

Version	Revision Date:	SDS Number:	Date of last issue: 06.04.2024
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SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier Trade name	: Florfenicol / Flunixin Injection Formulation
1.2 Relevant identified uses of	of the substance or mixture and uses advised against
Use of the Sub- stance/Mixture	: Veterinary product
Recommended restrictions on use	s : Not applicable
1.3 Details of the supplier of	the safety data sheet
Company	: MSD Kilsheelan Clonmel Tipperary, IE
Telephone	: 353-51-601000
E-mail address of person responsible for the SDS	: EHSDATASTEWARD@msd.com

1.4 Emergency telephone number

+1-908-423-6000

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008)

Acute toxicity, Category 4	H302: Harmful if swallowed.
Acute toxicity, Category 4	H332: Harmful if inhaled.
Skin irritation, Category 2	H315: Causes skin irritation.
Eye irritation, Category 2	H319: Causes serious eye irritation.
Reproductive toxicity, Category 1B	H360Df: May damage the unborn child. Suspected of damaging fertility.
Specific target organ toxicity - single ex- posure, Category 3	H335: May cause respiratory irritation.
Specific target organ toxicity - repeated exposure, Category 1	H372: Causes damage to organs through pro- longed or repeated exposure.
Short-term (acute) aquatic hazard, Cate- gory 1	H400: Very toxic to aquatic life.
Long-term (chronic) aquatic hazard, Cat- egory 1	H410: Very toxic to aquatic life with long lasting effects.



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2.2 Label elements

Labelling (REGULATION (EC) Hazard pictograms :	No 1272/2008)
Signal word :	Danger
Hazard statements :	 H302 + H332 Harmful if swallowed or if inhaled. H315 Causes skin irritation. H319 Causes serious eye irritation. H335 May cause respiratory irritation. H360Df May damage the unborn child. Suspected of damaging fertility. H372 Causes damage to organs through prolonged or repeated exposure. H410 Very toxic to aquatic life with long lasting effects.
Precautionary statements :	 Prevention: P201 Obtain special instructions before use. P273 Avoid release to the environment. P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.
	Response: P304 + P340 + P312 IF INHALED: Remove person to fresh air and keep comfortable for breathing. Call a POISON CENTER/ doctor if you feel unwell. P308 + P313 IF exposed or concerned: Get medical advice/ attention. P391 Collect spillage.

Hazardous components which must be listed on the label:

Florfenicol N-Methyl-2-pyrrolidone 1-deoxy-1-(methylamino)-D-glucitol 2-[2-methyl-3-(perfluoromethyl)anilino]nicotinate Citric acid

Restricted to professional users.

2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

Ecological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.



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Toxicological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Components

Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
Florfenicol	73231-34-2	Repr. 2; H361fd STOT RE 1; H372 (Liver, Brain, Tes- tis, Spinal cord, Blood, gallbladder) Aquatic Acute 1; H400 Aquatic Chronic 1; H410 M-Factor (Acute aquatic toxicity): 10	>= 30 - < 50
N-Methyl-2-pyrrolidone	872-50-4 212-828-1 606-021-00-7	M-Factor (Chronic aquatic toxicity): 10 Skin Irrit. 2; H315 Eye Irrit. 2; H319 Repr. 1B; H360D	>= 20 - < 30
		STOT SE 3; H335 specific concentra- tion limit STOT SE 3; H335 >= 10 %	
1-deoxy-1-(methylamino)-D-glucitol 2-[2-methyl-3- (perfluoromethyl)anilino]nicotinate	42461-84-7 255-836-0	Acute Tox. 3; H301 Acute Tox. 2; H330 Eye Dam. 1; H318 STOT SE 3; H335 STOT RE 1; H372 (Gastrointestinal tract, Kidney, Blood) Aquatic Chronic 2; H411	>= 2,5 - < 3
Citric acid	77-92-9 201-069-1 607-750-00-3	Eye Irrit. 2; H319 STOT SE 3; H335	>= 1 - < 10



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For explanation of abbreviations see section 16.

SECTION 4: First aid measures

4.1	Description of first aid mease	ures	5
	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 advice.
	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).
	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. Rinse mouth thoroughly with water. Never give anything by mouth to an unconscious person.
4.2	Most important symptoms ar	nd e	ffects, both acute and delayed
	Risks	:	Harmful if swallowed or if inhaled. Causes skin irritation. Causes serious eye irritation. May cause respiratory irritation. May damage the unborn child. Suspected of damaging fertili- ty. Causes damage to organs through prolonged or repeated exposure.
4.3	Indication of any immediate	med	lical attention and special treatment needed
	Treatment	:	Treat symptomatically and supportively.



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SECTION 5: Firefighting measures

5.1 Extinguishing media

	Suitable extinguishing media	:	Water spray Alcohol-resistant foam Carbon dioxide (CO2) Dry chemical
	Unsuitable extinguishing media	:	None known.
5.2	Special hazards arising from	the	substance or mixture
	Specific hazards during fire- fighting	:	Exposure to combustion products may be a hazard to health.
	Hazardous combustion prod- ucts	:	Carbon oxides Fluorine compounds Nitrogen oxides (NOx)
5.3	Advice for firefighters		
	Special protective equipment for firefighters	:	In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.
	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.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions	:	Use personal protective equipment. Follow safe handling advice (see section 7) and personal pro- tective equipment recommendations (see section 8).
6.2 Environmental precautions		
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.

6.3 Methods and material for containment and cleaning up

Methods for cleaning up : Soak up with inert absorbent material.



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		ment to keep ma be pumped, stor Clean up remain bent. Local or nationa posal of this mat employed in the mine which regu Sections 13 and	provide dyking or other appropriate contain- aterial from spreading. If dyked material can be recovered material in appropriate container. Aning materials from spill with suitable absor- I regulations may apply to releases and dis- terial, as well as those materials and items cleanup of releases. You will need to deter- lations are applicable. 15 of this SDS provide information regarding mational requirements.

6.4 Reference to other sections

See sections: 7, 8, 11, 12 and 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Technical measures	: See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.				
Local/Total ventilation	: If sufficient ventilation is unavailable, use with local exhaust ventilation.				
Advice on safe handling Hygiene measures	 Do not get on skin or clothing. Do not breathe mist or vapours. Do not swallow. Do not get in eyes. Wash skin thoroughly after handling. Handle in accordance with good industrial hygiene and safet practice, based on the results of the workplace exposure assessment Keep container tightly closed. Already sensitised individuals, and those susceptible to asthma, allergies, chronic or recurrent respiratory disease should consult their physician regarding working with respiratory irritants or sensitisers. Do not eat, drink or smoke when using this product. Take care to prevent spills, waste and minimize release to the environment. If exposure to chemical is likely during typical use, provide environment. If effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls. 	, i- ye			
2 Conditions for safe storage, including any incompatibilities					

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage	:	Keep in properly labelled containers. Store locked up. Keep
areas and containers		tightly closed. Keep in a cool, well-ventilated place. Store in
		accordance with the particular national regulations.



