Pneumo CEL IFA

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Section 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Product name: P

Pneumo CEL IFA Kit (50T)

(Components: Reagent, Positive Control & Mounting Fluid)

Product code: KP1

Components Code: (RP1, RP & RMF)

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

Use of substance / mixture: Direct Immunofluorescence assay (IFA) for the detection of *Pneumocystis jirovecii*. This product is intended for IN VITRO diagnostic use only.

1.3. Details of the supplier of the safety data sheet

Company Details

Cellabs Pty Ltd 7/27 Dale Street Brookvale 2100 NSW, Australia **Contact Details**

Telephone: +61 2 9905 0133 Fax: +61 2 9905 6426 email: <u>admin@cellabs.com.au</u>

1.4. Emergency telephone number

Emergency tel: + 61 2 9905 0133 (office hours only)

Section 2: Hazards identification

2.1. Classification of the substance or mixture

Classification under GHS, 1272/2008 EC Regulation and CLP:

The mixture contained in the reagent (RP1) is a monoclonal antibody coupled with a fluorescent label in aqueous solution. The reagent has no classification under CLP, however the mixture contains the following substances listed in Section 3.1, below the limit concentrations as described under the GHS. The mixture therefore is classified NON HAZARDOUS.

All other components listed in Section 1.1 are not classified in CLP.

IMPORTANT for TRANSPORT : NOTE THAT THE CONCENTRATIONS OF CLASSIFIED SOLUTIONS ARE VERY LOW, WITHIN ACCEPTABLE LIMITS. SEE TRANSPORT INFORMATION IN SECTION 14.

2.2. Label elements

| Label elements: GHS Hazard Pictograms: N/A | | | | |
|--|--|---|--|--|
| Signal Word | N/A | | | |
| Hazard statement(s): None applicable for the mixture and other kit components. | | | | |
| Precautionary statements: | P201: Obtain special instructions before u | use P102: Keep out of reach of children. | | |
| | P202: Do not handle until safety precautions have been read and understood | | | |
| | P234: Keep only in original container. | P281: Use personal protective equipment | | |
| | P273: Avoid release to the environment | P260: Do not get in eyes, skin or on clothing | | |





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P401: Store at 2-8oC P264: Wash skin thoroughly after handling

P308 + P313 +P314: If exposed or concerned, get medical advice/attention

P301 + P310 + P330: IF swallowed, immediately call a POISON CENTRE or doctor/physician

P302 + 352 + P314: IF on skin wash with plenty of water. Get medical advice if you feel unwell.

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

2.3. