

Creation Date 26-Mar-2012 Revision Date 10-Dec-2021 Revision Number 3

SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1. Product identifier

Product Description: <u>IDEIA Borrelia IgG Kit TM</u>

Cat No.: K602911-2

1.2. Relevant identified uses of the substance or mixture and uses advised against

Recommended Use In vitro diagnostic.
Uses advised against No Information available

1.3. Details of the supplier of the safety data sheet

Company Oxoid Ltd

Wade Road

Basingstoke, Hants, UK

RG24 8PW

Tel: +44 (0) 1256 841144

EU entity/business name Oxoid Deutschland GmbH

Postfach 10 07 53

D-46483 Wesel GERMANY

Tel: + 49 (0) 281 1520 Fax: 49 (0) 281 1521

E-mail address mbd-sds@thermofisher.com

1.4. Emergency telephone number

Chemtrec EU: 001-703-527-3887 Chemtrec US: (800) 424-9300

For customers in Switzerland:

Tox Info Suisse Emergency Number: 145 (24hr)

Tox Info Suisse: +41-44 251 51 51 (Emergency number from abroad)

Chemtrec (24h) Toll-Free: 0800 564 402 Chemtrec Local: +41-43 508 20 11 (Zurich)

SECTION 2: HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture

CLP Classification - Regulation (EC) No 1272/2008

Physical hazards

Based on available data, the classification criteria are not met

IDEIA Borrelia IgG Kit TM

Revision Date 10-Dec-2021

Health hazards

Skin Corrosion/Irritation Serious Eye Damage/Eye Irritation Reproductive Toxicity Not classified Not classified Category 1B (H360D)

Environmental hazards

Based on available data, the classification criteria are not met

Full text of Hazard Statements: see section 16

2.2. Label elements



Signal Word

Danger

Hazard Statements

H360D - May damage the unborn child

Precautionary Statements

P201 - Obtain special instructions before use

P202 - Do not handle until all safety precautions have been read and understood

P281 - Use personal protective equipment as required

P308 + P313 - IF exposed or concerned: Get medical advice/attention

Additional EU labelling

Restricted to professional users

2.3. Other hazards

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.2. Mixtures

Component	CAS No	EC No	Weight %	CLP Classification - Regulation (EC) No 1272/2008
1-Methyl-2-pyrrolidone	872-50-4	EEC No. 212-828-1	5 -9.99	Skin Irrit. 2 (H315)
				Eye Irrit. 2 (H319)
				Repr. 1B (H360D)
				STOT SE 3 (H335)
Sulfuric acid	7664-93-9	EEC No. 231-639-5	4.5	Skin Corr. 1A (H314)
				Eye Dam. 1 (H318)

Component	Specific concentration limits (SCL's)	M-Factor	Component notes
1-Methyl-2-pyrrolidone	STOT SE 3 (H335) :: C>=10%	-	-

IDEIA Borrelia IgG Kit TM Revision Date 10-Dec-2021

Sulfuric acid	Eye Irrit. 2 (H319) :: 5%<=C<15%	-	-
	Skin Corr. 1A (H314) :: C>=15%		
	Skin Irrit. 2 (H315) ::		
	5%<=C<15%		

Full text of Hazard Statements: see section 16

SECTION 4: FIRST AID MEASURES

4.1. Description of first aid measures

General Advice If symptoms persist, call a physician.

Eye Contact Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Get

medical attention.

Skin Contact Wash off immediately with plenty of water for at least 15 minutes. If skin irritation persists,

call a physician.

Ingestion Clean mouth with water and drink afterwards plenty of water. Get medical attention.

Inhalation Remove to fresh air. If not breathing, give artificial respiration. Get medical attention if

symptoms occur.

Self-Protection of the First Aider Ensure that medical personnel are aware of the material(s) involved, take precautions to

protect themselves and prevent spread of contamination.

4.2. Most important symptoms and effects, both acute and delayed

None reasonably foreseeable.

4.3. Indication of any immediate medical attention and special treatment needed

Notes to Physician Treat symptomatically.

SECTION 5: FIREFIGHTING MEASURES

5.1. Extinguishing media

Suitable Extinguishing Media

Water spray, carbon dioxide (CO2), dry chemical, alcohol-resistant foam.

Extinguishing media which must not be used for safety reasons

No information available.

5.2. Special hazards arising from the substance or mixture

Thermal decomposition can lead to release of irritating gases and vapors.

Hazardous Combustion Products

None under normal use conditions.

5.3. Advice for firefighters

As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear.

IDEIA Borrelia IgG Kit TM

Revision Date 10-Dec-2021

Page 4/15

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures

Do not get in eyes, on skin, or on clothing. Use personal protective equipment as required. Ensure adequate ventilation.

6.2. Environmental precautions

Should not be released into the environment. See Section 12 for additional Ecological Information.

6.3. Methods and material for containment and cleaning up

Soak up with inert absorbent material. Keep in suitable, closed containers for disposal.

6.4. Reference to other sections

Refer to protective measures listed in Sections 8 and 13.

SECTION 7: HANDLING AND STORAGE

7.1. Precautions for safe handling

Do not get in eyes, on skin, or on clothing. Wear personal protective equipment/face protection. Ensure adequate ventilation. Avoid ingestion and inhalation.

Hygiene Measures

Handle in accordance with good industrial hygiene and safety practice. Keep away from food, drink and animal feeding stuffs. Do not eat, drink or smoke when using this product. Remove and wash contaminated clothing and gloves, including the inside, before re-use. Wash hands before breaks and after work.

7.2. Conditions for safe storage, including any incompatibilities

Keep container tightly closed. Keep at temperatures between 2° and 8 °C.

Technical Rules for Hazardous Substances (TRGS) 510 Storage Class (LGK) (Germany)

Storage Class/LGK 6.1D

7.3. Specific end use(s)

Use in laboratories

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters

Exposure limits

List source(s): **EU** - Commission Directive (EU) 2019/1831 of 24 October 2019 establishing a fifth list of indicative occupational exposure limit values pursuant to Council Directive 98/24/EC and amending Commission Directive 2000/39/EC **UK** - EH40/2005 Work Exposure Limits, Third edition. Published 2018. **IRE** - 2010 Code of Practice for the Safety, Health and Welfare at Work (Chemical Agents) Regulations 2001. Published by the Health and Safety Authority. **CH** - The Government of Switzerland has set a directive on limit values for working materials (Grenzwerte am arbeitplatz) which is based on the Swiss Federal Regulation "Verordnung über die Verhütung von Unfällen und Berufskrankheiten". This directive is administered, periodically revised and enforced by SUVA (Swiss National Accident Insurance Fund).

	Component	European Union	The United Kingdom	France	Belgium	Spain
ı	1-Methyl-2-pyrrolidon	TWA: 10 ppm (8h)	STEL: 20 ppm 15 min	TWA / VME: 40 mg/m ³	TWA: 10 ppm 8 uren	STEL / VLA-EC: 20 ppm
	e	TWA: 40 mg/m ³ (8h)	STEL: 80 mg/m ³ 15 min	(8 heures). indicative	TWA: 40 mg/m ³ 8 uren	(15 minutos).

IDEIA Borrelia IgG Kit TM

		STEL: 20 ppm (15min)	TWA: 10 ppm 8 hr	limit	STEL: 20 ppm 15	STEL / VLA-EC: 80
		STEL: 80 mg/m ³	TWA: 40 mg/m ³ 8 hr	TWA / VME: 10 ppm (8	minuten	mg/m³ (15 minutos).
		(15min)	Skin	heures). indicative limit	STEL: 80 mg/m ³ 15	TWA / VLA-ED: 10 ppm
		Skin		STEL / VLCT: 80	minuten	(8 horas)
				mg/m³. indicative limit	Huid	TWA / VLA-ED: 40
				STEL / VLCT: 20 ppm.		mg/m³ (8 horas)
				indicative limit		Piel
				Peau		
1	Sulfuric acid	TWA: 0.05 mg/m ³ (8h)	STEL: 0.15 mg/m ³ 15	TWA / VME: 0.05 mg/m ³	TWA: 0.2 mg/m ³ 8 uren	TWA / VLA-ED: 0.05
			min	(8 heures).	_	mg/m³ (8 horas)
- 1			TWA: 0.05 mg/m ³ 8 hr			

