

Australian statement of hazardous nature : Classified as hazardous according to criteria of Safe Work Australia

Section 1 - Identification

Product Name IDEIA Borrelia IgG Kit TM

Product Code	K602911-2
Address	ThermoFisher Scientific Australia Pty Ltd 5 Caribbean Drive, Scoresby VICTORIA 3179, Australia
Emergency Tel.	CHEMTREC® 03 9757 4559 or +613 9757 4559
Telephone / Fax Numbers	Tel: 1300 735 292 Fax: 1800 067 639
E-mail address	ANZinfo@thermofisher.com

Recommended Use In vitro diagnostic.

Uses advised against This product contains one or more substance(s) on the Illicit Drug Precursors/Reagents list. Verify requirements related to using, handling and storing these substances. This product does not contain any substance(s) subject to Prohibition, Authorization or Restriction. This product contains one or more substance(s) listed on the voluntary National Code of Practice for Chemicals of Security Concern.

Section 2 - Hazard(s) Identification

Classification under Safe Work Australia

Classified as hazardous according to criteria of Safe Work Australia

Physical hazards
No hazards identified

Health hazards

Skin Corrosion/Irritation
Serious Eye Damage/Eye Irritation
Reproductive Toxicity

Category 2
Category 1
Category 1B

Environmental hazards
No hazards identified

Label Elements



Health Hazard



Corrosion

Signal Word**Danger****Hazard Statements**

H315 - Causes skin irritation

H318 - Causes serious eye damage

H360 - May damage fertility or the unborn child

Precautionary Statements

P201 - Obtain special instructions before use

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

P264 - Wash face, hands and any exposed skin thoroughly after handling

P280 - Wear protective gloves/protective clothing/eye protection/face protection

P302 + P352 - IF ON SKIN: Wash with plenty of soap and water

P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing

P310 - Immediately call a POISON CENTER or doctor

P362 + P364 - Take off contaminated clothing and wash it before reuse

P403 - Store in a well-ventilated place

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

Other information

This product does not contain any known or suspected endocrine disruptors

Section 3 - Composition and Information on Ingredients

Component	CAS No	Weight %
SUBSTRATE - N-Methyl-2-pyrrolidone (NMP)	872-50-4	5 -9.99

Section 4 - First Aid Measures

Inhalation	Remove to fresh air. If not breathing, give artificial respiration. Get medical attention if symptoms occur.
Ingestion	Clean mouth with water and drink afterwards plenty of water. Get medical attention.
Skin Contact	Wash off immediately with plenty of water for at least 15 minutes. If skin irritation persists, call a physician.
Eye Contact	Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Get medical attention.
General Advice	If symptoms persist, call a physician.
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.
First Aid Facilities	Eyewash, safety shower and washroom.
Most important symptoms and effects	None reasonably foreseeable. Causes eye burns.
Notes to Physician	Treat symptomatically.

Section 5 - Fire Fighting Measures

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.

Specific Hazards Arising from the Chemical

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

Special protective equipment and precautions for fire fighters

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

Section 6 - Accidental Release Measures

Emergency procedures

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

Environmental Precautions

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

Methods for Containment and Clean Up

Clean-up methods - small spillage

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

Clean-up methods - large spillage

Typically only supplied in small quantities as packaged goods.

If extremely toxic or used in larger quantities ensure a spillage action plan is in place. Evacuate area. Control the source and/or contain the spill if safe and able to do so. Use temporary diking, sand bags, dry sand, earth or proprietary booms/absorbent pads if available. Obtain advice on containment, neutralisation and clean-up from local emergency responders.

Reference to Other Sections

Refer to protective measures listed in Sections 8 and 13.

Section 7 - Handling and Storage

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.

Conditions for Safe Storage, Including any Incompatibilities

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

AS/NZS 2243.10:2004, Safety in laboratories - Storage of chemicals

Section 8 - Exposure Controls and Personal Protection

Exposure limits

AUS - Exposure Standards for Atmospheric Contaminants in the Occupational Environment - Guidance Note on the Interpretation of Exposure Standards for Atmospheric Contaminants in the Occupational Environment [NOHSC:3008(1995)]

Adopted National Exposure Standards for Atmospheric Contaminants in the Occupational Environment [NOHSC:1003(1995)] updated in August, 2005. Safe Work Australia

ACGIH - Threshold Limit Values - Ceiling (TLV-C) guidelines by the American Conference of Governmental Industrial Hygienists

(ACGIH) for controlling worker exposure to airborne chemical concentrations in the workplace.

