

Oxytetracycline Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 06.04.2024
6.0	06.07.2024	671612-00020	Date of first issue: 12.05.2016

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name	:	Oxytetracycline Formulation
Manufacturer or supplier's	deta	ails
Company name of supplier	:	MSD
Address	:	126 E. Lincoln Avenue
		Rahway, New Jersey U.S.A. 07065
Telephone	:	908-740-4000
Emergency telephone	:	1-908-423-6000
E-mail address	:	EHSDATASTEWARD@msd.com

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification Aerosols	:	Category 2
Serious eye damage/eye irritation	:	Category 2A
Skin sensitization	:	Category 1
Reproductive toxicity	:	Category 1A
Specific target organ toxicity - single exposure	:	Category 3
GHS label elements		
Hazard pictograms	:	
Signal Word	:	Danger
Hazard Statements	:	 H223 Flammable aerosol. H229 Pressurised container: May burst if heated. H317 May cause an allergic skin reaction. H319 Causes serious eye irritation. H336 May cause drowsiness or dizziness. H360D May damage the unborn child.
Precautionary Statements	:	Prevention: P201 Obtain special instructions before use. P202 Do not handle until all safety precautions have been read and understood. P210 Keep away from heat, hot surfaces, sparks, open flames



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		P211 Do not sp P251 Do not pi P261 Avoid bre P264 Wash ski P271 Use only P272 Contamir the workplace.	in thoroughly after handling. outdoors or in a well-ventilated area. nated work clothing should not be allowed out of ptective gloves/ protective clothing/ eye protection		
		P304 + P340 + and keep at res POISON CENT P305 + P351 + for several min to do. Continue P308 + P313 If attention. P333 + P313 If attention. P337 + P313 If tion.	F ON SKIN: Wash with plenty of water. • P312 IF INHALED: Remove victim to fresh air st in a position comfortable for breathing. Call a TER or doctor/ physician if you feel unwell. • P338 IF IN EYES: Rinse cautiously with water utes. Remove contact lenses, if present and eas a rinsing. F exposed or concerned: Get medical advice/ f skin irritation or rash occurs: Get medical advice f eye irritation persists: Get medical advice/ atten Take off contaminated clothing and wash it before		
		Storage: P405 Store locked up. P410 + P412 Protect from sunlight. Do not expose to temper tures exceeding 50 °C/ 122 °F.			
		Disposal: P501 Dispose o posal plant.	of contents/ container to an approved waste dis-		
	r hazards displace oxygen and c	ause rapid suffocation			

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)
Butane	106-97-8	>= 20 -< 30
Propan-2-ol	67-63-0	>= 10 -< 20
Isobutane	75-28-5	>= 10 -< 20
Propane	74-98-6	>= 10 -< 20
Oxytetracycline	79-57-2	>= 5 -< 10

SECTION 4. FIRST AID MEASURES



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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 immediately.		
In case of skin contact		:	In case of contact, immediately flush skin with plenty of water. Remove 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 for at least 15 min	t, immediately flush eyes with plenty of water nutes. ove contact lens, if worn.	
If swallowed		:	If swallowed, DO Get medical atter	NOT induce vomiting.	
	t important symptoms effects, both acute and yed	:	Gastrointestinal d May cause an all Causes serious e May cause drows May damage the	listurbance ergic skin reaction. ye irritation. iness or dizziness.	
	ection of first-aiders	:	First Aid respond and use the recor when the potentia	ers should pay attention to self-protection, mmended personal protective equipment al for exposure exists (see section 8).	
Note	es to physician	:	Treat symptomati	cally and supportively.	

SECTION 5. FIRE-FIGHTING MEASURES

Suitable extinguishing media	:	Water spray Alcohol-resistant foam Carbon dioxide (CO2) Dry chemical
Unsuitable extinguishing media	:	None known.
Specific hazards during fire fighting	:	Flash back possible over considerable distance. Vapors may form explosive mixtures with air. Exposure to combustion products may be a hazard to health. If the temperature rises there is danger of the vessels bursting due to the high vapor pressure.
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	:	In the event of fire, wear self-contained breathing apparatus.