Component	Italy	Germany	Portugal	The Netherlands	Finland
1-Methyl-2-pyrrolidon	TWA: 10 ppm 8 ore.	TWA: 20 ppm (8	STEL: 20 ppm 15	huid	TWA: 3.5 ppm 8
е	Media Ponderata nel	Stunden). AGW -	minutos	STEL: 80 mg/m ³ 15	tunteina
	Tempo	exposure factor 2	STEL: 80 mg/m ³ 15	minuten	TWA: 14 mg/m ³ 8
	TWA: 40 mg/m ³ 8 ore.	TWA: 82 mg/m ³ (8	minutos	TWA: 40 mg/m ³ 8 uren	tunteina
	Media Ponderata nel	Stunden). AGW -	TWA: 10 ppm 8 horas		STEL: 20 ppm 15
	Tempo	exposure factor 2	TWA: 40 mg/m ³ 8 horas		minuutteina
	STEL: 20 ppm 15	TWA: 20 ppm (8	Pele		STEL: 80 mg/m ³ 15
	minuti. Breve termine	Stunden). MAK can			minuutteina
	STEL: 80 mg/m ³ 15	occur as vapor and			lho
	minuti. Breve termine	aerosol at the same			
	Pelle	time			
		TWA: 82 mg/m ³ (8			
		Stunden). MAK can			
		occur as vapor and			
		aerosol at the same			
		time			
		Höhepunkt: 40 ppm			
		Höhepunkt: 164 mg/m ³			
		Haut			
Sulfuric acid	TWA: 0.05 mg/m ³ 8 ore.	TWA: 0.1 mg/m ³ (8	TWA: 0.05 mg/m ³ 8	TWA: 0.05 mg/m ³ 8	TWA: 0.05 mg/m ³ 8
	Media Ponderata nel	Stunden). AGW -	horas	uren	tunteina
	Tempo when choosing a	exposure factor 1			STEL: 0.1 mg/m ³ 15
	suitable method for	TWA: 0.1 mg/m ³ (8			minuutteina
	monitoring exposure	Stunden). MAK			
	should take into account	Höhepunkt: 0.1 mg/m ³			
	potential constraints and				
	interactions that may				
	occur in the presence of				
	other sulfur compounds,				
	respirable fraction				

Component	Austria	Denmark	Switzerland	Poland	Norway
1-Methyl-2-pyrrolidon	Haut	TWA: 5 ppm 8 timer	Haut/Peau	STEL: 80 mg/m ³ 15	TWA: 5 ppm 8 timer
е	MAK-KZGW: 20 ppm 15	TWA: 20 mg/m ³ 8 timer	STEL: 40 ppm 15	minutach	TWA: 20 mg/m ³ 8 timer
	Minuten	Hud	Minuten	TWA: 40 mg/m ³ 8	STEL: 20 ppm 15
	MAK-KZGW: 80 mg/m ³		STEL: 160 mg/m ³ 15	godzinach	minutter. value from the
	15 Minuten		Minuten	_	regulation
	MAK-TMW: 10 ppm 8		TWA: 20 ppm 8		STEL: 80 mg/m ³ 15
	Stunden		Stunden		minutter. value from the
	MAK-TMW: 40 mg/m ³ 8		TWA: 80 mg/m ³ 8		regulation
	Stunden		Stunden		Hud
Sulfuric acid	MAK-KZGW: 0.2 mg/m ³	TWA: 0.05 mg/m ³ 8	STEL: 0.2 mg/m ³ 15	TWA: 0.05 mg/m ³ 8	TWA: 0.1 mg/m ³ 8 timer
	15 Minuten	timer	Minuten	godzinach	STEL: 0.3 mg/m ³ 15
	MAK-TMW: 0.1 mg/m ³ 8		TWA: 0.1 mg/m ³ 8	_	minutter. value
	Stunden		Stunden		calculated thoracic
					fraction

Component	Bulgaria	Croatia	Ireland	Cyprus	Czech Republic
1-Methyl-2-pyrrolidon	TWA: 10 ppm	kože	TWA: 10 ppm 8 hr.	Skin-potential for	TWA: 40 mg/m ³ 8
е	TWA: 40 mg/m ³	TWA-GVI: 10 ppm 8	TWA: 40 mg/m ³ 8 hr.	cutaneous absorption	hodinách.
	STEL : 20 ppm	satima.	STEL: 20 ppm 15 min	STEL: 80 mg/m ³	Potential for cutaneous
	STEL: 80 mg/m ³	TWA-GVI: 40 mg/m ³ 8	STEL: 80 mg/m ³ 15 min	STEL: 20 ppm	absorption
	Skin notation	satima.	Skin	TWA: 40 mg/m ³	Ceiling: 80 mg/m³ toxic
		STEL-KGVI: 20 ppm 15		TWA: 10 ppm	for reproduction
		minutama.			
		STEL-KGVI: 80 mg/m ³			

OXDK602911-2

Revision Date 10-Dec-2021

IDEIA Borrelia IgG Kit TM

Revision Date 10-Dec-2021

		15 minutama.			
Sulfuric acid	TWA: 0.05 mg/m ³	TWA-GVI: 0.05 mg/m³ 8 satima. when selecting the appropriate exposure monitoring method the potential limitations and disturbances that may occur in the presence of other sulfur compounds should be taken into account fog, thoracic fraction	STEL: 0.15 ppm 15 min	TWA: 0.05 mg/m³	TWA: 1 mg/m³ 8 hodinách. SO3 TWA: 0.05 mg/m³ 8 hodinách. concentrated H2SO4 mist Ceiling: 2 mg/m³ SO3