UK - EH40/2005 Work Exposure Limits, Fourth edition. Published 2020.

DE - MAK and BAT values of Hazardous Chemical Compounds in the Work Area. Published by German Research Foundation on July 1, 2011

NZ - Workplace Exposure Standards and Biological Exposure Indices (6th edition). New Zealand Department of Labor

Component	Australia	New Zealand WEL	ACGIH TLV	The United Kingdom	Germany
SUBSTRATE - N-Methyl-2-pyrrolidone (NMP)	STEL: 75 ppm STEL: 309 mg/m ³ TWA: 25 ppm TWA: 103 mg/m ³	TWA: 25 ppm TWA: 103 mg/m ³ STEL: 75 ppm STEL: 309 mg/m ³ Skin		STEL: 20 ppm 15 min STEL: 80 mg/m ³ 15 min TWA: 10 ppm 8 hr TWA: 40 mg/m ³ 8 hr Skin	TWA: 20 ppm (8 Stunden). AGW - exposure factor 2 TWA: 82 mg/m ³ (8 Stunden). AGW - exposure factor 2 TWA: 20 ppm (8 Stunden). MAK can occur as vapor and aerosol at the same 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

Biological limit values

This product, as supplied, does not contain any hazardous materials with biological limits established by the region specific regulatory bodies

Component	Australia	New Zealand	European Union	United Kingdom	Germany
SUBSTRATE - N-Methyl-2-pyrrolidone (NMP)					5-Hydroxy-N-methyl-2-pyrrolidone: 150 mg/L urine (end of shift)

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) (Australian/New Zealand Standard AS/NZS 1337 - Eye protectors for Industrial applications)

Hand Protection

Protective gloves

Glove material	Breakthrough time	Glove thickness	AUS/NZ Standard	Glove comments
Disposable gloves	See manufacturers recommendations	-	AS/NZS 2161	(minimum requirement)

Inspect gloves before use.

Please observe the instructions regarding permeability and breakthrough time which are provided by the supplier of the gloves.

(Refer to manufacturer/supplier for information)

Ensure gloves are suitable for the task: Chemical compatibility, 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.

Remove gloves with care avoiding skin contamination.

Skin and body protection

Long sleeved clothing

Respiratory Protection

Use an AS/NZS 1716 approved respirator if exposure limits are exceeded or if irritation or other symptoms are experienced. To protect the wearer, respiratory protective equipment must be the correct fit and be used and maintained in line with AS/NZS 1715 on the use

and maintenance of respiratory protective devices (or AUS/NZ equivalent)
When RPE is used a face piece Fit Test should be conducted

Hygiene Measures Handle in accordance with good industrial hygiene and safety practice.

Environmental exposure controls No information available.

Section 9 - Physical and Chemical Properties

Information on basic physical and chemical properties

Appearance	Varies	
Physical State	Liquid	
Odor	No information available	
Odor Threshold	No data available	
pH	No information available	
Melting Point/Range	No data available	
Softening Point	No data available	
Boiling Point/Range	Not applicable	
Flash Point	Not applicable	Method - No information available
Evaporation Rate	No data available	
Flammability (solid,gas)	Not applicable	Liquid
Explosion Limits	No data available	
Vapor Pressure	No data available	
Vapor Density	No data available	(Air = 1.0)
Specific Gravity / Density	No data available	
Bulk Density	Not applicable	Liquid
Water Solubility	Soluble in water	
Solubility in other solvents	No information available	
Partition Coefficient (n-octanol/water)		
Component	log Pow	
SUBSTRATE -	-0.46	
N-Methyl-2-pyrrolidone (NMP)		
Autoignition Temperature	No data available	
Decomposition Temperature	No data available	
Viscosity	No data available	
Explosive Properties	No information available	
Oxidizing Properties	No information available	

Other information

Section 10 - Stability and Reactivity

Reactivity	None known, based on information available
Stability	Stable under recommended storage conditions.
Conditions to Avoid	Heat, flames and sparks.
Incompatible Materials	None known.
Hazardous Decomposition Products	None under normal use conditions.
Hazardous Polymerization	Hazardous polymerization does not occur.