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for fire	for fire-fighters Use personal protective equipment.								
SECTION	SECTION 6. ACCIDENTAL RELEASE MEASURES								
Personal precautions, protec- tive equipment and emer- gency procedures			Evacuate personnel to safe areas. Remove all sources of ignition. Ventilate the area. 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. 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.						
	ods and materials for inment and cleaning up		Soak up with inerd Suppress (knock jet. For large spills, pr containment to ke can be pumped, s container. Clean up remainir absorbent. Local or national r disposal of this ma employed in the c determine which r Sections 13 and 1	s should be used. absorbent material. down) gases/vapors/mists with a water spray rovide diking or other appropriate ep material from spreading. If diked material tore recovered material in appropriate ng materials from spill with suitable regulations may apply to releases and aterial, as well as those materials and items leanup of releases. You will need to egulations are applicable. 5 of this SDS provide information regarding tional requirements.					

SECTION 7. HANDLING AND STORAGE

Technical measures	See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.	
Local/Total ventilation	If sufficient ventilation is unavailable, use with local e ventilation. If advised by assessment of the local exposure poter only in an area equipped with explosion-proof exhaust	itial, use
	tion.	
Advice on safe handling	Do not get on skin or clothing. Avoid breathing spray. Do not swallow. Do not get in eyes. Wash skin thoroughly after handling. Handle in accordance with good industrial hygiene at practice, based on the results of the workplace expos assessment	



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		other ignition sc Take precautior Take care to pre environment.	n heat, hot surfaces, sparks, open flames and burces. No smoking. hary measures against static discharges. event spills, waste and minimize release to the	
Hygie	ne measures	 Do not spray on an open flame or other ignition source. If exposure to chemical is likely during typical use, provide flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. Contaminated work clothing should not be allowed out of th workplace. 		
Conditions for safe storage		 Wash contaminated clothing before re-use. Store locked up. Keep tightly closed. Keep in a cool, well-ventilated place. Store in accordance with the particular national regulations. Do not pierce or burn, even after use. Keep cool. Protect from sunlight. 		
Mater	ials to avoid	: Do not store wit Self-reactive su Organic peroxic Oxidizing agent Flammable solid Pyrophoric liqui Pyrophoric solid Self-heating sub	th the following product types: bstances and mixtures des is ds ds ds ostances and mixtures d mixtures which in contact with water emit	

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components	CAS-No.	Value type (Form of exposure)	Control parame- ters / Permissible concentration	Basis
Butane	106-97-8	VLE-PPT	1,000 ppm	NOM-010- STPS-2014
		STEL	1,000 ppm	ACGIH
Propan-2-ol	67-63-0	VLE-PPT	200 ppm	NOM-010- STPS-2014
		VLE-CT	400 ppm	NOM-010- STPS-2014
		TWA	200 ppm	ACGIH
		STEL	400 ppm	ACGIH
Isobutane	75-28-5	VLE-PPT	1,000 ppm	NOM-010- STPS-2014
		STEL	1,000 ppm	ACGIH
Propane	74-98-6	VLE-PPT	1,000 ppm	NOM-010- STPS-2014

Ingredients with workplace control parameters



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Oxyte	Oxytetracycline		TWA	500 µg/m3 (OEB 2)	Internal		
			ation: DSEN		·		
			Wipe limit	100 µg/100 cm ²	Internal		

Biological occupational exposure limits

Components	CAS-No.	Control parameters	Biological specimen	Sam- pling time	Permissible concentra- tion	Basis
Propan-2-ol	67-63-0	Acetone	Urine	End of shift at end of work- week	40 mg/l	MX BEI
		Acetone	Urine	End of shift at end of work- week	40 mg/l	ACGIH BEI

Personal protective equipment

Respiratory protection	:	If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.
Filter type Hand protection	:	Self-contained breathing apparatus
Remarks	:	Take note that the product is flammable, which may impact the selection of hand protection.
Skin and body protection	:	Skin should be washed after contact.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	:	Aerosol containing a liquefied gas
Color	:	blue
Odor	:	solvent
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	:	-80 °C
Evaporation rate	:	No data available
Flammability (solid, gas)	:	Flammable aerosol.



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	Flamma	ability (liquids)	:	Not applicable	
		explosion limit / Upper bility limit	:	9.5 %(V)	
		explosion limit / Lower bility limit	:	1.8 %(V)	
	Vapor p	pressure	:	No data available	9
	Relative	e vapor density	:	No data available	9
	Relative	e density	:	No data available)
	Density	,	:	0.92 g/cm ³	
	Solubili Wat	ty(ies) er solubility	:	No data available	
		n coefficient: n-	:	No data available	9
	octanol, Autoign	/water iition temperature	:	No data available)
	Decom	position temperature	:	No data available)
	Viscosi Visc	ty osity, kinematic	:	No data available	9
	Explosi	ve properties	:	Not explosive	
	Oxidizir	ng properties	:	The substance of	r mixture is not classified as oxidizing.
	Particle Particle	characteristics size	:	No data available	9

SECTION 10. STABILITY AND REACTIVITY

Reactivity Chemical stability Possibility of hazardous reac- tions	:	Not classified as a reactivity hazard. Stable under normal conditions. Flammable aerosol. Vapors may form explosive mixture with air. If the temperature rises there is danger of the vessels bursting due to the high vapor pressure. Can react with strong oxidizing agents.
Conditions to avoid Incompatible materials Hazardous decomposition products	:	Heat, flames and sparks. Oxidizing agents No hazardous decomposition products are known.



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ECTION	11. TOXICOLOGICAL I	NF				
	nation on likely routes	of	exposure			
Inhala Skin o	ation contact					
Inges	tion ontact					
•	e toxicity					
	assified based on availa	ble	information.			
Comp	oonents:					
Butar	ne:					
Acute	inhalation toxicity	:	LC50 (Rat): 57			
			Exposure time Test atmosphe			
				ed on data from similar materials		
II						
	an-2-ol: • oral toxicity		LD50 (Rat): > :	5,000 mg/kg		
		•				
Acute	inhalation toxicity	:	LC50 (Rat): > 2 Exposure time			
			Test atmosphe			
Acute	dermal toxicity	:	LD50 (Rabbit): > 5,000 mg/kg			
	,					
Isobu						
Acute	inhalation toxicity	:	LC50 (Rat): 57 Exposure time			
			Test atmosphe			
II						
Propa	ane: inhalation toxicity		LC50 (Rat): > 3	800000 ppm		
Acuto		•	Exposure time	: 15 min		
			Test atmosphe	ere: gas		
Oxyte	etracycline:					
•	oral toxicity	:	LD50 (Rat): 4,8	800 mg/kg		
			LD50 (Mouse)	: 2.240 ma/ka		
				lence of phototoxicity was observed		
Acute	inhalation toxicity	:	Remarks: No c	data available		
	dermal toxicity	:	Remarks: No c	data available		
	toxicity (other routes of nistration)	•		840 mg/kg pute: Intramuscular		



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			LD50 (Mouse): Application Rou	3,500 mg/kg ite: Subcutaneous
Skin	corrosion/irritation			
Not cl	assified based on ava	ilable	information.	
<u>Comp</u>	oonents:			
	an-2-ol:			
Speci Resul		:	Rabbit No skin irritatior	1
-	etracycline:			
Rema	arks	:	No data availab	le
	us eye damage/eye i es serious eye irritation		on	
Comp	oonents:			
Propa	an-2-ol:			
Speci Resul		:	Rabbit Irritation to eyes	s, reversing within 21 days
Oxyte Rema	etracycline: arks	:	No data availab	le
-	iratory or skin sensit	izatio	on	
-	sensitization	roactiv		
-	ause an allergic skin i	eacin		
-	assified based on ava	ilable	information.	
Comp	oonents:			
Propa	an-2-ol:			
Test	Гуре	:	Buehler Test	
	es of exposure	:	Skin contact	
Speci Metho		:	Guinea pig OECD Test Gui	deline 406
Resul	t	:	negative	
Oxvte	etracycline:			
Test T Resul	Гуре	:	Human repeat i Sensitizer	nsult patch test (HRIPT)
	cell mutagenicity assified based on ava	ilable	information.	