Component	Estonia	Gibraltar	Greece	Hungary	Iceland
1-Methyl-2-pyrrolidon	Nahk	Skin notation	skin - potential for	STEL: 80 mg/m ³ 15	STEL: 20 ppm
е	TWA: 10 ppm 8	TWA: 40 mg/m ³ 8 hr	cutaneous absorption	percekben. CK	STEL: 80 mg/m ³
	tundides.	TWA: 10 ppm 8 hr	STEL: 20 ppm	TWA: 40 mg/m ³ 8	TWA: 10 ppm 8
	TWA: 40 mg/m ³ 8	STEL: 80 mg/m ³ 15 min	STEL: 80 mg/m ³	órában. AK	klukkustundum.
	tundides.	STEL: 20 ppm 15 min	TWA: 10 ppm	lehetséges borön	TWA: 40 mg/m ³ 8
	STEL: 20 ppm 15		TWA: 40 mg/m ³	keresztüli felszívódás	klukkustundum.
	minutites.				
	STEL: 80 mg/m ³ 15				
	minutites.				
Sulfuric acid	TWA: 0.05 mg/m ³ 8 tundides. particles that reach the upper respiratory tract	TWA: 0.05 mg/m³ 8 hr when selecting an appropriate exposure monitoring method, account should be taken of potential limitations and interferences that may arise in the presence of other sulphur compounds thoracic fraction	TWA: 0.05 mg/m ³	TWA: 0.05 mg/m³ 8 órában. AK	TWA: 0.05 mg/m³ 8 klukkustundum. thoracic fraction Ceiling: 0.1 mg/m³ aerosol

Component	Latvia	Lithuania	Luxembourg	Malta	Romania
1-Methyl-2-pyrrolidon	skin - potential for	TWA: 10 ppm IPRD	Possibility of significant	possibility of significant	Skin notation
е	cutaneous exposure	TWA: 40 mg/m ³ IPRD	uptake through the skin	uptake through the skin	TWA: 10 ppm 8 ore
	STEL: 20 ppm	Oda	TWA: 40 mg/m ³ 8	TWA: 40 mg/m ³	TWA: 40 mg/m ³ 8 ore
	STEL: 80 mg/m ³	STEL: 20 ppm	Stunden	TWA: 10 ppm	STEL: 20 ppm 15
	TWA: 10 ppm	STEL: 80 mg/m ³	TWA: 10 ppm 8	STEL: 80 mg/m ³ 15	minute
	TWA: 40 mg/m ³		Stunden	minuti	STEL: 80 mg/m ³ 15
			STEL: 80 mg/m ³ 15	STEL: 20 ppm 15 minuti	minute
			Minuten		
			STEL: 20 ppm 15		
			Minuten		
Sulfuric acid	TWA: 0.05 mg/m ³	TWA: 0.05 mg/m ³ vapor	TWA: 0.05 mg/m ³ 8	TWA: 0.05 mg/m ³	TWA: 0.05 mg/m ³ 8 ore
		IPRD	Stunden		
		STEL: 3 mg/m ³			

Component	Russia	Slovak Republic	Slovenia	Sweden	Turkey
1-Methyl-2-pyrrolidon	MAC: 100 mg/m ³	Ceiling: 80 mg/m ³	TWA: 10 ppm 8 urah	Binding STEL: 20 ppm	Deri
e		Potential for cutaneous	vapor	15 minuter	TWA: 10 ppm 8 saat
		absorption	TWA: 40 mg/m ³ 8 urah	Binding STEL: 80	TWA: 40 mg/m ³ 8 saat
		TWA: 40 mg/m ³	vapor	mg/m ³ 15 minuter	STEL: 20 ppm 15
		TWA: 10 ppm	Koža	TLV: 3.6 ppm 8 timmar.	dakika
			STEL: 20 ppm 15	NGV	STEL: 80 mg/m ³ 15
			minutah vapor	TLV: 14.4 mg/m ³ 8	dakika
			STEL: 80 mg/m ³ 15	timmar. NGV	
			minutah vapor	Hud	
Sulfuric acid	Skin notation	TWA: 0.05 mg/m ³	TWA: 0.05 mg/m ³ 8	Indicative STEL: 0.2	TWA: 0.05 mg/m ³ 8 saat
	MAC: 1 mg/m ³	_	urah inhalable fraction,	mg/m³ 15 minuter	_
	_		fog	TLV: 0.1 mg/m ³ 8	
			STEL: 0.05 mg/m ³ 15	timmar. NGV	
			minutah inhalable		
			fraction, fog		

IDEIA Borrelia IgG Kit TM

Revision Date 10-Dec-2021

Biological limit values

List source(s):

