

Amoxicillin Trihydrate / Potassium Clavulanate Formulation

Vers 3.0	sion	Revision Date: 06.07.2024		S Number: 5220-00011	Date of last issue: 06.04.2024 Date of first issue: 13.07.2021
SEC	TION 1 Produc	: IDENTIFICATION t name	:	Amoxicillin Trihyc	drate / Potassium Clavulanate Formulation
	Manufa	acturer or supplier's d	letai	ls	
	Compa	ny	:	Intervet Australia	Pty Limited (trading as MSD Animal Health)
	Addres	S	:	91-105 Harpin St Bendigo 3550, V	
	Telepho	one	:	1 800 033 461	
	Emerge	ency telephone number	·:	Poisons Informat	ion Centre: Phone 13 11 26
	E-mail a	address	:	EHSDATASTEW	ARD@msd.com
	Recom	mended use of the ch	nemi	ical and restrictio	ons on use
		mended use tions on use	:	Pharmaceutical Not applicable	

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification Respiratory sensitisation	:	Category 1
GHS label elements		
Hazard pictograms	:	
Signal word	:	Danger
Hazard statements	:	H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.
Precautionary statements	:	Prevention: P261 Avoid breathing mist or vapours. P284 Wear respiratory protection.
		Response:
		P304 + P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing. P342 + P311 If experiencing respiratory symptoms: Call a POISON CENTER/ doctor.



Amoxicillin Trihydrate / Potassium Clavulanate Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 06.04.2024
3.0	06.07.2024	8845220-00011	Date of first issue: 13.07.2021

Disposal:

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

Other hazards which do not result in classification

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)
Amoxicillin Trihydrate	61336-70-7	>= 10 -< 30
Aluminum tristearate	637-12-7	< 10
Benzyl alcohol	100-51-6	< 10

SECTION 4. FIRST AID MEASURES

General advice	:	In the case of accident or if you feel unwell, seek medical ad- vice immediately. When symptoms persist or in all cases of doubt seek medical
If inhaled	:	advice. If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention.
In case of skin contact	:	Wash with water and soap as a precaution. Get medical attention if symptoms occur.
In case of eye contact	:	Flush eyes with water as a precaution. Get medical attention if irritation develops and persists.
If swallowed	:	If swallowed, DO NOT induce vomiting. Get medical attention if symptoms occur. Rinse mouth thoroughly with water.
Most important symptoms and effects, both acute and delayed	:	May cause allergy or asthma symptoms or breathing difficul- ties if inhaled. Excessive exposure may aggravate preexisting asthma and other respiratory disorders (e.g. emphysema, bronchitis, reac- tive airways dysfunction syndrome).
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. FIREFIGHTING MEASURES

Suitable extinguishing media	:	Alcohol-resistant foam
		Carbon dioxide (CO2)



Amoxicillin Trihydrate / Potassium Clavulanate Formulation

Vers 3.0	sion	Revision Date: 06.07.2024		9S Number: 45220-00011	Date of last issue: 06.04.2024 Date of first issue: 13.07.2021
	Unsuita media	able extinguishing	:	Dry chemical None known.	
	Specific fighting	c hazards during fire-	:	Exposure to comb	oustion products may be a hazard to health.
	0 0	ous combustion prod-	:	Carbon oxides Metal oxides Nitrogen oxides (I	NOx)
	Specific ods	c extinguishing meth-	:	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
	for firef	l protective equipment ighters em Code	:	In the event of fire Use personal prot •3Z	e, wear self-contained breathing apparatus. ective 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 pro- tective equipment recommendations (see section 8).
Environmental precautions	Avoid release to the environment. Prevent further leakage or spillage if safe to do so. Prevent spreading over a wide area (e.g. by containment or oil barriers). 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	 Soak up with inert absorbent material. For large spills, provide dyking or other appropriate containment to keep material from spreading. If dyked material can be pumped, store recovered material in appropriate container. 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.