Sutane: Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES) Method: OECD Test Guideline 471 Result: negative Genotoxicity in vivo :: Test Type: Chromosome aberration test in vitro Method: OECD Test Guideline 473 Result: negative Genotoxicity in vivo :: Test Type: Mammalian erythrocyte micronucleus test (in vi cytogenetic assay) Species: Rat Application Route: inhalation (gas) Method: OECD Test Guideline 474 Result: negative Remarks: Based on data from similar materials Propan-2-ol: :: Genotoxicity in vitro :: Test Type: Bacterial reverse mutation assay (AMES) Result: negative Genotoxicity in vitro :: Test Type: Bacterial reverse mutation assay (AMES) Result: negative Genotoxicity in vitro :: Test Type: Mammalian erythrocyte micronucleus test (in vi cytogenetic assay) Species: Mouse Application Route: Intraperitoneal injection Result: negative Sobutane: : Test Type: Chromosome aberration test in vitro Method: OECD Test Guideline 473 Result: negative Genotoxicity in vitro :: Test Type: Chromosome aberration test in vitro Method: OECD Test Guideline 473 Result: negative Genotoxicity in vitro :: Test Type: Chromosome aberration test in vitro Method: OECD Test Guideline 473 Result: negative Genotoxicity in vitro :: Test Type: Bacterial reverse mutation assay (AMES) Result: negative Genotoxicity in vitro :: Test Type: Bacterial reverse mutation assay (AMES) Result: negative	rsion)	Revision Date: 06.07.2024	SDS Number: 671612-00020	Date of last issue: 06.04.2024 Date of first issue: 12.05.2016
Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES) Method: OECD Test Guideline 471 Result: negative Genotoxicity in vivo : Test Type: Chromosome aberration test in vitro Method: OECD Test Guideline 473 Result: negative Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vi cytogenetic assay) Species: Rat Application Route: inhalation (gas) Method: OECD Test Guideline 474 Result: negative Remarks: Based on data from similar materials Propan-2-ol: : Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES) Result: negative Test Type: In vitro mammalian cell gene mutation test Result: negative Genotoxicity in vitro : Test Type: Mammalian erythrocyte micronucleus test (in vi cytogenetic assay) Species: Mouse Application Route: Intraperitoneal injection Result: negative Genotoxicity in vitro : Test Type: Chromosome aberration test in vitro Method: OECD Test Guideline 473 Result: negative Isobutane: : Result: negative Remarks: Based on data from similar materials Test Type: Chromosome aberration test in vitro Method: OECD Test Guideline 473 Result: negative Remarks: Based on data from similar materials Test Type: Bacterial reverse mutation assay (AMES) Result: negative Remarks: Based on data from similar materials	Comp	oonents:		
Method: OECD Test Guideline 471 Result: negative Test Type: Chromosome aberration test in vitro Method: OECD Test Guideline 473 Result: negative Genotoxicity in vivo Test Type: Mammalian erythrocyte micronucleus test (in vicytogenetic assay) Species: Rat Application Route: inhalation (gas) Method: OECD Test Guideline 474 Result: negative Remarks: Based on data from similar materials Propan-2-ol: Genotoxicity in vitro Test Type: Bacterial reverse mutation assay (AMES) Result: negative Genotoxicity in vitro Test Type: In vitro mammalian erythrocyte micronucleus test (in vicytogenetic assay) Species: Mouse Application Route: Intraperitoneal injection Result: negative Sebutane: Genotoxicity in vitro Test Type: Chromosome aberration test in vitro Method: OECD Test Guideline 473 Result: negative Remarks: Based on data from similar materials <td>Butar</td> <td>ne:</td> <td></td> <td></td>	Butar	ne:		
Method: OECD Test Guideline 473 Result: negative Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vicytogenetic assay) Species: Rat Application Route: inhalation (gas) Method: OECD Test Guideline 474 Result: negative Remarks: Based on data from similar materials Propan-2-ol: Genotoxicity in vitro Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES) Result: negative Genotoxicity in vitro : Test Type: In vitro mammalian cell gene mutation test Result: negative Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vicytogenetic assay) Species: Mouse Application Route: Intraperitoneal injection Result: negative Isobutane: : Genotoxicity in vitro : Test Type: Chromosome aberration test in vitro Method: OECD Test Guideline 473 Result: negative Remarks: Based on data from similar materials Test Type: Bacterial reverse mutation assay (AMES) Result: negative : Test Type: Bacterial reverse mutation assay (AMES) Result: negative Remarks: Based on data from similar materials	Geno	toxicity in vitro	Method: OE Result: nega	CD Test Guideline 471 Itive
cytogenetic assay) Species: Rat Application Route: inhalation (gas) Method: OECD Test Guideline 474 Result: negative Remarks: Based on data from similar materials Propan-2-ol: Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES) Result: negative Test Type: In vitro mammalian cell gene mutation test Result: negative Genotoxicity in vivo Test Type: Mammalian erythrocyte micronucleus test (in vicytogenetic assay) Species: Mouse Application Route: Intraperitoneal injection Result: negative Isobutane: Genotoxicity in vitro : Test Type: Chromosome aberration test in vitro Method: OECD Test Guideline 473 Result: negative Result: negative Result: negative Result: negative Remarks: Based on data from similar materials Test Type: Bacterial reverse mutation assay (AMES) Result: negative Remarks: Based on data from similar materials Test Type: Bacterial reverse mutation assay (AMES) Result: negative Remarks:			Method: OE	CD Test Guideline 473
Remarks: Based on data from similar materials Propan-2-ol: Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES) Result: negative Test Type: In vitro mammalian cell gene mutation test Result: negative Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vir cytogenetic assay) Species: Mouse Application Route: Intraperitoneal injection Result: negative Isobutane: : Genotoxicity in vitro : Test Type: Chromosome aberration test in vitro Method: OECD Test Guideline 473 Result: negative Remarks: Based on data from similar materials Test Type: Bacterial reverse mutation assay (AMES) Result: negative Remarks: Based on data from similar materials	Geno	toxicity in vivo	cytogenetic a Species: Rat Application F Method: OE0	assay) t Route: inhalation (gas) CD Test Guideline 474
Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES) Result: negative Test Type: In vitro mammalian cell gene mutation test Result: negative Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vicytogenetic assay) Species: Mouse Application Route: Intraperitoneal injection Result: negative Isobutane: : Genotoxicity in vitro : Test Type: Chromosome aberration test in vitro Method: OECD Test Guideline 473 Result: negative Remarks: Based on data from similar materials Test Type: Bacterial reverse mutation assay (AMES) Result: negative Remarks: Based on data from similar materials				
Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES) Result: negative Test Type: In vitro mammalian cell gene mutation test Result: negative Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vir cytogenetic assay) Species: Mouse Application Route: Intraperitoneal injection Result: negative Isobutane: : Genotoxicity in vitro : Test Type: Chromosome aberration test in vitro Method: OECD Test Guideline 473 Result: negative Remarks: Based on data from similar materials Test Type: Bacterial reverse mutation assay (AMES) Result: negative Remarks: Based on data from similar materials	Propa	an-2-ol:		
Result: negative Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vicytogenetic assay) Species: Mouse Application Route: Intraperitoneal injection Result: negative Isobutane: : Genotoxicity in vitro : Test Type: Chromosome aberration test in vitro Method: OECD Test Guideline 473 Result: negative Remarks: Based on data from similar materials Test Type: Bacterial reverse mutation assay (AMES) Result: negative Remarks: Based on data from similar materials				
cytogenetic assay) Species: Mouse Application Route: Intraperitoneal injection Result: negative Isobutane: Genotoxicity in vitro : Test Type: Chromosome aberration test in vitro Method: OECD Test Guideline 473 Result: negative Remarks: Based on data from similar materials Test Type: Bacterial reverse mutation assay (AMES) Result: negative Remarks: Based on data from similar materials				
Genotoxicity in vitro : Test Type: Chromosome aberration test in vitro Method: OECD Test Guideline 473 Result: negative Remarks: Based on data from similar materials Test Type: Bacterial reverse mutation assay (AMES) Result: negative Remarks: Based on data from similar materials	Geno	toxicity in vivo	cytogenetic a Species: Mo Application F	assay) use Route: Intraperitoneal injection
Method: OECD Test Guideline 473 Result: negative Remarks: Based on data from similar materials Test Type: Bacterial reverse mutation assay (AMES) Result: negative Remarks: Based on data from similar materials	Isobu	itane:		
Result: negative Remarks: Based on data from similar materials	Geno	toxicity in vitro	Method: OE Result: nega	CD Test Guideline 473 Itive
Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vi			Result: nega	tive
cytogenetic assay) Species: Rat	Geno	toxicity in vivo	cytogenetic a Species: Rat	assay) t
Application Route: inhalation (gas) Method: OECD Test Guideline 474 Result: negative Remarks: Based on data from similar materials			Method: OE Result: nega	CD Test Guideline 474 tive
II Propane:	Pron	ane:		
Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES) Result: negative				