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Advice	e on common storage	:	Strong oxidizing	stances and mixtures
7.3 Specific end use(s) Specific use(s)		:	No data available	9

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational Exposure Limits

CAS-No.	Value type (Form	Control parameters	Basis		
	of exposure)				
73231-34-2	TWA	100 µg/m3 (OEB 2)	Internal		
872-50-4	TWA	14,4 mg/m3	FOR-2011-		
		-	12-06-1358		
Further inform	ation: Substances c	onsidered to be reprotoxic, C	Chemicals that		
can be absorb	ed through the skin.				
	STEL	20 ppm	FOR-2011-		
		80 mg/m3	12-06-1358		
			Chemicals that		
can be absorb	¥		1		
	TWA		2009/161/EU		
		possibility of significant uptal	ke through the		
skin, Indicativ					
	STEL		2009/161/EU		
Further information: Identifies the possibility of significant uptake through the					
SKIN, Mulcaliv		10 nnm	2004/37/EC		
	IVVA		2004/37/EC		
Further inform	Letion, Ekin, Coroina				
Further inform		<u> </u>	2004/27/50		
	SIEL		2004/37/EC		
Funth an inform	ations Olin Consing				
57-55-6	IWA		FOR-2011-		
			12-06-1358		
42461-84-7	IWA	40 μg/m3 (OEB 3)	Internal		
	73231-34-2 872-50-4 Further inform can be absort Further inform skin, Indicative Further inform skin, Indicative Further inform	of exposure) 73231-34-2 TWA 872-50-4 TWA Further information: Substances c can be absorbed through the skin. STEL Further information: Substances c can be absorbed through the skin. Further information: Substances c can be absorbed through the skin. Further information: Substances c can be absorbed through the skin. Further information: Substances c can be absorbed through the skin. Further information: Identifies the skin. Further information: Skin, Carcino STEL Further information: Skin, Carcino STEL	of exposure)100 μg/m3 (OEB 2)73231-34-2TWA100 μg/m3 (OEB 2)872-50-4TWA14,4 mg/m3Further information: Substances considered to be reprotoxic, C can be absorbed through the skin.20 ppm 80 mg/m3Further information: Substances considered to be reprotoxic, C can be absorbed through the skin.20 ppm 80 mg/m3Further information: Substances considered to be reprotoxic, C can be absorbed through the skin.10 ppm 40 mg/m3Further information: Identifies the possibility of significant uptal skin, IndicativeSTEL20 ppm 80 mg/m3Further information: Identifies the possibility of significant uptal skin, IndicativeTWA10 ppm 40 mg/m3Further information: Identifies the possibility of significant uptal skin, IndicativeTWA10 ppm 40 mg/m3Further information: Skin, Carcinogens or mutagensSTEL20 ppm 80 mg/m3Further information: Skin, Carcinogens or mutagensSTEL20 ppm 79 mg/m3		

Commission Regulation (EU) 2020/878



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IL		Further information: Skin		
		Wipe limit	400 μg/100 cm ²	Internal

Derived No Effect Level (DNEL) according to Regulation (EC) No. 1907/2006

Substance name	End Use	Exposure routes	Potential health ef- fects	Value
N-Methyl-2- pyrrolidone	Workers	Inhalation	Long-term systemic effects	14,4 mg/m3
	Workers	Inhalation	Long-term local ef- fects	40 mg/m3
	Workers	Skin contact	Long-term systemic effects	4,8 mg/kg bw/day
	Consumers	Inhalation	Long-term systemic effects	3,6 mg/m3
	Consumers	Inhalation	Long-term local ef- fects	4,5 mg/m3
	Consumers	Skin contact	Long-term systemic effects	2,4 mg/kg bw/day
	Consumers	Ingestion	Long-term systemic effects	0,85 mg/kg bw/day
Propylene glycol	Workers	Inhalation	Long-term local ef- fects	10 mg/m3
	Workers	Inhalation	Long-term systemic effects	168 mg/m3
	Consumers	Inhalation	Long-term local ef- fects	10 mg/m3
	Consumers	Inhalation	Long-term systemic effects	50 mg/m3

Predicted No Effect Concentration (PNEC) according to Regulation (EC) No. 1907/2006

Substance name	Environmental Compartment	Value
N-Methyl-2-pyrrolidone	Fresh water	0,25 mg/l
	Freshwater - intermittent	5 mg/l
	Marine water	0,025 mg/l
	Sewage treatment plant	10 mg/l
	Fresh water sediment	1,09 mg/kg dry weight (d.w.)
	Marine sediment	1,09 mg/kg dry weight (d.w.)
	Soil	0,07 mg/kg dry weight (d.w.)
Propylene glycol	Fresh water	260 mg/l
	Freshwater - intermittent	183 mg/l
	Marine water	26 mg/l
	Sewage treatment plant	20000 mg/l
	Fresh water sediment	572 mg/kg dry weight (d.w.)
	Marine sediment	57,2 mg/kg dry weight (d.w.)
	Soil	50 mg/kg dry weight (d.w.)

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



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Citric	acid	Fresh water	0,44 mg	j/l	
		Marine water	0,044 m	ng/l	
		Sewage treatn	nent plant 1000 mg	g/l	
		Fresh water se	ediment 34,6 mg weight (
		Marine sedime	ent 3,46 mg weight (
		Soil	33,1 mg weight (

8.2 Exposure controls

Engineering measures

Use appropriate engineering controls and manufacturing technologies to control airborne concentrations (e.g., drip-less quick connections).