Section 11 - Toxicological Information

Information on Toxicological Effects

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

(a) acute toxicity;

Oral

Based on available data, the classification criteria are not met

Dermal

Based on available data, the classification criteria are not met

Inhalation

Based on available data, the classification criteria are not met

Toxicology data for the components

Component	LD50 Oral	LD50 Dermal	LC50 Inhalation
SUBSTRATE - N-Methyl-2-pyrrolidone (NMP)	LD50 = 3914 mg/kg (Rat)	LD50 = 8 g/kg (Rabbit)	LC50 > 5.1 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

(g) reproductive toxicity;
Developmental Effects

Category 1B

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 delayed No information available

Section 12 - Ecological Information

Ecotoxicity effects

Component	Freshwater Fish	Water Flea	Freshwater Algae	Microtox
SUBSTRATE - N-Methyl-2-pyrrolidone (NMP)	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)	

Persistence and Degradability**Persistence**

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

Bioaccumulative Potential

Bioaccumulation is unlikely

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

Mobility

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

Endocrine Disruptor Information

This product does not contain any known or suspected endocrine disruptors

Persistent Organic Pollutant

This product does not contain any known or suspected substance

Ozone Depletion Potential

This product does not contain any known or suspected substance

Section 13 - Disposal Considerations

Waste from Residues/Unused Products

Do not allow into drains or watercourses or dispose of where ground or surface waters may be affected. Wastes, including emptied containers, are controlled wastes and should be disposed of in accordance with all federal, E.P.A., state and local regulations. Assure conformity with all applicable regulations.

Contaminated Packaging

Dispose of in accordance with local regulations. Dispose of this container to hazardous or special waste collection point.

Other Information

Chemical wastes should be disposed through a licensed commercial waste collection service. Waste codes should be assigned by the user based on the application for which the product was used. Do not empty into drains.

Section 14 - Transport Information

IMDG/IMO

UN-No	UN2796
Proper Shipping Name	Sulphuric acid
Hazard Class	8
Packing Group	II

ADG

UN-No	UN2796
Proper Shipping Name	Sulphuric acid
Hazard Class	8
Packing Group	II

IATA

UN-No	UN2796
Proper Shipping Name	Sulphuric acid
Hazard Class	8
Packing Group	II

Environmental hazards

No hazards identified

Special Precautions

No special precautions required

Additional information

None known

Section 15 - Regulatory Information

Safety, health and environmental regulations/legislation specific for the substance or mixture**National Regulations****Australia**

See section 8 for national exposure control parameters.

Standard for the Uniform Scheduling of Medicines and Poisons

Classified as a scheduled poison according to the Standard for Uniform Scheduling of Medicines and Poisons.

Component	Standard for the Uniform Scheduling of Medicines and Poisons
SUBSTRATE - N-Methyl-2-pyrrolidone (NMP) - 872-50-4	Schedule 5 listed - when packed in single use containers having a capacity of <=2 mL Schedule 5 listed - in preparations of N-Methyl-2-pyrrolidone or preparations containing <=50% of a mixture of any two or more of N-Methyl-2-pyrrolidone, N-(N-Octyl)-2-pyrrolidone or N-(N-Dodecyl)-2-pyrrolidone except in preparations containing <=25% of designated solvent Schedule 6 listed - except when included in Schedule 5, or in preparations containing <=25% of designated solvent

Australian Industrial Chemicals Introduction Scheme (AICIS)

Component	Australian Industrial Chemicals Introduction Scheme (AICIS)	Additional information
SUBSTRATE - N-Methyl-2-pyrrolidone (NMP) - 872-50-4	Present	-

Australian - Illicit Drug Precursors/Reagents Substance List

This product contains one or more substance(s) on the Illicit Drug Precursors/Reagents list. Verify requirements related to using, handling and storing these substances.