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II			Remarks: Based	on data from similar materials		
Geno	otoxicity in vivo	:	cytogenetic assa Species: Rat Application Rout Method: OECD T Result: negative	malian erythrocyte micronucleus test (in vivo y) Fest Guideline 474 on data from similar materials		
Oxyt	etracycline:					
	otoxicity in vitro	:	Test Type: Micro Result: negative	bial mutagenesis assay (Ames test)		
			Test Type: Mous Metabolic activat	e Lymphoma ion: Metabolic activation		
			Result: positive			
				chromatid exchange assay inese hamster ovary cells I		
			Test Type: Chroi Result: negative	mosomal aberration		
Gend	otoxicity in vivo	:	Test Type: Micro Species: Mouse Cell type: Bone r Application Rout Result: equivoca	narrow e: Oral		
			Test Type: in viv Species: Mouse Application Rout Result: negative	o assay e: Intraperitoneal injection		
Gern Asse	n cell mutagenicity - essment	:	Weight of eviden cell mutagen.	ce does not support classification as a germ		
	inogenicity classified based on ava	ailable	information.			
Com	ponents:					
Prop	an-2-ol:					
Spec	cies	:	Rat			
	ication Route	:	inhalation (vapor 104 weeks)		
Meth	osure time lod	: OECD Test Guideline 451				
Resu		:	negative	-		
Οχντ	etracycline:					
Spec	-	:	Mouse			
			11 / 20			
			11/20			