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

Eye/face protection :		Wear safety glasses with side shields or goggles. If the work environment or activity involves dusty conditions, 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, or aerosols.	
Hand protection			
Material	:	Chemical-resistant gloves	
Remarks Skin and body protection	:	Consider double gloving. 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 potentially contaminated clothing.	
Respiratory protection Filter type	:	If adequate local exhaust ventilation is not available or expo- sure assessment demonstrates exposures outside the rec- ommended guidelines, use respiratory protection. Equipment should conform to NS EN 14387 Combined particulates and organic vapour type (A-P)	
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SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Physical state	:	liquid
Colour	:	light yellow



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				Straw-coloured	
C	Ddour		:	No data available	
C	Ddour T	hreshold	:	No data available	•
Ν	Melting	point/freezing point	:	No data available	•
	nitial bo ange	biling point and boiling	:	No data available	
F	lamma	ability (solid, gas)	:	Not applicable	
F	lamma	ability (liquids)	:	No data available	•
		explosion limit / Upper bility limit	:	No data available	
		explosion limit / Lower bility limit	:	No data available	
F	-lash p	oint	:	No data available	
A	Auto-igr	nition temperature	:	No data available	
C	Decomp	oosition temperature	:	No data available	
р	ъН		:	No data available	
V	/iscosit Visco	y osity, kinematic	:	No data available	
S	Solubilit Wate	y(ies) er solubility	:	No data available	
	Partitior	n coefficient: n- /water	:	Not applicable	
V	/apour	pressure	:	No data available	
F	Relative	edensity	:	No data available	
۵	Density		:	No data available	
F	Relative	e vapour density	:	No data available	
F		characteristics cle size	:	Not applicable	

9.2 Other information



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Explo	osives	: Not explosive	
Oxidizing properties		: The substance or mixture is not c	lassified as oxidizing.
Evaporation rate		: No data available	
Molecular weight		: No data available	

SECTION 10: Stability and reactivity

10.1 Reactivity

Not classified as a reactivity hazard.

10.2 Chemical stability

Stable under normal conditions.

10.3 Possibility of hazardous reactions

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Hazardous reactions	: Can rea	act with strong oxidizing agents.

10.4 Conditions to avoid

Conditions to avoid : None known.

10.5 Incompatible materials

Materials to avoid	:	Oxidizing agents
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10.6 Hazardous decomposition products

No hazardous decomposition products are known.

SECTION 11: Toxicological information

11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

Information on likely routes of : Inhalation exposure Skin contact Ingestion Eye contact

Acute toxicity

Harmful if swallowed or if inhaled.

Product:

Acute oral toxicity	:	Acute toxicity estimate: 1.935 mg/kg Method: Calculation method
Acute inhalation toxicity	:	Acute toxicity estimate: 1,86 mg/l Exposure time: 4 h Test atmosphere: dust/mist Method: Calculation method



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Comp	onents:			
Florfe	nicol:			
Acute	oral toxicity	:	LD50 (Rat): > 2.00	00 mg/kg
			LD50 (Mouse): > 2	2.000 mg/kg
			LD50 (Dog): > 1.2	80 mg/kg
Acute	inhalation toxicity	:	LC50 (Rat): > 0,28 Exposure time: 4	
Acute	dermal toxicity	:	Remarks: No data	available
	toxicity (other routes of istration)	:	LD50 (Rat): 1.913 Application Route	
			LD50 (Mouse): 10 Application Route	
N-Mot	hyl-2-pyrrolidone:			
	oral toxicity	:	LD50 (Rat): 4.150	mg/kg
Acute	inhalation toxicity	:	LC50 (Rat): > 5,1 Exposure time: 4 Test atmosphere: Method: OECD Te	n dust/mist
Acute	dermal toxicity	:	LD50 (Rat): > 5.00	00 mg/kg
II 1-deo	xy-1-(methylamino)-D-	alu	cital 2-[2-mathyl-3	-(perfluoromethyl)anilino]nicotinate:
	oral toxicity	-	LD50 (Rat): 53 - 1	
			LD50 (Mouse): 17	6 - 249 mg/kg
			LD50 (Guinea pig): 488,3 mg/kg
			LD50 (Monkey): 3	00 mg/kg
Acute	inhalation toxicity	:	LC50 (Rat): < 0,52 Exposure time: 4 Test atmosphere:	n -
	toxicity (other routes of istration)	:	LD50 (Rat): 59,4 - Application Route	
			LD50 (Mouse): 16 Application Route	
Citric	acid:			
	oral toxicity	:	LD50 (Mouse): 5.4	400 mg/kg



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Acute	e dermal toxicity	:		00 mg/kg est Guideline 402 substance or mixture has no acute dermal
Caus	corrosion/irritation es skin irritation.			
Com	ponents:			
	enicol:			
Spec Resu		:	Rabbit No skin irritation	
N-Me	thyl-2-pyrrolidone:			
Resu		:	Skin irritation	
1-deo	oxy-1-(methylamino)-D	-glu	citol 2-[2-methyl-	3-(perfluoromethyl)anilino]nicotinate:
Spec	ies	:	Rabbit	
Resu	lt	:	Mild skin irritation	
Citric	c acid:			
Spec	ies	:	Rabbit	
Meth		:	OECD Test Guide	eline 404
Resu	lt	:	No skin irritation	
Serio	ous eye damage/eye irr	ritat	ion	
Caus	es serious eye irritation.			
<u>Com</u>	ponents:			
Florf	enicol:			
Spec	ies	:	Rabbit	
Resu	lt	:	Mild eye irritation	
N-Me	thyl-2-pyrrolidone:			
Spec	ies	:	Rabbit	
Resu	lt	:	Irritation to eyes,	reversing within 21 days
1-deo	oxy-1-(methylamino)-D	-glu	citol 2-[2-methyl-	3-(perfluoromethyl)anilino]nicotinate:
Spec		:	Rabbit	
Resu	lt	:	Irreversible effect	s on the eye
Citric	c acid:			
Spec	ies	:	Rabbit	
Meth	od	:	OECD Test Guide	
Resu	lt	:	Irritation to eyes,	reversing within 21 days



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Respiratory or skin sensitisation

Skin sensitisation

Not classified based on available information.

Respiratory sensitisation

Not classified based on available information.

Components:

Florfenicol:

Test Type	: Maximisation Test
Species	: Guinea pig
Test Type Species Result	: negative

N-Methyl-2-pyrrolidone:

Test Type	: Local lymph node assay (LLNA)
Exposure routes	: Skin contact
Species	: Mouse
Method	: OECD Test Guideline 429
Result	: negative
Test Type Exposure routes Species Method Result Remarks	: Based on data from similar materials

1-deoxy-1-(methylamino)-D-glucitol 2-[2-methyl-3-(perfluoromethyl)anilino]nicotinate:

Test Type	:	Maximisation Test
Exposure routes	:	Dermal
Species	:	Guinea pig
Assessment	:	Does not cause skin sensitisation.
Test Type Exposure routes Species Assessment Result	:	negative

Germ cell mutagenicity

Not classified based on available information.