SECTION 7. HANDLING AND STORAGE

Technical measures	:	See Engineering measures under EXPOSURE
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Amoxicillin Trihydrate / Potassium Clavulanate Formulation

Versior 3.0	n Revision Date: 06.07.2024	SDS Number: 8845220-00011	Date of last issue: 06.04.2024 Date of first issue: 13.07.2021
	ocal/Total ventilation dvice on safe handling	 Use only with Avoid breathin Do not swallow Avoid contact Avoid prolonge Handle in according practice, base 	
Ну	/giene measures	Already sensit to asthma, alle should consult tory irritants of Take care to p environment. : If exposure to	er tightly closed. ised individuals, and those susceptible ergies, chronic or recurrent respiratory disease, their physician regarding working with respira- sensitisers. revent spills, waste and minimize release to the chemical is likely during typical use, provide eye ms and safety showers close to the working
		When using de Wash contami The effective of engineering co appropriate de industrial hygi	o not eat, drink or smoke. nated clothing before re-use. operation of a facility should include review of ontrols, proper personal protective equipment, egowning and decontamination procedures, ene monitoring, medical surveillance and the strative controls.
	onditions for safe storage aterials to avoid	 Keep in prope Keep tightly cl Store in accor Do not store w 	rly labelled containers. osed. dance with the particular national regulations. rith the following product types:
		Strong oxidizir	ng agents

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parame- ters / Permissible concentration	Basis
Amoxicillin Trihydrate	61336-70-7	TWA	1 mg/m3 (OEB 1)	Internal
	Further inform	ation: RSEN		
Aluminum tristearate	637-12-7	TWA	10 mg/m3	AU OEL
		TWA (Inhal- able particu-	10 mg/m3	ACGIH
		late matter)		
		TWA (Res- pirable par- ticulate mat- ter)	3 mg/m3	ACGIH
		TWA (Res-	1 mg/m3	ACGIH



Amoxicillin Trihydrate / Potassium Clavulanate Formulation

ersion 0	Revision Date: 06.07.2024	SDS Number: 8845220-00011	Date of last issue: 06.04.2024 Date of first issue: 13.07.2021		
			pirable par- ticulate mat- ter)	(Aluminium)	
Engir	neering measures	technologies to less quick con All engineering design and op protect produc	te engineering o o control airborr nections). g controls shoul erated in accord ts, workers, and	controls and manuf ne concentrations (d be implemented l dance with GMP pr d the environment. require special con	e.g., drip- oy facility inciples to
Perso	onal protective equip	oment			
Fil Hand	iratory protection ter type protection aterial	sure assessme ommended gu	ent demonstrate idelines, use re ticulates and or	tilation is not availa es exposures outsic spiratory protectior ganic vapour type	de the rec-
	protection and body protection	If the work env mists or aeros Wear a facesh potential for di aerosols.	vironment or act ols, wear the ap iield or other full	shields or goggles ivity involves dusty propriate goggles. I face protection if t he face with dusts,	conditions, here is a

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	:	suspension
Colour	:	cream
Odour	:	No data available
Odour 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	:	No data available
Evaporation rate	:	No data available
Flammability (solid, gas)	:	Not applicable



Amoxicillin Trihydrate / Potassium Clavulanate Formulation

Versio 3.0	on	Revision Date: 06.07.2024		S Number: I5220-00011	Date of last issue: 06.04.2024 Date of first issue: 13.07.2021
F	lamma	bility (liquids)	:	No data available	9
		explosion limit / Upper pility limit	:	No data available	9
		explosion limit / Lower pility limit	:	No data available	9
V	/apour	pressure	:	Not applicable	
F	Relative	vapour density	:	No data available	9
F	Relative	edensity	:	No data available	
C	Density		:	0.900 - 1.100 g/c	m ³
S	Solubilit Wate	y(ies) er solubility	:	No data available	9
	Partitior	n coefficient: n-	:	No data available	9
-		nition temperature	:	No data available	9
C	Decomp	oosition temperature	:	No data available	9
V	/iscosit/ Visco	y osity, kinematic	:	No data available	9
E	Explosiv	ve properties	:	Not explosive	
C	Dxidizin	g properties	:	The substance o	r mixture is not classified as oxidizing.
Ν	Nolecul	ar weight	:	No data available	9
	Particle Particle	characteristics size	:	No data available	

SECTION 10. STABILITY AND REACTIVITY

Reactivity	:	Not classified as a reactivity hazard.
Chemical stability	:	Stable under normal conditions.
Possibility of hazardous reac- tions	:	Can react with strong oxidizing agents.
Conditions to avoid	:	None known.
Incompatible materials	:	Oxidizing agents
Hazardous decomposition products	:	No hazardous decomposition products are known.