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	ation Route ure time	:	Oral 104 weeks negative	
Exposi Result	ation Route ure time Organs	:	Rat Oral 103 weeks equivocal Adrenal gland, Pit The mechanism c mans.	uitary gland or mode of action may not be relevant in hu-
Carcine ment	ogenicity - Assess-	:	Weight of evidenc cinogen	e does not support classification as a car-
May da Compo	ductive toxicity amage the unborn child onents:	I.		
Butan Effects	e: on fertility	:		
Effects	on fetal development	:		
Propa	n-2-ol:			
	on fertility	:	Test Type: Two-g Species: Rat Application Route Result: negative	eneration reproduction toxicity study : Ingestion
Effects	on fetal development	:	Test Type: Embry Species: Rat Application Route Result: negative	ro-fetal development : Ingestion
Isobut	ane:			
	on fertility	:		



/ersion 6.0	Revision Date: 06.07.2024		0S Number: 1612-00020	Date of last issue: 06.04.2024 Date of first issue: 12.05.2016
Effect	s on fetal development	:	reproduction/deve Species: Rat Application Route	ined repeated dose toxicity study with the elopmental toxicity screening test e: inhalation (gas) est Guideline 422
II Propa	ane.			
	s on fertility	:	reproduction/deve Species: Rat Application Route	ined repeated dose toxicity study with the elopmental toxicity screening test e: inhalation (gas) est Guideline 422
Effect	s on fetal development	:	reproduction/deve Species: Rat Application Route	ined repeated dose toxicity study with the elopmental toxicity screening test e: inhalation (gas) est Guideline 422
Oxyte	etracycline:			
-	s on fertility	:	Species: Rat Application Route Fertility: NOAEL: Result: No effects	eneration reproduction toxicity study e: Oral 18 mg/kg body weight s on fertility., No effect on reproduction hificant adverse effects were reported
Effect	s on fetal development	:	Species: Rat Application Route Embryo-fetal toxi	vo-fetal development e: Oral city.: LOAEL: 48 mg/kg body weight intation loss., Skeletal malformations.
			Species: Rat Application Route General Toxicity Embryo-fetal toxic Result: No terato	Maternal: LOAEL: 1,200 mg/kg body weight city.: NOAEL: 1,500 mg/kg body weight
			Species: Mouse Application Route General Toxicity Embryo-fetal toxic Result: No terato	Maternal: LOAEL: 1,325 mg/kg body weight city.: NOAEL: 2,100 mg/kg body weight



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			Species: Rabbit Application Route Embryo-fetal toxi	yo-fetal development e: Intramuscular city.: LOAEL: 41.5 mg/kg body weight antation loss., No fetal abnormalities.
			Species: Dog Application Route Embryo-fetal toxi	yo-fetal development e: Intramuscular city.: LOAEL: 20.75 mg/kg body weight and visceral variations ., Postimplantation
	oductive toxicity - As- ment	:	Positive evidence human epidemiol	e of adverse effects on development from ogical studies.
	T-single exposure cause drowsiness or diz	zine	SS.	
Com	ponents:			
Buta	ne:			
Asse Rem	ssment arks	:		siness or dizziness. om similar materials
Prop	an-2-ol:			
Asse	ssment	:	May cause drows	siness or dizziness.
Isob	utane:			
Asse	ssment	:	May cause drows	siness or dizziness.
Prop	ane:			
	ssment	:	May cause drows	siness or dizziness.
STO	T-repeated exposure			
Not o	classified based on avail	able	information.	
Repe	eated dose toxicity			
<u>Com</u>	ponents:			
Buta	ne:			
Spec		:	Rat	
NOA	EL cation Route	:	>= 9000 ppm inhalation (gas)	
	sure time	÷	6 Weeks	
Meth		:	OECD Test Guid	eline 422
Prop	an-2-ol:			
Spec		:	Rat	
NOA	EL	:	12.5 mg/l	



