time: 7	a flos-aquae): 26 mg/l '2 h
Toxicity to fish (Chronic to: icity)	x- :	NOEC (Zebrafish Exposure time: 2	
Toxicity to daphnia and oth aquatic invertebrates (Chro		NOEC (Daphnia Exposure time: 2	magna (Water flea)): 6 mg/l 1 d



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ic toxi Toxici	city) ty to microorganisms	:	EC10: 16,7 mg/l Exposure time: 3 Test Type: Respi Method: OECD T	
			EC50: > 1.000 m Exposure time: 3 Test Type: Respi Method: OECD T	hrs
Persi	stence and degradab	ility		
<u>Comp</u>	oonents:			
	diazine: gradability	:	Result: Not readi Biodegradation:	
			Exposure time: 2	
Trime	ethoprim:			
Biode	gradability	:	Result: Not readi Biodegradation: Exposure time: 2 Method: OECD T	4 %
			Biodegradation: Exposure time: 2	
Bioad	cumulative potential			
<u>Comp</u>	oonents:			
Partiti	diazine: on coefficient: n- ol/water	:	log Pow: 0,12	
Partiti	ethoprim: on coefficient: n- ol/water	:	log Pow: 0,91	
	l ity in soil Ita available			
	adverse effects			



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SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods	
Waste from residues	: Do not dispose of waste into sewer. 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	 UN 3077 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,
UN number	N.O.S.
Proper shipping name	(sulfadiazine)
Class	: 9
Packing group	: III
Labels	: 9
Environmentally hazardous	: yes
IATA-DGR UN/ID No. Proper shipping name	 : UN 3077 : Environmentally hazardous substance, solid, n.o.s. (sulfadiazine)
Class Packing group Labels Packing instruction (cargo aircraft)	: 9 : III : Miscellaneous : 956
Packing instruction (passen- ger aircraft) Environmentally hazardous	: 956 : yes
IMDG-Code	 UN 3077 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,
UN number	N.O.S.
Proper shipping name	(sulfadiazine)
Class	: 9
Packing group	: III
Labels	: 9
EmS Code	: F-A, S-F
Marine pollutant	: yes

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

Not applicable for product as supplied.

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



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Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

SECTION 15. REGULATORY INFORMATION

Safety, health and environr mixture	nental regulations/legislation specific for the substance or
Argentina. Carcinogenic Sub Registry.	stances and Agents : Not applicable
Control of precursors and ess preparation of drugs.	sential chemicals for the : Not applicable
•	duct are reported in the following inventories:
AICS	: not determined
DSL	: not determined

: not determined

SECTION 16. OTHER INFORMATION

Revision Date Date format	30.09.2023 dd.mm.yyyy

Further information

IECSC

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

Full text of other abbreviations

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR -Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation: DSL - Domestic Substances List (Canada): 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; ERG - Emergency Response Guide; 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;



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n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; 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; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; 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; WHMIS - Workplace Hazardous Materials Information System

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.

AR / Z8