Chemicals of Security Concern

This product contains one or more substance(s) listed on the voluntary National Code of Practice for Chemicals of Security Concern

Legend

Category 3 - Chemicals and apparatus that may be used in the illicit production of drugs. Purchases from this list should alert companies or organizations to seek further indicators of any suspicious orders or enquiries. No official reporting is required for items on this list unless considered warranted

Chemicals of Security Concern - for further information see <http://www.chemicalsecurity.gov.au/securityconcerns>

National pollutant inventory

Subject to reporting requirements

Prohibition or notification/licensing requirements

Shown below are details of specific prohibition/notifications or licensing requirements when they apply.

This product does not contain any substance(s) subject to Prohibition, Authorization or Restriction.

International Inventories

Component	AICS	NZIoC	EINECS	ELINCS	TSCA	DSL	NDSL	PICCS	ENCS	ISHL	IECSC	KECL
SUBSTRATE - N-Methyl-2-pyrrolidone (NMP)	X	X	212-828-1	-	X	X	-	X	X	X	X	KE-25324

Legend: X - Listed. '-' - Not Listed. R - Indicates a substance that is the subject of a Section 6 risk management rule under TSCA. **KECL** - NIER number or KE number (<http://ncis.nier.go.kr/en/main.do>)

International Regulations

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

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

Rotterdam Convention (PIC) Not applicable

Basel convention on the control of transboundary movements of hazardous wastes and their disposal

Take note that wastes may be subject to export, import, or transit controls pursuant to the Basel convention and/or local regulations implementing the Basel convention.

Component	CAS No	OECD HPV	Restriction of Hazardous Substances (RoHS)	Seveso III Directive (2012/18/EC) - Qualifying Quantities for Major Accident Notification	Seveso III Directive (2012/18/EC) - Qualifying Quantities for Safety Report Requirements
SUBSTRATE - N-Methyl-2-pyrrolidone (NMP)	872-50-4	Listed	Not applicable	Not applicable	Not applicable

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)
SUBSTRATE - N-Methyl-2-pyrrolidone (NMP)	-	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

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>

Section 16 - Other InformationLegend

AICS - Australian Inventory of Chemical Substances
TSCA - United States Toxic Substances Control Act Section 8(b) Inventory
DSL/NDL - Canadian Domestic Substances List/Non-Domestic Substances List
IECSC - Chinese Inventory of Existing Chemical Substances
PICCS - Philippines Inventory of Chemicals and Chemical Substances
TWA - Time Weighted Average
IARC - International Agency for Research on Cancer
ICAO/IATA - International Civil Aviation Organization/International Air Transport Association

NZIoC - New Zealand Inventory of Chemicals
EINECS/ELINCS - European Inventory of Existing Commercial Chemical Substances/EU List of Notified Chemical Substances
ENCS - Japanese Existing and New Chemical Substances
KECL - Korean Existing and Evaluated Chemical Substances
CAS - Chemical Abstracts Service
ACGIH - American Conference of Governmental Industrial Hygienists
 Predicted No Effect Concentration (PNEC)
IMO/IMDG - International Maritime Organization/International Maritime Dangerous Goods Code

MARPOL - International Convention for the Prevention of Pollution from Ships

NZS 5433:2020 - Transport of Dangerous Goods on Land

LD50 - Lethal Dose 50%

EC50 - Effective Concentration 50%

WEL - Workplace Exposure Limit

DNEL - Derived No Effect Level

POW - Partition coefficient Octanol:Water

vPvB - very Persistent, very Bioaccumulative

VOC - (Volatile Organic Compound)

ADG - Australian Code for the Transport of Dangerous Goods by Road and Rail

OECD - Organisation for Economic Co-operation and Development

LC50 - Lethal Concentration 50%

ATE - Acute Toxicity Estimate

RPE - Respiratory Protective Equipment

NOEC - No Observed Effect Concentration

BCF - Bioconcentration factor

PBT - Persistent, Bioaccumulative, Toxic

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.

Revision Date 30-Jun-2023

Revision Summary Update to CLP Format.

This Safety Data Sheet (SDS) is prepared in accordance to and complies with the requirements of Safe Work Australia - Work Health and Safety Regulations (WHS Regulations).

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 materials or in any process, unless specified in the text

End of Safety Data Sheet