Components:

Florfenicol:

Genotoxicity in vitro	: Test Type: Bacterial reverse mutation assay (AMES) Result: negative
	Test Type: DNA damage and repair, unscheduled DNA syn- thesis in mammalian cells (in vitro) Test system: rat hepatocytes Result: negative
	Test Type: In vitro mammalian cell gene mutation test Test system: mouse lymphoma cells Result: negative
	Test Type: Chromosome aberration test in vitro Test system: Chinese hamster ovary cells



Result: positive Genotoxicity in vivo : Test Type: Micronucleus test Species: Mouse Cell type: Bone marrow Application Route: Oral Result: negative N-Methyl-2-pyrrolidone: : Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES) Method: OECD Test Guideline 471 Result: negative Test Type: In vitro mammalian cell gene mutation test Method: OECD Test Guideline 476 Result: negative : Genotoxicity in vivo : Test Type: In vitro mammalian cells (in vitro) Result: negative Genotoxicity in vivo : Test Type: Mammalian cells (in vitro) Result: negative Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay) Species: Mouse Application Route: Ingestion Method: OECD Test Guideline 474 Result: negative Test Type: Mutagenicity (in vivo mammalian bone-marrow cytogenetic test; (hormosomal analysis) Species: Hamster Application Route: Ingestion Method: OECD Test Guideline 475 Result: negative 1-deoxy-1-(methylamino)-D-glucitol 2-[2-methyl-3-[perfluoromethyl)anilino]nicotinate: Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES) Result: negative 1-deoxy-1-(methylamino)-D-glucitol 2-[2-methyl-3-[perfluoromethyl]anilino]nicotinate: Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES) Result: negative <	Version 4.0	Revision Date: 28.09.2024	SDS Number: 10846445-00005	Date of last issue: 06.04.2024 Date of first issue: 06.09.2022
Species: Mouse Cell type: Bone marrow Application Route: Oral Result: negative N-Methyl-2-pyrrolidone: Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES) Method: OECD Test Guideline 471 Result: negative Test Type: In vitro mammalian cell gene mutation test Method: OECD Test Guideline 476 Result: negative Test Type: DNA damage and repair, unscheduled DNA synthesis in mammalian cells (in vitro) Result: negative Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay) Species: Mouse Application Route: Ingestion Method: OECD Test Guideline 474 Result: negative Genotoxicity in vivo : Test Type: Mutagenicity (in vivo mammalian bone-marrow cytogenetic test, chromosomal analysis) Species: Hamster Application Route: Ingestion Method: OECD Test Guideline 475 Result: negative 1-deoxy-1-(methylamino)-D-glucitol 2-[2-methyl-3-(perfluoromethyl)anilino]nicotinate: Genotoxicity in vitro : Test Type: In vitro assay Test Type: in vitro assay Test system: mouse lymphoma cells Result: positive Test Type: In vitro assay Test system: Chinese hamster ovary cells Result: positive Test Type: in vitro assay Test system: Echerichia coli Result: positive	II		Result: positiv	e
Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES) Method: OECD Test Guideline 471 Result: negative Test Type: In vitro mammalian cell gene mutation test Method: OECD Test Guideline 476 Result: negative Test Type: DNA damage and repair, unscheduled DNA syn- thesis in mammalian cells (in vitro) Result: negative Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay) Species: Mouse Application Route: Ingestion Method: OECD Test Guideline 474 Result: negative Test Type: Mutagenicity (in vivo mammalian bone-marrow cytogenetic test, chromosomal analysis) Species: Hamster Application Route: Ingestion Method: OECD Test Guideline 475 Result: negative 1-deoxy-1-(methylamino)-D-glucitol 2-[2-methyl-3-(perfluoromethyl)anilino]nicotinate: Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES) Result: negative 1-deoxy-1-(methylamino)-D-glucitol 2-[2-methyl-3-(perfluoromethyl)anilino]nicotinate: Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES) Result: negative Test Type: in vitro assay Test system: mouse lymphoma cells Result: positive Test Type: Chromosomal aberration Test system: Chinese hamster ovary cells Result: positive Test Type: in vitro assay Test system: Escherichia coli Result: positive	Genc	otoxicity in vivo	Species: Mous Cell type: Bon Application Ro	se e marrow pute: Oral
Method: OECD Test Guideline 471 Result: negative Test Type: In vitro mammalian cell gene mutation test Method: OECD Test Guideline 476 Result: negative Test Type: DNA damage and repair, unscheduled DNA synthesis in mammalian cells (in vitro) Result: negative Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay) Species: Mouse Application Route: Ingestion Method: OECD Test Guideline 474 Result: negative Test Type: Mutagenicity (in vivo mammalian bone-marrow cytogenetic test, chromosomal analysis) Species: Hamster Application Route: Ingestion Method: OECD Test Guideline 475 Result: negative 1-deoxy-1-(methylamino)-D-glucitol 2-[2-methyl-3-(perfluoromethyl)anilino]nicotinate: Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES) Result: negative Test Type: in vitro assay Test Type: in vitro assay Test Type: Chromosomal aberration Test Type: Chromosomal aberration Test Type: Chromosomal aberration Test Type: in vitro assay Test Type: in vitro assay Test Type: in vitro assay <td>N-Me</td> <td>thyl-2-pyrrolidone:</td> <td></td> <td></td>	N-Me	thyl-2-pyrrolidone:		
Method: OECD Test Guideline 476 Result: negative Test Type: DNA damage and repair, unscheduled DNA synthesis in mammalian cells (in vitro) Result: negative Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay) Species: Mouse Application Route: Ingestion Method: OECD Test Guideline 474 Result: negative Test Type: Mutagenicity (in vivo mammalian bone-marrow cytogenetic test, chromosomal analysis) Species: Hamster Application Route: Ingestion Method: OECD Test Guideline 475 Result: negative 1-deoxy-1-(methylamino)-D-glucitol 2-[2-methyl-3-(perfluoromethyl)anilino]nicotinate: Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES) Result: negative Test Type: in vitro assay Test system: mouse lymphoma cells Result: positive Test Type: Chromosomal aberration Test system: Chinese hamster ovary cells Result: positive Test Type: in vitro assay Test system: Escherichia coli Result: positive	Geno	otoxicity in vitro	Method: OECI	D Test Guideline 471
Genotoxicity in vivo Test Type: Mammalian cells (in vitro) Result: negative Genotoxicity in vivo Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay) Species: Mouse Application Route: Ingestion Method: OECD Test Guideline 474 Result: negative Test Type: Mutagenicity (in vivo mammalian bone-marrow cytogenetic test, chromosomal analysis) Species: Hamster Application Route: Ingestion Method: OECD Test Guideline 475 Result: negative 1-deoxy-1-(methylamino)-D-glucitol 2-[2-methyl-3-(perfluoromethyl)anilino]nicotinate: Genotoxicity in vitro Test Type: Bacterial reverse mutation assay (AMES) Result: negative Test Type: in vitro assay Test system: mouse lymphoma cells Result: positive Test Type: Chromosomal aberration Test system: Chinese hamster ovary cells Result: positive Test Type: in vitro assay Test system: Escherichia coli Result: positive			Method: OECI	D Test Guideline 476
cytogenetic assay) Species: Mouse Application Route: Ingestion Method: OECD Test Guideline 474 Result: negative Test Type: Mutagenicity (in vivo mammalian bone-marrow cytogenetic test, chromosomal analysis) Species: Hamster Application Route: Ingestion Method: OECD Test Guideline 475 Result: negative 1-deoxy-1-(methylamino)-D-glucitol 2-[2-methyl-3-(perfluoromethyl)anilino]nicotinate: Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES) Result: negative Test Type: in vitro assay Test system: mouse lymphoma cells Result: positive Test Type: Chromosomal aberration Test system: Chinese hamster ovary cells Result: positive Test Type: in vitro assay Test system: Escherichia coli Result: positive			thesis in mam	malian cells (in vitro)
cytogenetic test, chromosomal analysis) Species: Hamster Application Route: Ingestion Method: OECD Test Guideline 475 Result: negative 1-deoxy-1-(methylamino)-D-glucitol 2-[2-methyl-3-(perfluoromethyl)anilino]nicotinate: Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES) Result: negative Test Type: in vitro assay Test system: mouse lymphoma cells Result: positive Test Type: Chromosomal aberration Test system: Chinese hamster ovary cells Result: positive Test Type: in vitro assay Test system: Escherichia coli Result: positive	Genc	otoxicity in vivo	cytogenetic as Species: Mous Application Ro Method: OECI	ssay) se pute: Ingestion D Test Guideline 474
1-deoxy-1-(methylamino)-D-glucitol 2-[2-methyl-3-(perfluoromethyl)anilino]nicotinate: Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES) Result: negative Test Type: in vitro assay Test system: mouse lymphoma cells Result: positive Test Type: Chromosomal aberration Test system: Chinese hamster ovary cells Result: positive Test Type: in vitro assay Test system: Escherichia coli Result: positive			cytogenetic te Species: Ham Application Rc Method: OECI	st, chromosomal analysis) ster oute: Ingestion D Test Guideline 475
Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES) Result: negative Test Type: in vitro assay Test system: mouse lymphoma cells Result: positive Test Type: Chromosomal aberration Test system: Chinese hamster ovary cells Result: positive Test Type: in vitro assay Test Type: in vitro assay Test system: Escherichia coli Result: positive		ovu 1_(mothulamino)	D alucital 2 [2 moth	v. 2 (norfluoromothyl)anilinolnicotinato.
Test system: mouse lymphoma cells Result: positive Test Type: Chromosomal aberration Test system: Chinese hamster ovary cells Result: positive Test Type: in vitro assay Test system: Escherichia coli Result: positive		• • • •	: Test Type: Ba	cterial reverse mutation assay (AMES)
Test system: Chinese hamster ovary cells Result: positive Test Type: in vitro assay Test system: Escherichia coli Result: positive			Test system: r	nouse lymphoma cells
Test system: Escherichia coli Result: positive			Test system: (Chinese hamster ovary cells
Genotoxicity in vivo			Test system: E	Escherichia coli
Techoloxioly in vivo . Test Type, micronacieas lest	Geno	otoxicity in vivo	: Test Type: Mid	cronucleus test