Oxytetracycline Formulation

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Applic	cation Route	: inhalation (vap	or)
Expos	sure time	: 104 Weeks	
Isobu	itane:		
Speci		: Rat	
NOAE		: >= 9000 ppm	
Applic	ation Route	: inhalation (gas)
Expos	sure time	: 6 Weeks	ideline 400
Metho	ba	: OECD Test Gu	
Propa	ane:		
Speci		: Rat	
NOAE		: 7.214 mg/l	
	ation Route	: inhalation (gas)
	sure time	: 6 Weeks	idalia a 100
Metho	bd	: OECD Test Gu	lideline 422
Oxyte	etracycline:		
Speci		: Rat	
LOAE		: 198 mg/kg	
Applic	cation Route	: Oral	
	sure time	: 13 Weeks	
	t Organs	: Bone	
Rema	irks	: No significant a	adverse effects were reported
Speci	es	: Mouse	
LÓAE	E	: 7,990 mg/kg	
Applic	cation Route	: Oral	
Expos	sure time	: 13 Weeks	
Targe	t Organs	: Bone	
Rema	ırks	: No significant a	adverse effects were reported
Speci	es	: Dog	
NOAE		: 125 mg/kg	
LOAE		: 250 mg/kg	
	cation Route	: Oral	
	sure time	: 12 Months	
	t Organs	: Testis	aity abaatyod in tasting
Rema	11.42	. Significant toxi	city observed in testing
Speci		: Rat	
NOAE		: 40 mg/kg	
LOAE		: 100 mg/kg	
	cation Route	: Intraperitoneal	
	sure time	: 14 Days	
Targe	t Organs	: Kidney	

Aspiration toxicity

Not classified based on available information.



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rience with human exp	osu	ire	
oonents:			
etracycline: tion	:		ointestinal disturbance, tooth discoloration use birth defects.
12. ECOLOGICAL INFO	ORN	IATION	
oxicity			
oonents:			
an-2-ol: ity to fish	:	· ·	s promelas (fathead minnow)): 9,640 mg/l Sh
ty to daphnia and other ic invertebrates	:		
ty to microorganisms	:		nas putida): > 1,050 mg/l š h
etracycline:			
ty to fish	:	Exposure time: 96	
ty to daphnia and other ic invertebrates	:	Exposure time: 48	3 h
		Exposure time: 48	
ty to algae/aquatic	:		
ty to microorganisms	:	Test Type: Respir	ation inhibition
		Test Type: Respir	ation inhibition
	06.07.2024 rience with human exp ponents: etracycline: tion 12. ECOLOGICAL INFO points: an-2-ol: ty to daphnia and other ic invertebrates ty to microorganisms etracycline: ty to fish ty to daphnia and other ic invertebrates ty to fish ty to daphnia and other ic invertebrates ty to fish ty to daphnia and other ic invertebrates	06.07.2024 67 rience with human exposu- conents: 1 paracycline: 1 tion 1 12. ECOLOGICAL INFORM ponents: an-2-ol: ty to fish ty to daphnia and other ic invertebrates ty to microorganisms etracycline: ty to fish ty to fish ty to daphnia and other ic invertebrates ty to fish ty to daphnia and other ty to fish ty to algae/aquatic ty to algae/aquatic	06.07.2024 671612-00020 rience with human exposure ponents: etracycline: tion : Symptoms: Gastring an-2-ol: ty to fish : ic invertebrates ty to daphnia and other ic invertebrates ty to microorganisms ic invertebrates ty to fish : LC50 (Pimephale: ty to daphnia and other : EC50 (Daphnia m Exposure time: 24 ty to microorganisms : EC50 (Oryzias lati Exposure time: 48 Method: OECD To ty to daphnia and other ic invertebrates : EC50 (Daphnia m Exposure time: 48 Method: OECD To ty to algae/aquatic : : EC50 (Anabaena) Exposure time: 72 NOEC (Anabaena) Exposure time: 72 NOEC (Anabaena) Exposure time: 3 Test Type: Respir Method: OECD To