Component	European Union	United Kingdom	France	Spain	Germany
1-Methyl-2-pyrrolidon				2-Hydroxy-N-methylsuc	5-Hydroxy-N-methyl-2-p
е				cinimide: 20 mg/g	yrrolidone: 150 mg/L
				Creatinine urine	urine (end of shift)
				pre-shift	
				5-Hydroxy-N-methyl-2-p	
				yrrolidone: 70 mg/g	
				Creatinine urine	
				between 2-4 hours after	
				the final exposure	

Component	Italy	Finland	Denmark	Bulgaria	Romania
1-Methyl-2-pyrrolidon		5-Hydroxy-N-methyl-2-p			
е		yrrolidone: 8 µmol/mol			
		Creatinine urine in the			
		morning after a working			
		day.			
		2-Hydroxy-N-methyl-suc			
		cinimide: 5 µmol/mol			
		Creatinine urine after			
		the shift.			

Monitoring methods

BS EN 14042:2003 Title Identifier: Workplace atmospheres. Guide for the application and use of procedures for the assessment of exposure to chemical and biological agents.

Derived No Effect Level (DNEL) / Derived Minimum Effect Level (DMEL)

See table for values

Component	Acute effects local (Dermal)	Acute effects systemic (Dermal)	Chronic effects local (Dermal)	Chronic effects systemic (Dermal)
1-Methyl-2-pyrrolidone 872-50-4 (5 -9.99)				DNEL = 4.8mg/kg bw/day

Component	Acute effects local (Inhalation)	Acute effects systemic (Inhalation)	Chronic effects local (Inhalation)	Chronic effects systemic (Inhalation)
1-Methyl-2-pyrrolidone 872-50-4 (5 -9.99)			DNEL = 40mg/m ³	DNEL = 14.4mg/m ³
Sulfuric acid 7664-93-9 (4.5)	DNEL = 0.1mg/m ³		DNEL = 0.05mg/m ³	

Predicted No Effect Concentration (PNEC)

See values below.

	Component	Fresh water	Fresh water sediment	Water Intermittent	Microorganisms in sewage treatment	Soil (Agriculture)
	1-Methyl-2-pyrrolidone 872-50-4 (5 -9.99)	PNEC = 0.25mg/L	PNEC = 1.09mg/kg sediment dw	PNEC = 5mg/L	PNEC = 10mg/L	PNEC = 0.0701mg/kg soil dw
I	Sulfuric acid 7664-93-9 (4.5)	PNEC = 0.0025mg/L	PNEC = 0.002mg/kg sediment dw		PNEC = 8.8mg/L	

Component Marine water Marine water Food chain Air
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IDEIA Borrelia IgG Kit TM

		sediment	Intermittent	
1-Methyl-2-pyrrolidone	PNEC = 0.025mg/L	PNEC =		
872-50-4 (5 -9.99)		0.109mg/kg		
, ,		sediment dw		
Sulfuric acid	PNEC =	PNEC =		
7664-93-9 (4.5)	0.00025mg/L	0.002mg/kg		
		sediment dw		

8.2. Exposure controls

Engineering Measures

Ensure adequate ventilation, especially in confined areas.

Wherever possible, engineering control measures such as the isolation or enclosure of the process, the introduction of process or equipment changes to minimise release or contact, and the use of properly designed ventilation systems, should be adopted to control hazardous materials at source

Personal protective equipment

Eye Protection Wear safety glasses with side shields (or goggles) (European standard - EN 166)

Hand Protection Protective gloves

Glove material	Breakthrough time	Glove thickness	EU standard	Glove comments
Disposable gloves	See manufacturers	-	EN 374	(minimum requirement)
	recommendations			

Skin and body protection Long sleeved clothing.

Inspect gloves before use. observe the instructions regarding permeability and breakthrough time which are provided by the supplier of the gloves. (Refer to manufacturer/supplier for information) gloves are suitable for the task: Chemical compatability, Dexterity, Operational conditions, User susceptibility, e.g. sensitisation effects, also take into consideration the specific local conditions under which the product is used, such as the danger of cuts, abrasion. gloves with care avoiding skin contamination.

Respiratory Protection When workers are facing concentrations above the exposure limit they must use

appropriate certified respirators.

To protect the wearer, respiratory protective equipment must be the correct fit and be used

and maintained properly

Large scale/emergency use In case of insufficient ventilation, wear suitable respiratory equipment

Small scale/Laboratory use Use a NIOSH/MSHA or European Standard EN 149:2001 approved respirator if exposure

limits are exceeded or if irritation or other symptoms are experienced.