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			Species: Mouse Application Route Result: negative	e: Oral
Germ sessr	n cell mutagenicity- As- nent	:	Weight of eviden cell mutagen.	ce does not support classification as a germ
Citric	acid:			
	toxicity in vitro	:	Test Type: Bacte Result: negative	rial reverse mutation assay (AMES)
			Test Type: in vitro Result: positive	o micronucleus test
			Test Type: Bacte Result: negative	rial reverse mutation assay (AMES)
Geno	toxicity in vivo	:		genicity (in vivo mammalian bone-marrow chromosomal analysis) e: Ingestion
Not c	i nogenicity lassified based on availa ponents:	able	information.	
Spec Applie Expo Resu	cation Route sure time		Rat oral (gavage) 2 Years negative Liver, Testes	
Expo Resu	cation Route sure time		Mouse oral (gavage) 2 Years negative Testes, Blood	
N-Me	thyl-2-pyrrolidone:			
Spec Appli	ies cation Route sure time	:	Rat Ingestion 2 Years negative	
	cation Route sure time		Rat inhalation (vapou 2 Years negative	r)



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1-deoxy-1-(methylamino)-D-glucitol 2-[2-methyl-3-(perfluoromethyl)anilino]nicotinate:

Species Application Route Exposure time LOAEL Result Target Organs Remarks	 Rat oral (feed) 104 w 2 mg/kg body weight negative Gastrointestinal tract Significant toxicity observed in testing
Species Application Route Exposure time NOAEL Result Target Organs Remarks	 Mouse oral (feed) 97 w 0,6 mg/kg body weight negative Gastrointestinal tract Significant toxicity observed in testing

Reproductive toxicity

May damage the unborn child. Suspected of damaging fertility.

Components:

Florfe	nicol	

Effects on fertility	:	Test Type: Two-generation reproduction toxicity study Species: Rat Application Route: Oral Fertility: LOAEL: 12 mg/kg body weight Result: decreased pup survival, reduced lactation
Effects on foetal develop- ment	:	Test Type: Embryo-foetal development Species: Rat General Toxicity Maternal: NOAEL: 4 mg/kg body weight Embryo-foetal toxicity: LOAEL: 40 mg/kg body weight Result: No teratogenic effects, Fetotoxicity Remarks: The effects were seen only at maternally toxic dos- es.
		Test Type: Embryo-foetal development Species: Mouse Application Route: oral (gavage) General Toxicity Maternal: NOAEL: 120 mg/kg body weight Embryo-foetal toxicity: LOAEL: 40 mg/kg body weight Result: Fetotoxicity
Reproductive toxicity - As- sessment	:	Some evidence of adverse effects on sexual function and fertility, based on animal experiments., Some evidence of adverse effects on development, based on animal experiments.

N-Methyl-2-pyrrolidone:



rsion	Revision Date: 28.09.2024	SDS Number:Date of last issue: 06.04.202410846445-00005Date of first issue: 06.09.2022			
Effects on fertility		: Test Type: Two-generation reproduction toxicity study Species: Rat Application Route: Ingestion Method: OECD Test Guideline 416 Result: negative			
Effects ment	s on foetal develop-	: Test Type: Embryo-foetal development Species: Rat Application Route: Ingestion Method: OECD Test Guideline 414 Result: positive			
		Test Type: Fertility/early embryonic development Species: Rat Application Route: inhalation (vapour) Result: positive			
		Test Type: Embryo-foetal development Species: Rabbit Application Route: Ingestion Result: positive			
Repro sessm	ductive toxicity - As- nent	: Clear evidence of adverse effects on development, base animal experiments.	d oi		
1-deo	w 4 (mothylomino) [glucitol 2-[2-methyl-3-(perfluoromethyl)anilino]nicotinate			
1-460	xy-i-(methylamino)-L	giucitor z-[z-metriyi-3-(pernuorometriyi)ammojmcotmate	:		
	s on fertility	 Test Type: Two-generation reproduction toxicity study Species: Rat Application Route: Oral General Toxicity - Parent: LOAEL: 1 - 1,5 mg/kg body we Symptoms: No foetal abnormalities Result: No effects on fertility and early embryonic develo ment were detected. 	eigh		
Effects	• • • •	 Test Type: Two-generation reproduction toxicity study Species: Rat Application Route: Oral General Toxicity - Parent: LOAEL: 1 - 1,5 mg/kg body we Symptoms: No foetal abnormalities Result: No effects on fertility and early embryonic develor ment were detected. Test Type: Development Species: Rat Application Route: Oral General Toxicity Maternal: LOAEL: 2 mg/kg body weight Embryo-foetal toxicity: NOAEL: 2 mg/kg body weight Result: Embryotoxic effects and adverse effects on the or spring were detected only at high maternally toxic doses Test Type: Embryo-foetal development 	eigh p-		
Effects	s on fertility	 Test Type: Two-generation reproduction toxicity study Species: Rat Application Route: Oral General Toxicity - Parent: LOAEL: 1 - 1,5 mg/kg body we Symptoms: No foetal abnormalities Result: No effects on fertility and early embryonic develor ment were detected. Test Type: Development Species: Rat Application Route: Oral General Toxicity Maternal: LOAEL: 2 mg/kg body weight Embryo-foetal toxicity: NOAEL: 2 mg/kg body weight Result: Embryotoxic effects and adverse effects on the or spring were detected only at high maternally toxic doses 	∍igh p- fff-		
Effects	s on foetal develop-	 Test Type: Two-generation reproduction toxicity study Species: Rat Application Route: Oral General Toxicity - Parent: LOAEL: 1 - 1,5 mg/kg body we Symptoms: No foetal abnormalities Result: No effects on fertility and early embryonic develor ment were detected. Test Type: Development Species: Rat Application Route: Oral General Toxicity Maternal: LOAEL: 2 mg/kg body weight Embryo-foetal toxicity: NOAEL: 2 mg/kg body weight Result: Embryotoxic effects and adverse effects on the c spring were detected only at high maternally toxic doses Test Type: Embryo-foetal development Species: Rabbit Application Route: Oral General Toxicity Maternal: LOAEL: 3 mg/kg body weight Result: Embryo-foetal toxicity: NOAEL: 3 mg/kg body weight Embryo-foetal toxicity: NOAEL: 3 mg/kg body weight Result: Embryotoxic effects and adverse effects on the c 	∍igh p- fff-		



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ment			Species: Rat Application Route Result: negative	: Ingestion
STOT	- single exposure			
May c	ause respiratory irritation	on.		
<u>Comp</u>	onents:			
	hyl-2-pyrrolidone:			
Asses	sment	:	May cause respire	atory irritation.
1-deo	xy-1-(methylamino)-D)-glu	citol 2-[2-methyl-3	3-(perfluoromethyl)anilino]nicotinate:
Asses		:	May cause respire	
Citric	acid			
Asses		:	May cause respira	atory irritation.
Cause <u>Comp</u> Florfe Target Asses 1-deo	t Organs sment	:	Liver, Brain, Testi Causes damage t exposure. citol 2-[2-methyl-3 Gastrointestinal tr	eated exposure. is, Spinal cord, Blood, gallbladder to organs through prolonged or repeated 3-(perfluoromethyl)anilino]nicotinate: ract, Kidney, Blood to organs through prolonged or repeated
Repea	ated dose toxicity			
-	oonents:			
Florfe				
Specie NOAE Expos	es	:	Dog 3 mg/kg 13 Weeks Liver, Testis, Brai	n, Spinal cord
		:	Mouse 200 mg/kg 13 Weeks Liver, Testis	
Specie NOAE	es EL	:	Rat 30 mg/kg	

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



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Expos Targe	sure time t Organs	: 13 Weeks : Liver, Testis	
	EL	: Dog : 3 mg/kg : 12 mg/kg : 52 Weeks : Liver, gallblad	dder
	EL	: Rat : 1 mg/kg : 3 mg/kg : 52 Weeks : Testis	
N-Met	hyl-2-pyrrolidone:		
	L L ation Route sure time	: Rat, male : 169 mg/kg : 433 mg/kg : Ingestion : 90 Days : OECD Test 0	Guideline 408
	L L ation Route sure time	: Rat : 0,5 mg/l : 1 mg/l : inhalation (du : 96 Days : OECD Test 0	
	EL	: Rabbit : 826 mg/kg : 1.653 mg/kg : Skin contact : 20 Days	
1-deo	xy-1-(methylamino)-D	-glucitol 2-[2-met	hyl-3-(perfluoromethyl)anilino]nicotinate:
Specie NOAE LOAE Applic Expos	es	: Rat : 2 mg/kg : < 4 mg/kg : Oral : 6 w : Gastrointestin	
Expos		: Rat : 1 mg/kg : Oral : 1 y : Gastrointestin	nal tract, Kidney
Specie NOAE	es L	: Monkey : 15 mg/kg	

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



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Application Route Exposure time Target Organs		: Oral : 90 d : Gastrointestinal tract, Blood	90 d		
	EL cation Route sure time	: Rabbit : 80 mg/kg : Dermal : 21 d : Severe irritation			
Expos	EL cation Route sure time et Organs	 Dog 11 mg/kg Oral 9 d Gastrointestinal tract Vomiting 			
Citric	acid:				
Speci NOAE LOAE Applio	es EL	: Rat : 4.000 mg/kg : 8.000 mg/kg : Ingestion : 10 Days			
Aspiration toxicity Not classified based on available information.					
11.2 Infor	mation on other haz	ds			
Endo	crine disrupting pro	erties			
Produ Asses	uct: ssment	: The substance/mixture does not contain components consid	d-		
		ered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605	at		

Experience with human exposure

Components:

N-Methyl-2-pyrrolidone:

Skin contact

: Symptoms: Skin irritation

levels of 0.1% or higher.