Amoxicillin Trihydrate / Potassium Clavulanate Formulation

3.0 06.07.2024 8845220-00011 Date of first issue: 13.07.2021	Version 3.0	Revision Date: 06.07.2024	SDS Number: 8845220-00011	Date of last issue: 06.04.2024 Date of first issue: 13.07.2021	
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SECTION 11. TOXICOLOGICAL INFORMATION

:	Inhalation Skin contact Ingestion Eye contact
ailable	information.
:	Acute toxicity estimate: > 2,000 mg/kg Method: Calculation method
:	Acute toxicity estimate: > 5 mg/l Exposure time: 4 h Test atmosphere: dust/mist Method: Calculation method
:	LD50 (Rat): > 8,000 mg/kg
	LD50 (Mouse): > 10,000 mg/kg
	LD50 (Dog): > 3,000 mg/kg
:	LD50 (Rat, female): > 2,000 mg/kg Remarks: Based on data from similar materials
:	()
	Exposure time: 4 h Test atmosphere: dust/mist
	Method: OECD Test Guideline 403 Remarks: Based on data from similar materials
-	L DEQ (Dot): 1 620 mg/kg
:	LD50 (Rat): 1,620 mg/kg
:	LC50 (Rat): > 4.178 mg/l Exposure time: 4 h Test atmosphere: dust/mist Method: OECD Test Guideline 403
	:

Skin corrosion/irritation

Not classified based on available information.



Amoxicillin Trihydrate / Potassium Clavulanate Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 06.04.2024
3.0	06.07.2024	8845220-00011	Date of first issue: 13.07.2021

Components:

Aluminum tristearate: Species Method Remarks	::	reconstructed human epidermis (RhE) OECD Test Guideline 439 Based on data from similar materials
Result	:	No skin irritation
Benzyl alcohol: Species Method Result	: :	Rabbit OECD Test Guideline 404 No skin irritation

Serious eye damage/eye irritation

Not classified based on available information.

Components:

Aluminum tristearate:

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

Benzyl alcohol:

Species : Result : Method :	Rabbit
Result :	Irritation to eyes, reversing within 21 days
Method :	OECD Test Guideline 405

Respiratory or skin sensitisation

Skin sensitisation

Not classified based on available information.

Respiratory sensitisation

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

Components:

Amoxicillin Trihydrate:

Result Remarks	:	Sensitiser May cause sensitisation by inhalation. largely based on human evidence
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Aluminum tristearate:

Test Type	:	Local lymph node assay (LLNA)
Exposure routes	:	Skin contact



Amoxicillin Trihydrate / Potassium Clavulanate Formulation

Version 3.0	Revision Date: 06.07.2024	SDS Number: 8845220-00011	Date of last issue: 06.04.2024 Date of first issue: 13.07.2021
Speci Metho Resu Rema	od It	: negative	Guideline 429 ata from similar materials
Benz	yl alcohol:		
Test	Type sure routes ies od	: Maximisatio : Skin contac : Guinea pig : OECD Test : negative	
Chro	nic toxicity		
	n cell mutagenicity lassified based on ava	ailable information.	
Com	ponents:		
Amo	xicillin Trihydrate:		
Geno	otoxicity in vitro	: Test Type: I Result: neg	Bacterial reverse mutation assay (AMES) ative
Geno	otoxicity in vivo	Species: Mo Result: neg	ative Rodent dominant lethal test (germ cell) (in vivo) buse
II		0	
	inum tristearate: otoxicity in vitro	Method: OE Result: neg Remarks: B Test Type: I	ased on data from similar materials Bacterial reverse mutation assay (AMES)
		Result: neg	CD Test Guideline 471 ative ased on data from similar materials
Geno	otoxicity in vivo	cytogenetic Species: Ra Application Method: OE Result: neg	at Route: Ingestion CD Test Guideline 474



Amoxicillin Trihydrate / Potassium Clavulanate Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 06.04.2024
3.0	06.07.2024	8845220-00011	Date of first issue: 13.07.2021

II

Benzyl alcohol:	
Genotoxicity in vitro	: Test Type: Bacterial reverse mutation assay (AMES) Result: negative
Genotoxicity in vivo	: Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay) Species: Mouse Application Route: Intraperitoneal injection Result: negative

Carcinogenicity

Not classified based on available information.

Components:

Benzyl alcohol:

Species	: Mouse
Application Route	: Ingestion
Exposure time	: 103 weeks
Method	: OECD Test Guideline 451
Species Application Route Exposure time Method Result	: negative

Reproductive toxicity

Not classified based on available information.