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Persi	stence and degrada	bility		
<u>Com</u>	oonents:			
Buta	ne:			
Biode	gradability	:		ly biodegradable. sed on data from similar materials
Propa	an-2-ol:			
	egradability	:	Result: rapidly	/ degradable
BOD/	COD	:	BOD: 1,19 (B COD: 2,23 BOD/COD: 53	
Isobu	itane:			
Biode	gradability	:		ly biodegradable. sed on data from similar materials
Propa	ane:			
Biode	gradability	:		ly biodegradable. sed on data from similar materials
Bioad	cumulative potentia	al		
<u>Com</u>	ponents:			
Butar	ne:			
	ion coefficient: n- ol/water	:	log Pow: 2.89	
Propa	an-2-ol:			
	ion coefficient: n- ol/water	:	log Pow: 0.05	
Isobu	itane:			
	ion coefficient: n- ol/water	:	log Pow: 2.8	
Propa	ane:			
	ion coefficient: n- ol/water	:	log Pow: 2.36	
Mobi	lity in soil			
No da	ata available			
Othe	r adverse effects			
No da	ata available			

Disposal methods

Waste from residues

: Do not dispose of waste into sewer.



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Conta	aminated packaging	 Please ensure (including prop Empty containe handling site for Empty containe Do not pressur expose such co sources of igniti death. 	accordance with local regulations. aerosol cans are sprayed completely empty ellant) ers should be taken to an approved waste or recycling or disposal. ers retain residue and can be dangerous. rize, cut, weld, braze, solder, drill, grind, or ontainers to heat, flame, sparks, or other tion. They may explode and cause injury and/or e specified: Dispose of as unused product.

SECTION 14. TRANSPORT INFORMATION

International Regulations

UNRTDG UN number Proper shipping name Class Packing group Labels Environmentally hazardous	:	UN 1950 AEROSOLS 2.1 Not assigned by regulation 2.1 yes
IATA-DGR UN/ID No. Proper shipping name Class Packing group Labels Packing instruction (cargo aircraft) Packing instruction (passen- ger aircraft)	· · · ·	UN 1950 Aerosols, flammable 2.1 Not assigned by regulation Flammable Gas 203
IMDG-Code UN number Proper shipping name Class Packing group Labels EmS Code Marine pollutant	:	UN 1950 AEROSOLS (Oxytetracycline) 2.1 Not assigned by regulation 2.1 F-D, S-U yes Annex II of MARPOL 73/78 and the IBC Code
Tansport in bulk according	, 10	ATTICK II OF WARFOL 13/10 ATTU THE IDC COUP

Not applicable for product as supplied.

Domestic regulation

NOM-002-SCT

UN number	:	UN 1950
Proper shipping name	:	AEROSOLS
Class	:	2.1
Packing group	:	Not assigned by regulation
Labels	:	2.1



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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

Federal Law for the control of chemical precursors,	:	Not applicable
essential chemical products and machinery for		
producing capsules, tablets and pills.		

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

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

SECTION 16. OTHER INFORMATION

Revision Date Date format	:	06.07.2024 dd.mm.yyyy					
Full text of other abbreviation	Full text of other abbreviations						
ACGIH	:	USA. ACGIH Threshold Limit Values (TLV)					
ACGIH BEI	:	ACGIH - Biological Exposure Indices (BEI)					
MX BEI	:	Official Mexican Norm NOM-047-SSA1-2011, Environmental					
		Health - Biological exposure indices for workers occupational-					
		ly exposed to chemical agents					
NOM-010-STPS-2014	:	Mexico. Norm NOM-010-STPS-2014 on Chemicals Polluting					
		the Work Environment - Identification, Assessment and Con-					
		trol - Appendix 1 Occupational Exposure Limits					
ACGIH / TWA	:	8-hour, time-weighted average					
ACGIH / STEL	:	Short-term exposure limit					
NOM-010-STPS-2014 / VLE-	:	Time weighted average limit value					
PPT							
NOM-010-STPS-2014 / VLE- CT	:	Short term exposure limit value					

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 con-



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centration; 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 - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

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/

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

The information is considered as correct, but not exhaustive, and will be used only as a guide, which is based in the current knowledge of the substance or mixture, and is applicable to proper safety precautions for the product.

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