1-deoxy-1-(methylamino)-D-glucitol 2-[2-methyl-3-(perfluoromethyl)anilino]nicotinate:

Inhalation Skin contact Eye contact Ingestion	: Symptoms: respiratory tract irritation
Skin contact	: Symptoms: Skin irritation
Eye contact	: Symptoms: Severe irritation
Ingestion	: Symptoms: Gastrointestinal disturbance, bleeding, hyperten-
	sion, Kidney disorders



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SECTION 12: Ecological information

12.1 Toxicity

Components:						
Florfenicol:						
		LC50 (Lepomis macrochirus (Bluegill sunfish)): > 830 mg/l Exposure time: 96 h Method: FDA 4.11				
		LC50 (Oncorhynchus mykiss (rainbow trout)): > 780 mg/l Exposure time: 96 h Method: FDA 4.11				
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia magna (Water flea)): > 330 mg/l Exposure time: 48 h Method: OECD Test Guideline 202				
Toxicity to algae/aquatic plants	:	EC50 (Pseudokirchneriella subcapitata (green algae)): > 2,9 mg/l Exposure time: 14 d Method: FDA 4.01				
		NOEC (Pseudokirchneriella subcapitata (green algae)): 2,9 mg/l Exposure time: 14 d Method: FDA 4.01				
		IC50 (Skeletonema costatum (marine diatom)): 0,0336 mg/l Exposure time: 72 h Method: ISO 10253				
		NOEC (Skeletonema costatum (marine diatom)): 0,00423 mg/l Exposure time: 72 h Method: ISO 10253				
		EC50 (Lemna gibba (gibbous duckweed)): 0,76 mg/l Exposure time: 7 d Method: OECD Test Guideline 221				
		NOEC (Lemna gibba (gibbous duckweed)): 0,39 mg/l Exposure time: 7 d Method: OECD Test Guideline 221				
		EC50 (Navicula pelliculosa (Freshwater diatom)): 61 mg/l Exposure time: 72 h Method: OECD Test Guideline 201				
		NOEC (Navicula pelliculosa (Freshwater diatom)): 19 mg/l Exposure time: 72 h Method: OECD Test Guideline 201				



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rsion)	Revision Date: 28.09.2024		OS Number: 846445-00005	Date of last issue: 06.04.2024 Date of first issue: 06.09.2022
			EC50 (Anabaena Exposure time: 72 Method: OECD T	
			NOEC (Anabaena Exposure time: 72 Method: OECD T	
M-Fao icity)	ctor (Acute aquatic tox-	:	10	
Toxic icity)	ity to fish (Chronic tox-	:	NOEC: 5,5 mg/l Exposure time: 32 Species: Pimepha Method: OECD T	ales promelas (fathead minnow)
	ity to daphnia and other ic invertebrates (Chron- icity)		NOEC: 1,5 mg/l Exposure time: 2 ⁷ Species: Daphnia Method: OECD T	magna (Water flea)
M-Factoric	ctor (Chronic aquatic	:	10	
N-Me	thyl-2-pyrrolidone:			
	ity to fish	:	LC50 (Oncorhync Exposure time: 96	hus mykiss (rainbow trout)): > 500 mg/l ວິ h
	ity to daphnia and other ic invertebrates	:	EC50 (Daphnia m Exposure time: 24 Method: DIN 384	
Toxic plants	ity to algae/aquatic	:	ErC50 (Desmode Exposure time: 72	smus subspicatus (green algae)): 600,5 m 2 h
			EC10 (Desmodes Exposure time: 72	smus subspicatus (green algae)): 92,6 mg/ 2 h
Toxic	ity to microorganisms	:	EC50 : > 600 mg/ Exposure time: 30 Method: ISO 8192) min
	ity to daphnia and other ic invertebrates (Chron- icity)	:	NOEC: 12,5 mg/l Exposure time: 2 ⁷ Species: Daphnia Method: OECD T	magna (Water flea)
		glu	citol 2-[2-methyl-3	3-(perfluoromethyl)anilino]nicotinate:
Toxic	ity to fish	:	LC50 (Lepomis m	acrochirus (Bluegill sunfish)): 28 mg/l

Exposure time: 96 h Method: FDA 4.11



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			LC50 (Oncorhync Exposure time: 96 Method: FDA 4.1		
	cicity to daphnia and other atic invertebrates	:	EC50 (Daphnia magna (Water flea)): 15 mg/l Exposure time: 48 h Method: FDA 4.08		
To» plai	ricity to algae/aquatic nts	:	NOEC (Microcyst Exposure time: 13 Method: FDA 4.0		
			NOEC (Selenastr Exposure time: 12	rum capricornutum (green algae)): 96 mg/l 2 d	
Cit	ric acid:				
	cicity to fish	:	LC50 (Pimephale Exposure time: 96	s promelas (fathead minnow)): > 100 mg/l 6 h	
	cicity to daphnia and other natic invertebrates	:	EC50 (Daphnia magna (Water flea)): 1.535 mg/l Exposure time: 24 h		
12.2 Pe	sistence and degradabil	ity			
Co	mponents:				
	lethyl-2-pyrrolidone:				
	degradability	:	Result: Readily bi	iodegradable.	
			Biodegradation: Exposure time: 28		
				est Guideline 301C	
II 1-d	eoxy-1-(methylamino)-D-	alu	citol 2-[2-methyl-	3-(perfluoromethyl)anilino]nicotinate:	
	bility in water	:	Hydrolysis: 0 %(2		
Cit	ric acid:				
Bio	degradability	:	Result: Readily bi Biodegradation: 9 Exposure time: 28	97 %	
			Metriod. OECD 1	est Guideline 301b	
12.3 Bio	accumulative potential				
Co	mponents:				
Flo	rfenicol:				
	tition coefficient: n- anol/water	:	log Pow: 0,373 pH: 7		
N-N	lethyl-2-pyrrolidone:				



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	ion coefficient: n- ol/water		log Pow: -0,46 Method: OECD Test Guideline 107				
1-deo	oxy-1-(methylamino)-E	D-glucitol 2-[2-met	hyl-3-(perfluoromethyl)anilino]nicotinate:				
	ion coefficient: n- ol/water	: log Pow: 1,3	4				
Citric	acid:						
Partit octar	ion coefficient: n- ol/water	: log Pow: -1,7	2				
12.4 Mobi	lity in soil						
Com	ponents:						
Florf	enicol:						
	bution among environ- al compartments	: Koc: 52 Method: FDA	x 3.08				
1-deo	oxy-1-(methylamino)-[D-glucitol 2-[2-met	hyl-3-(perfluoromethyl)anilino]nicotinate:				
	bution among environ- al compartments	: log Koc: 1,92					
12.5 Resu	Ilts of PBT and vPvB a	assessment					
Prod	uct:						
Asse	ssment	to be either p	ce/mixture contains no components considered persistent, bioaccumulative and toxic (PBT), or nt and very bioaccumulative (vPvB) at levels of er.				
12.6 Endo	ocrine disrupting prop	erties					
Prod							
	ssment	ered to have REACH Artic	ce/mixture does not contain components consid- endocrine disrupting properties according to le 57(f) or Commission Delegated regulation 00 or Commission Regulation (EU) 2018/605 at 6 or higher.				
12.7 Othe	r adverse effects						
	ata available						