When RPE is used a face piece Fit Test should be conducted

Environmental exposure controls No information available.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

Physical State Liquid

Appearance Varies

Odor No information available
Odor Threshold No data available

Odor ThresholdNo data availableMelting Point/RangeNo data availableSoftening PointNo data availableBoiling Point/RangeNot applicableFlammability (liquid)No data available

Flammability (solid,gas) Not applicable Liquid

Explosion Limits No data available

OXDK602911-2

Revision Date 10-Dec-2021

IDEIA Borrelia IgG Kit TM Revision Date 10-Dec-2021

Flash Point Not applicable Method - No information available

Autoignition Temperature
Decomposition Temperature
pH
Viscosity
Vater Solubility

No data available
No data available
No information available
No data available
Soluble in water

Solubility in other solvents No information available

Partition Coefficient (n-octanol/water)

Component log Pow 1-Methyl-2-pyrrolidone -0.46

Vapor Pressure
Density / Specific Gravity
Bulk Density
No data available
No data available
Not applicable

Vapor Density
Particle characteristics
No data available
Not applicable (liquid)

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9.2. Other information

SECTION 10: STABILITY AND REACTIVITY

Liquid

(Air = 1.0)

10.1. Reactivity

None known, based on information available

10.2. Chemical stability

Stable under recommended storage conditions.

10.3. Possibility of hazardous reactions

Hazardous Polymerization Hazardous polymerization does not occur.

Hazardous Reactions None under normal processing.

10.4. Conditions to avoid

Incompatible products. Excess heat.

10.5. Incompatible materials

None known.

10.6. Hazardous decomposition products

None under normal use conditions.

SECTION 11: TOXICOLOGICAL INFORMATION

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

Product Information Product does not present an acute toxicity hazard based on known or supplied information

(a) acute toxicity;

OralBased on available data, the classification criteria are not metDermalBased on available data, the classification criteria are not metInhalationBased on available data, the classification criteria are not met

Toxicology data for the components

Component	LD50 Oral	LD50 Dermal	LC50 Inhalation
1-Methyl-2-pyrrolidone	LD50 = 3914 mg/kg (Rat)	LD50 = 8 g/kg (Rabbit)	LC50 > 5.1 mg/L (Rat) 4 h

IDEIA Borrelia IgG Kit TM

Sulfuric acid LD50 = 2140 mg/kg (Rat) - LC50 = 0.375 mg/L (Rat) 4 h

(b) skin corrosion/irritation; No data available

(c) serious eye damage/irritation; No data available

(d) respiratory or skin sensitization;

Respiratory No data available Skin No data available

(e) germ cell mutagenicity; No data available

(f) carcinogenicity; No data available

The table below indicates whether each agency has listed any ingredient as a carcinogen

Revision Date 10-Dec-2021

Component	EU	UK	Germany	IARC
Sulfuric acid				Group 1

(g) reproductive toxicity; Category 1B

Developmental Effects May cause harm to the unborn child.

(h) STOT-single exposure; No data available

(i) STOT-repeated exposure; No data available

Target Organs No information available.

(j) aspiration hazard; No data available

Symptoms / effects,both acute and No information available.

delayed

11.2. Information on other hazards

Endocrine Disrupting Properties Assess endocrine disrupting properties for human health. This product does not contain any

known or suspected endocrine disruptors.

SECTION 12: ECOLOGICAL INFORMATION

12.1. Toxicity
Ecotoxicity effects

Component	Freshwater Fish	Water Flea	Freshwater Algae
1-Methyl-2-pyrrolidone	LC50: = 1400 mg/L, 96h static (Poecilia reticulata) LC50: = 1072 mg/L, 96h static (Pimephales promelas) LC50: = 832 mg/L, 96h static (Lepomis macrochirus)	EC50: = 4897 mg/L, 48h (Daphnia magna)	EC50: > 500 mg/L, 72h (Desmodesmus subspicatus)
Sulfuric acid	LC50: > 500 mg/L, 96h static	EC50: 29 mg/L/24h	

IDEIA Borrelia IgG Kit TM

Revision Date 10-Dec-2021

(Brachydanio rerio)	

12.2. Persistence and degradability

Persistence

Soluble in water, Persistence is unlikely, based on information available.

12.3. Bioaccumulative potential Bioaccumulation is unlikely

Component	log Pow	Bioconcentration factor (BCF)	
1-Methyl-2-pyrrolidone	-0.46	No data available	

12.4. Mobility in soil The product is water soluble, and may spread in water systems Will likely be mobile in the

environment due to its water solubility. Highly mobile in soils

12.5. Results of PBT and vPvB

assessment

No data available for assessment.

12.6. Endocrine disrupting

properties

Endocrine Disruptor Information

This product does not contain any known or suspected endocrine disruptors

12.7. Other adverse effects

Persistent Organic Pollutant Ozone Depletion Potential This product does not contain any known or suspected substance This product does not contain any known or suspected substance

SECTION 13: DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Waste from Residues/Unused

Products

Dispose of in accordance with federal, state and local regulations. Waste is classified as hazardous. Dispose of in accordance with the European Directives on waste and

hazardous waste. Dispose of in accordance with local regulations.

