

Safety Data Sheet

Section 1: Identification of Substance/Mixture and of the company/undertaking

1.1 Product identifiers

Product Name: C6 Lyme ELISA™ kit
Product Number: DK-E601-096, DK-E601-096-A
REACH Number: A registration number is not available for these substances, as the substances or their uses are exempted from registration or the annual tonnage does not require registration

1.2 Relevant identified uses and uses advised against

Identified uses: Enzyme-linked immunosorbent assay for the qualitative presumptive detection of total IgG and IgM antibodies to *Borrelia burgdorferi* in human serum

1.3 Details of the supplier of the safety data sheet

Manufacturer/Supplier: Immunetics Inc.
320 Norwood Park South
Norwood
MA 02062-4659
USA
Telephone: 800-227-4765 or 617-896-9100
Fax: 617-896-9110
Website: www.oxfordimmunotec.com

1.4 Emergency Telephone Number

Emergency Telephone: 617-896-9100

Section 2: Hazards Identification

2.1 Classification of substance or mixture (CLP Classification)

May be harmful if swallowed. May cause skin burns

2.2 Label elements

Pictogram:



Hazard Statement:

May be harmful if swallowed. May cause skin burns.

Precautionary Statements:

Wear protective gloves.
Wash hands thoroughly after handling.
Do not eat or drink while using this product.

2.3 Other hazards

None

Section 3: Composition/information on Components

Positive Control (CB-L018-300)

1 vial, 300 µL volume

Components	Weight %	CAS Number	EINECS-No.
2-Methyl-2H-isothiazol-3-one	0.04	2682-20-4	220-239-6
Gentamicin Sulfate	0.005	1405-41-0	215-778-9

Negative Control (CB-N023-300)

1 vial, 300 µL volume

Components	Weight %	CAS Number	EINECS-No.
2-Methyl-2H-isothiazol-3-one	0.04	2682-20-4	220-239-6
Gentamicin Sulfate	0.005	1405-41-0	215-778-9

Cutoff Calibrator (CB-N030-300)

1 vial, 300 µL volume

Components	Weight %	CAS Number	EINECS-No.
2-Methyl-2H-isothiazol-3-one	0.04	2682-20-4	220-239-6
Gentamicin Sulfate	0.005	1405-41-0	215-778-9

Congugate (CB-A028-015/CB-A028-025)

1 Bottle, 15/25 mL volume

Components	Weight %	CAS Number	EINECS-No.
Peroxidase-conjugated AffiniPure Goat Anti-Human IgG + IgM (H+L)	0.00026	n/a	n/a
Sodium Phosphate	0.00046	7558-79-4	231-448-7
Sodium Chloride	0.0047	7647-14-5	231-598-3
Mixture; 3(2H)-isothiazolone, 5-chloro-2-methyl-isothiazolone, 2-methyl-isothiazolone, 2-methyle-3(2H)-isothiazolone	0.0024	55965-84-9	613-167-00-5

Sample Diluent (CC-S004-030/CC-S004-060)

1 Bottle, 30/60 mL volume

Components	Weight %	CAS Number	EINECS-No.
Casein	1.0	9000-71-9	232-555-1
Tween 20	0.2	900-64-5	500-018-3
Gentamicin sulfate	0.005	1405-41-0	215-778-9
2-methyle-2H-isothiazol-3-one	0.04	2682-20-4	220-239-6
NaCl	0.0039	7647-14-5	231-598-3
KCl	0.0001	7447-40-7	231-211-8
Na ₂ HPO ₄	0.0007	7558-79-4	231-448-7
KH ₂ PO ₄	0.0002	7758-11-4	231-834-5

TMB ELISA Substrate (CC-S003-015/CC-S003-025)

1 Bottle, 15/25 mL volume

Components	Weight %	CAS Number	EINECS-No.
3,3',5,5'-Tetramethylbenzidine	<0.06	54827-17-7	259-364-6
Hydrogen peroxide	<0.03	7722-84-1	231-765-0

10X Wash Buffer Concentrate (CC-B001-060)

1 Bottle (or 3 bottles in automated kit), 60 mL volume each

Components	Weight %	CAS Number	EINECS-No.
Tween 20	0.5	900-64-5	500-018-3
2-methyle-2H-isothiazol-3-one	0.05	2682-20-4	220-239-6
NaCl	0.079	7647-14-5	231-598-3
KCl	0.002	7447-40-7	231-211-8
Na ₂ HPO ₄	0.014	7558-79-4	231-448-7
KH ₂ PO ₄	0.003	7758-11-4	231-834-5

Stop Solution (CC-S005-015/CC-S005-030)

1 Bottle, 15/30 mL volume

Components	Weight %	CAS Number	EINECS-No.
1N Sulfuric Acid	9.8	7664-93-9	231-639-5

Section 4: First Aid Measures

Eye contact:	For eye contact with kit reagents, rinse immediately with plenty of water for at least 15 minutes and seek medical attention. For eye contact with test specimens, Controls, and other kit reagents, flush with plenty of water and seek medical attention.
Ingestion:	If ingested, seek medical attention immediately and show the label.
Inhalation:	Move to fresh air immediately. Seek medical attention.
Skin contact:	Remove contaminated clothing and wash affected area with soap and water. If symptoms of skin irritation appear, seek medical attention. For skin contact with Stop Solution, flush with plenty of water for at least 15 minutes and seek immediate medical attention.
Protection of first-aiders:	Wear suitable gloves and eye/face protection.
Notes to physician:	None.