13.1 Waste treatment methods

Product

: Dispose of in accordance with local regulations. According to the European Waste Catalogue, Waste Codes are not product specific, but application specific. Waste codes should be assigned by the user, preferably in



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Contaminated packaging		:	discussion with the waste disposal authorities. Do not dispose of waste into sewer. Empty containers should be taken to an approved waste had dling site for recycling or disposal. If not otherwise specified: Dispose of as unused product.				
SECTIO	SECTION 14: Transport information						
14.1 UN r	number or ID number						
ADN		÷	UN 3082				
ADR			UN 3082				
RID		÷	UN 3082				
IMD	G	:	UN 3082				
ΙΑΤΑ	N N	:	UN 3082				
14.2 UN p	proper shipping name						
ADN		:	ENVIRONMENT/ N.O.S. (Florfenicol)	ALLY HAZARDOUS SUBSTANCE, LIQUID,			
ADR		:	ENVIRONMENT/ N.O.S. (Florfenicol)	ALLY HAZARDOUS SUBSTANCE, LIQUID,			
RID		:	ENVIRONMENT/ N.O.S. (Florfenicol)	ALLY HAZARDOUS SUBSTANCE, LIQUID,			
IMD	3	:	ENVIRONMENT N.O.S. (Florfenicol)	ALLY HAZARDOUS SUBSTANCE, LIQUID,			
ΙΑΤΑ	N N	:	Environmentally I (Florfenicol)	nazardous substance, liquid, n.o.s.			
14.3 Tran	sport hazard class(es)						
			Class	Subsidiary risks			
ADN		:	9				
ADR		:	9				
RID		:	9				
IMD	3	:	9				
ΙΑΤΑ	۱.	:	9				
14.4 Pacl	king group						
Clas	ing group sification Code ard Identification Number	:	III M6 90				



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	Labels		:	9	
	Classifi Hazard Labels	g group cation Code Identification Number restriction code	:	III M6 90 9 (-)	
	Classifi	g group cation Code Identification Number	:	III M6 90 9	
	IMDG Packing Labels EmS C	g group ode	:	III 9 F-A, S-F	
i	aircraft Packing	g instruction (cargo	:	964 Y964 III Miscellaneous	
	Packing ger airc Packing	J	:	964 Y964 III Miscellaneous	
14.5	Enviro	nmental hazards			
	ADN Enviror	mentally hazardous	:	yes	
	ADR Enviror	mentally hazardous	:	yes	
	RID Enviror	mentally hazardous	:	yes	
	IMDG Marine	pollutant	:	yes	

14.6 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.

14.7 Maritime transport in bulk according to IMO instruments

Remarks : Not applicable for product as supplied.



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SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mix-ture

th _m	EACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, ixtures and articles (Annex XVII)	:		striction for the fol- hould be considered:
th	EACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, ixtures and articles (Annex XVII)		Number on list 3 pyrrolidone	0: N-Methyl-2-
			Number on list 7 pyrrolidone	1: N-Methyl-2-
	EACH - Restrictions on the manufacture, placing on		Number on list 7 pyrrolidone	2: N-Methyl-2-
th	e market and use of certain dangerous substances, ixtures and articles (Annex XVII)			5: If you intend to as tattoo ink, please dor.
			here according to in the regulation, use/purpose or t restriction. Pleas tions in correspondetermine wheth	mixture(s) are listed o their appearance i rrespective of their he conditions of the se refer to the condi- nding Regulation to her an entry is appli- ing on the market or
	EACH - Candidate List of Substances of Very High oncern for Authorisation (Article 59).	:	N-Methyl-2-pyrro	blidone
R	EACH - List of substances subject to authorisation	:	Not applicable	
Ŕ	egulation (EC) on substances that deplete the ozone yer	:	Not applicable	
R	egulation (EU) 2019/1021 on persistent organic pollu-	:	Not applicable	
R m	Ints (recast) egulation (EU) No 649/2012 of the European Parlia- ient and the Council concerning the export and import dangerous chemicals	:	Not applicable	
S	eveso III: Directive 2012/18/EU of the European Parliar ajor-accident hazards involving dangerous substances		and of the Counc	il on the control of
-		•	Quantity 1	Quantity 2

		Quantity I	Quantity Z
E1	ENVIRONMENTAL	100 t	200 t
	HAZARDS		

Other regulations:

Note the Working Environment Act § 4-1 and § 4-2 on requirements for the employer to protect



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pregnant employees against discomfort and injury as a result of the work situation and the working environment.

Note the regulation on organization, leadership and participation, chapter 12 on the work of children and young people.

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

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

15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

Other information	:	Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.
Full text of H-Statements H301 H315 H318 H319 H330 H335 H360D H361fd	:	Toxic if swallowed. Causes skin irritation. Causes serious eye damage. Causes serious eye irritation. Fatal if inhaled. May cause respiratory irritation. May damage the unborn child. Suspected of damaging fertility. Suspected of damaging the
H372 H400 H410 H411	: : :	unborn child. Causes damage to organs through prolonged or repeated exposure. Very toxic to aquatic life. Very toxic to aquatic life with long lasting effects. Toxic to aquatic life with long lasting effects.
Full text of other abbreviation Acute Tox. Aquatic Acute Aquatic Chronic Eye Dam. Eye Irrit. Repr. Skin Irrit. STOT RE STOT SE 2004/37/EC 2009/161/EU	ons	Acute toxicity Short-term (acute) aquatic hazard Long-term (chronic) aquatic hazard Serious eye damage Eye irritation Reproductive toxicity Skin irritation Specific target organ toxicity - repeated exposure Specific target organ toxicity - single exposure Europe. Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work Europe. COMMISSION DIRECTIVE 2009/161/EU establishing a third list of indicative occupational exposure limit values in



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2004/3 2004/3 2009/1 2009/1 FOR-2 TWA	2011-12-06-1358 37/EC / STEL 37/EC / TWA 161/EU / TWA 161/EU / STEL 2011-12-06-1358 / 2011-12-06-1358 /	 Commission Dire	ional Exposure limits ure limit ure limit t hours ure limit ure limit

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by Road; AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA -European Chemicals Agency; EC-Number - European Community number; 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; 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; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of very high concern; TCSI - Taiwan Chemical Substance Inventory; TECI -Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

Further information

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

Classification of the mixture:

Classification procedure:

Acute Tox. 4

H302

Calculation method



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Acute	Tox. 4	H332	Calculation method
Skin I	rrit. 2	H315	Calculation method
Eye lı	rrit. 2	H319	Calculation method
Repr.	1B	H360Df	Calculation method
STOT	- SE 3	H335	Calculation method
STOT	RE 1	H372	Calculation method
Aquat	tic Acute 1	H400	Calculation method
Aquat	tic Chronic 1	H410	Calculation method

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NO / EN