Contaminated Packaging Dispose of in accordance with local regulations. Dispose of this container to hazardous or

special waste collection point.

European Waste Catalogue (EWC) According to the European Waste Catalog, Waste Codes are not product specific, but

application specific.

Other Information Waste codes should be assigned by the user based on the application for which the product

was used. Do not empty into drains.

Switzerland - Waste Ordinance Disposal should be in accordance with applicable regional, national and local laws and

regulations. Ordinance on the Avoidance and the Disposal of Waste (Waste Ordinance,

ADWO) SR 814.600

https://www.fedlex.admin.ch/eli/cc/2015/891/en

SECTION 14: TRANSPORT INFORMATION

IMDG/IMO

14.1. UN numberUN279614.2. UN proper shipping nameSulphuric acid

IDEIA Borrelia IgG Kit TM Revision Date 10-Dec-2021

14.3. Transport hazard class(es) 8
14.4. Packing group II

ADR

14.1. UN numberUN279614.2. UN proper shipping nameSulphuric acid

14.3. Transport hazard class(es) 8
14.4. Packing group II

<u>IATA</u>

14.1. UN numberUN279614.2. UN proper shipping nameSulphuric acid

14.3. Transport hazard class(es) 8 14.4. Packing group 8

14.5. Environmental hazards No hazards identified

14.6. Special precautions for user No special precautions required

14.7. Maritime transport in bulk according to IMO instruments

Not applicable, packaged goods

SECTION 15: REGULATORY INFORMATION

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

International Inventories

Europe (EINECS/ELINCS/NLP), China (IECSC), Taiwan (TCSI), Korea (KECL), Japan (ENCS), Japan (ISHL), Canada (DSL/NDSL), Australia (AICS), New Zealand (NZIoC), Philippines (PICCS). US EPA (TSCA) - Toxic Substances Control Act, (40 CFR Part 710)

Component	CAS No	EINECS	ELINCS	NLP	IECSC	TCSI	KECL	ENCS	ISHL
1-Methyl-2-pyrrolidone	872-50-4	212-828-1	-	-	X	X	KE-25324	X	X
Sulfuric acid	7664-93-9	231-639-5	-	-	X	X	KE-32570	X	Х

Component	CAS No	TSCA	TSCA Inventory notification - Active-Inactive	DSL	NDSL	AICS	NZIoC	PICCS
1-Methyl-2-pyrrolidone	872-50-4	X	ACTIVE	X	-	X	X	Х
Sulfuric acid	7664-93-9	Х	ACTIVE	Х	-	Х	Х	Х

Legend: X - Listed '-' - Not Listed KECL - NIER number or KE number (http://ncis.nier.go.kr/en/main.do)

Authorisation/Restrictions according to EU REACH

	Component	REACH (1907/2006) - Annex XIV - Substances Subject to Authorization	REACH (1907/2006) - Annex XVII - Restrictions on Certain Dangerous Substances	REACH Regulation (EC 1907/2006) article 59 - Candidate List of Substances of Very High Concern (SVHC)
	1-Methyl-2-pyrrolidone	-	Use restricted. See item 72. (see link for restriction details) Use restricted. See item 30. (see link for restriction details) Use restricted. See item 71. (see link for restriction details) Use restricted. See item 75. (see link for restriction details)	SVHC Candidate list - 212-828-1 - Toxic for reproduction, Article 57c
ı	Sulfuric acid	-	Use restricted. See item 75.	_

IDEIA Borrelia IgG Kit TM

Revision Date 10-Dec-2021

	(see link for restriction details)	

After the sunset date the use of this substance requires either an authorization or can only be used for exempted uses, e.g. use in scientific research and development which includes routine analytics or use as intermediate.

https://echa.europa.eu/authorisation-list

https://echa.europa.eu/substances-restricted-under-reach

https://echa.europa.eu/candidate-list-table

Component	CAS No	Seveso III Directive (2012/18/EC) -	Seveso III Directive (2012/18/EC) -
		Qualifying Quantities for Major	Qualifying Quantities for Safety
		Accident Notification	Report Requirements
1-Methyl-2-pyrrolidone	872-50-4	Not applicable	Not applicable
Sulfuric acid	7664-93-9	Not applicable	Not applicable

Regulation (EC) No 649/2012 of the European Parliament and of the Council of 4 July 2012 concerning the export and import of dangerous chemicals

Not applicable

Take note of Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work .