Components:

Amoxicillin Trihydrate:

: Test Type: Fertility Species: Rat Application Route: Oral Fertility: NOAEL: 200 mg/kg body weight Result: Reduced fertility Remarks: Not classified due to inconclusive data.
Test Type: Fertility Species: Rat Application Route: Oral Fertility: LOAEL: 500 mg/kg body weight Result: Reduced fertility Remarks: Not classified due to inconclusive data.
 Test Type: Development Species: Rat Application Route: Oral Developmental Toxicity: NOAEL: >= 1,000 mg/kg body weight Result: No embryo-foetal toxicity Test Type: Development



Amoxicillin Trihydrate / Potassium Clavulanate Formulation

rsion)	Revision Date: 06.07.2024	SDS Number: 8845220-0001	Date of last issue: 06.04.2024 Date of first issue: 13.07.2021
		Developme Result: Son based on a	ouse Route: Oral ntal Toxicity: LOAEL: 200 mg/kg body weight ne evidence of adverse effects on development, nimal experiments. lot classified due to inconclusive data.
		Species: Ra Application Developme Result: Rec weight gain	Route: Oral ntal Toxicity: LOAEL: 200 mg/kg body weight luced embryonic survival, Reduced offspring
Alumi	inum tristearate:		
	s on fertility	Species: Ra Application Method: OE Result: neg	Route: Ingestion CD Test Guideline 416
Effect ment	s on foetal develop-	Species: Ra Application Result: neg	Route: Ingestion
Benzy	yl alcohol:		
-	s on fertility	Species: Ra Application Result: neg	Route: Ingestion
Effect ment	s on foetal develop-	Species: M	Route: Ingestion

STOT - single exposure

Not classified based on available information.

STOT - repeated exposure

Not classified based on available information.



Amoxicillin Trihydrate / Potassium Clavulanate Formulation

ersion .0	Revision Date: 06.07.2024	SDS Nun 8845220		Date of last issue: 06.04.2024 Date of first issue: 13.07.2021
	ponents: xicillin Trihydrate: arks	: Not c	lassified du	e to inconclusive data.
Repe	ated dose toxicity			
Com	ponents:			
Spec Appli	cation Route sure time	: Rat : Oral : 6 Moi : No si		verse effects were reported
	cation Route sure time	: Dog : Oral : 6 Moi : No si		verse effects were reported
Spec NOAI Applie	EL cation Route sure time	: Inges : 90 Da	ays	om similar materials
Speci NOAI Applie	EL cation Route sure time	: 28 Da	ation (dust/i	
-	r ation toxicity lassified based on ava	ilable inform	ation.	
-	rience with human e	xposure		
<u>Com</u>	ponents:			
Amo: Inges	xicillin Trihydrate: tion	flatule	ence, skin r	sea, Vomiting, Abdominal pain, Diarrhoea ash, Breathing difficulties roduce an allergic reaction.



Amoxicillin Trihydrate / Potassium Clavulanate Formulation

Version	Revision Date:
3.0	06.07.2024

SDS Number: 8845220-00011 Date of last issue: 06.04.2024 Date of first issue: 13.07.2021

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Amoxicillin Trihydrate:	
Toxicity to fish	 LC50 (Carassius auratus (goldfish)): 0.035 mg/l Exposure time: 96 h Method: OECD Test Guideline 203
Toxicity to algae/aquatic plants	: NOEC (green algae): 530 mg/l Exposure time: 72 h
	EC50 (Synechococcus leopoliensis (blue-green algae)): 0.0022 mg/l Exposure time: 96 h
	NOEC (blue-green algae): 0.0057 mg/l Exposure time: 72 h

Aluminum tristearate:

Ecotoxicology Assessment Acute aquatic toxicity	:	Toxic effects cannot be excluded
Chronic aquatic toxicity	:	Toxic effects cannot be excluded
Benzyl alcohol:		
Toxicity to fish	:	LC50 (Pimephales promelas (fathead minnow)): 460 mg/l Exposure time: 96 h
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia magna (Water flea)): 230 mg/l Exposure time: 48 h Method: OECD Test Guideline 202
Toxicity to algae/aquatic plants	:	EC50 (Pseudokirchneriella subcapitata (green algae)): 770 mg/l Exposure time: 72 h Method: OECD Test Guideline 201
		NOEC (Pseudokirchneriella subcapitata (green algae)): 310 mg/l Exposure time: 72 h Method: OECD Test Guideline 201
Toxicity to daphnia and other aquatic invertebrates (Chron- ic toxicity)	:	NOEC (Daphnia magna (Water flea)): 51 mg/l Exposure time: 21 d Method: OECD Test Guideline 211