Section 5: Fire Fighting Measures

Suitable extinguishing media:	Use any extinguishing media that is suitable for the surrounding fire.
Extinguishing media which must not be used for safety reasons:	None.
Specific hazards:	The plastic components of the Microwell Plates will melt and/or decompose under fire conditions. Once ignited, the plastic materials will add to the intensity of the fire and can be expected to emit hazardous gases, vapours, fumes and smoke particles.
Special protective equipment for firefighters:	Wear self-contained breathing apparatus and protective suit for firefighting if necessary.
Combustion products or resulting gases:	Carbon monoxide, Carbon dioxide, Nitrogen oxides, Phosphorous oxides, Hydrogen chloride, Hydrogen bromide.

Section 6: Accidental Release Measures

Personal precautions:	Ensure adequate ventilation. Use suitable PPE for size of release and surrounding environment.
Environmental precautions:	Waste disposal must be in accordance with appropriate international, national, state and local laws and regulations.
Methods for cleaning up:	If Stop Solution spills, neutralise with soda ash, lime or a commercially available acid neutralizer. Decontaminate all other spills with a bleach solution or appropriate germicide prior to pick up.

Section 7: Handling and Storage

Precautions for safe handling:	Wear protective safety glasses, gloves and clothing. Wash hands afterwards.
Conditions for safe storage:	Keep refrigerated. Store in light protected bottles.
Incompatible products:	No special restrictions on storage with other products.
Specific use(s):	Apart from the uses stated in 1.2 no other uses are stipulated.

Section 8: Exposure Controls/Personal Protection

8.1 Control parameters

Contains no substances with occupational exposure limit values

8.2 Exposure controls

Engineering controls:	Ensure adequate ventilation.
Respiratory protection:	None required.
Hand protection:	Wear disposable gloves while handling the reagent. Wash hands after use.
Eye protection:	Wear safety glasses with side-shields.
Skin and body protection:	Wear suitable protective clothing.

8.3 Environmental exposure controls

Do not let product enter drains

Section 9: Physical and Chemical Properties

9.1 Positive Control (CB-L018-300)

Appearance:	Pale yellow clear liquid
pH:	7.0 - 7.4

9.2 Negative Control (CB-N023-300)

Appearance:	Pale yellow clear liquid
pH:	7.0 - 7.4

9.3 Cutoff Calibrator (CB-N030-300)

Appearance:	Pale yellow clear liquid
pH:	7.0 - 7.4

9.4 Conjugate (CB-A028-015/CB-A028-025)

Appearance:	Pale yellow clear liquid
pH:	6.3 - 6.5

9.5 Sample Diluent (CC-S004-030/CC-S004-060)

Appearance:	Colourless cloudy liquid
pH:	7.0 - 7.2

9.6 TMB ELISA Substrate (CC-S003-015/CC-S003-025)

Appearance: Colourless clear liquid
pH: 3.1 – 3.3

9.7 10X Wash Buffer Concentrate (CC-B001-060)

Appearance: Colourless clear liquid
pH: 6.7 – 6.9

9.8 Stop Solution (CC-S005-015/CC-S005-030)

Appearance: Colourless clear liquid
pH: 1.2 - 1.4

Section 10: Stability and Reactivity

- 10.1 Reactivity** No data available
- 10.2 Chemical stability** Stable under recommended storage conditions.
- 10.3 Possibility of hazardous reactions** Under normal conditions hazardous reactions will not occur.
- 10.4 Conditions to avoid** None known.
- 10.5 Materials to avoid** Stop Solution is incompatible with common metals, organic materials, strong oxidising agents, strong reducing agents, combustible materials, sulfides, cyanides and carbides.
- 10.6 Hazardous decomposition products:** Carbon monoxide, Carbon dioxide, Nitrogen oxides, Phosphorous oxides, Hydrogen chloride, Hydrogen bromide

Section 11: Toxicological Information

11.1 Information on toxicology effects

Acute toxicity: May cause irritation.
Skin corrosion/irritation: May cause irritation.
Serious eye damage/eye irritation: May cause irritation.
Respiratory or skin sensitisation: May cause irritation to mucous membranes and upper respiratory tract.
Germ cell mutagenicity: Not classified. No known significant effects or critical hazards.
Carcinogenicity: Not classified. No data available.
Reproductive toxicity: Not classified. No data available.
Aspiration hazard: Not classified. No data available.

Section 12: Ecological Information

Toxicity: No known significant effects or critical hazards.
Persistence and degradability: No data available.
Bioaccumulative potential: No data available.
Mobility in soil: No data available.
Results of PBT and vPvB: No data available.
Other adverse effects: No data available.

Section 13: Disposable Consideration

Waste from residues/unused products: Waste disposal must be in accordance with appropriate international, national, state and local laws and regulations.
Contaminated packaging: Waste disposal must be in accordance with appropriate international, national, state and local laws and regulations.
Methods for cleaning up: Wipe up with an inert adsorbent material (e.g. cloth, fleece) and clean contaminated surface thoroughly.

For Stop Solution, neutralise with soda ash, lime or a commercially available acid neutralizer. Decontaminate all other spills with a bleach solution or appropriate germicide prior to pick up.

Section 14: Transportation Information

The transport of this product is not regulated by IMO/IMDG, ADR/RID or IATA/ICAO as a hazardous material or dangerous goods.

Section 15: Regulatory Information

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

This safety data sheet complies with Regulation (EC) No. 1907/2006 REACH

The product is judged not to be hazardous to health or the environment according to current legislation.

15.2 Chemical safety assessment

Not required. No data available

Section 16: Other Information

Revisions:	Update in line with REACH/CLP/GHS regulations
MSDS Format:	European format in accordance with Directive 93/112/EEC.
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