Take note of Directive 2000/39/EC establishing a first list of indicative occupational exposure limit values

Take note of Directive 94/33/EC on the protection of young people at work

Take note of Dir 92/85/EC on the protection of pregnant and breastfeeding women at work

National Regulations

UK - Take note of Control of Substances Hazardous to Health Regulations (COSHH) 2002 and 2005 Amendment

WGK Classification

Water endangering class = 1 (self classification)

	Component	Germany - Water Classification (VwVwS)	Germany - TA-Luft Class
1-Me	thyl-2-pyrrolidone	WGK1	
	Sulfuric acid	WGK1	

Component	France - INRS (Tables of occupational diseases)
1-Methyl-2-pyrrolidone	Tableaux des maladies professionnelles (TMP) - RG 84

Swiss Regulations

Article 4 para. 4 of the Ordinance on the protection of young people in the workplace (SR 822.115) and Article 1 lit. f of the EAER regulation on hazardous work and young people (SR 822.115.2).

Take note on Article 13 Maternity Ordinance (SR 822.111.52) with regards expectant and nursing mothers.

Component	Switzerland - Ordinance on the Reduction of Risk from handling of hazardous substances preparation (SR 814.81)	Switzerland - Ordinance on Incentive Taxes on Volatile Organic Compounds (OVOC)	Switzerland - Ordinance of the Rotterdam Convention on the Prior Informed Consent Procedure
1-Methyl-2-pyrrolidone 872-50-4 (5 -9.99)		Group I	
Sulfuric acid 7664-93-9 (4.5)	Prohibited and Restricted Substances		

15.2. Chemical safety assessment

Chemical Safety Assessment/Reports (CSA/CSR) are not required for mixtures

SECTION 16: OTHER INFORMATION

Full text of H-Statements referred to under sections 2 and 3

IDEIA Borrelia IgG Kit TM

Revision Date 10-Dec-2021

H315 - Causes skin irritation

H318 - Causes serious eye damage H360D - May damage the unborn child

H314 - Causes severe skin burns and eye damage

H319 - Causes serious eye irritation H335 - May cause respiratory irritation

Legend

CAS - Chemical Abstracts Service

WEL - Workplace Exposure Limit

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory

EINECS/ELINCS - European Inventory of Existing Commercial Chemical DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances FU List of Notified Chemical Substances

PICCS - Philippines Inventory of Chemicals and Chemical Substances

ENCS - Japanese Existing and New Chemical Substances

PICCS - Philippines Inventory of Chemicals and Chemical Substances **IECSC** - Chinese Inventory of Existing Chemical Substances

KECL - Korean Existing and Evaluated Chemical Substances

TWA - Time Weighted Average **IARC** - International Agency for Research on Cancer

AICS - Australian Inventory of Chemical Substances

NZIoC - New Zealand Inventory of Chemicals

Predicted No Effect Concentration (PNEC)

ACGIH - American Conference of Governmental Industrial Hygienists **DNEL** - Derived No Effect Level

RPE - Respiratory Protective Equipment LC50 - Lethal Concentration 50% NOEC - No Observed Effect Concentration PBT - Persistent, Bioaccumulative, Toxic LD50 - Lethal Dose 50%
EC50 - Effective Concentration 50%
POW - Partition coefficient Octanol:Water
vPvB - very Persistent, very Bioaccumulative

ADR - European Agreement Concerning the International Carriage of Dangerous Goods by Road

IMO/IMDG - International Maritime Organization/International Maritime Dangerous Goods Code

OECD - Organisation for Economic Co-operation and Development

BCF - Bioconcentration factor

ICAO/IATA - International Civil Aviation Organization/International Air Transport Association

MARPOL - International Convention for the Prevention of Pollution from

Ships

ATE - Acute Toxicity Estimate VOC - (volatile organic compound)

Key literature references and sources for data

https://echa.europa.eu/information-on-chemicals

Suppliers safety data sheet, Chemadvisor - LOLI, Merck index, RTECS

Classification and procedure used to derive the classification for mixtures according to Regulation (EC) 1272/2008 [CLP]:

Physical hazards
On basis of test data
Health Hazards
Calculation method
Environmental hazards
Calculation method

Training Advice

Chemical hazard awareness training, incorporating labelling, Safety Data Sheets (SDS), Personal Protective Equipment (PPE) and hygiene.

Creation Date26-Mar-2012Revision Date10-Dec-2021

Revision Summary Update to CLP Format.

This safety data sheet complies with the requirements of Regulation (EC) No. 1907/2006. COMMISSION REGULATION (EU) 2020/878 amending Annex II to Regulation (EC) No 1907/2006

For Switzerland - Compiled in accordance with the technical provisions referred to in Annex 2, Number 3, ChemO (SR 813.11 - Ordinance on Protection against Dangerous Substances and Preparations).

Disclaimer

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other

Revision Date 10-Dec-2021

materials or in any process, unless specified in the text

End of Safety Data Sheet