Amoxicillin Trihydrate / Potassium Clavulanate Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 06.04.2024
3.0	06.07.2024	8845220-00011	Date of first issue: 13.07.2021

Persistence and degradability	
Components:	
Amoxicillin Trihydrate: Biodegradability :	Result: Readily biodegradable. Biodegradation: 88 % Exposure time: 28 d Method: OECD Test Guideline 301B
Benzyl alcohol:	
Biodegradability :	Result: Readily biodegradable. Biodegradation: 92 - 96 % Exposure time: 14 d
Bioaccumulative potential	
Components:	
Amoxicillin Trihydrate:	
Bioaccumulation :	Remarks: Bioaccumulation is unlikely.
Partition coefficient: n- : octanol/water	log Pow: -0.124 Method: OECD Test Guideline 107
Benzyl alcohol:	
Partition coefficient: n- : octanol/water	log Pow: 1.05
Mobility in soil No data available	
Other adverse effects	
Components:	
Amoxicillin Trihydrate: Results of PBT and vPvB : assessment	Substance is not persistent, bioaccumulative, and toxic (PBT). Product does not contain substances which are very persis- tent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

SECTION 13. DISPOSAL CONSIDERATIONS

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



Amoxicillin Trihydrate / Potassium Clavulanate Formulation

/ersion 3.0	Revision Date: 06.07.2024	-	0S Number: 45220-00011	Date of last issue: 06.04.2024 Date of first issue: 13.07.2021
Conta	minated packaging	:	dling site for re	ers should be taken to an approved waste har ecycling or disposal. e specified: Dispose of as unused product.
ECTION	14. TRANSPORT INFO	RM	ATION	
Intern	ational Regulations			
UNRT UN nu Prope		:	N.O.S.	NTALLY HAZARDOUS SUBSTANCE, LIQUIE
Labels	ng group s nmentally hazardous	: : : :	(Amoxicillin T 9 III 9 yes	rinydrate)
IATA- UN/ID Prope		:	UN 3082 Environmental (Amoxicillin T	ly hazardous substance, liquid, n.o.s. rihydrate)
Labels Packir aircraf Packir ger air	ng instruction (cargo t) ng instruction (passen-		9 III Miscellaneous 964 964	
IMDG UN nu	Code	:	N.O.S.	NTALLY HAZARDOUS SUBSTANCE, LIQUI
Labels EmS (: : : : : : : : : : : : : : : : : : : :	(Amoxicillin Tr 9 III 9 F-A, S-F yes	inyarate)
	port in bulk according			RPOL 73/78 and the IBC Code
Nation	nal Regulations			
	mher		LINI 3082	

UN number Proper shipping name	-	UN 3082 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.
Class	:	(Amoxicillin Trihydrate) 9



Amoxicillin Trihydrate / Potassium Clavulanate Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 06.04.2024
3.0	06.07.2024	8845220-00011	Date of first issue: 13.07.2021

Packing group	:	Ш
Labels	:	9
Hazchem Code	:	•3Z
Environmentally hazardous	:	yes

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

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

Therapeutic Goods (Poisons	:	No poison schedule number allocated (Please use the original
Standard) Instrument		publication to check for specific uses, specific conditions or
		threshold limits that might apply for this chemical)

Prohibition/Licensing Requirements

: There is no applicable prohibition, authorisation and restricted use requirements, including for carcinogens referred to in Schedule 10 of the model WHS Act and Regulations.

The components of this product are reported in the following inventories:

AICS	:	not determined
DSL	:	not determined
IECSC	:	not determined

SECTION 16: ANY OTHER RELEVANT INFORMATION

Further information		
Revision Date Sources of key data used to compile the Safety Data Sheet	:	06.07.2024 Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agen- cy, http://echa.europa.eu/

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

Date format	:	dd.mm.yyyy
Full text of other abbreviation	ons	
ACGIH AU OEL		USA. ACGIH Threshold Limit Values (TLV) Australia. Workplace Exposure Standards for Airborne Con-



Amoxicillin Trihydrate / Potassium Clavulanate Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 06.04.2024
3.0	06.07.2024	8845220-00011	Date of first issue: 13.07.2021

taminants.

ACGIH / TWA	:	8-hour, time-weighted average
AU OEL / TWA	:	Exposure standard - time weighted average

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; 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 - Verv Persistent and Verv 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.

AU / EN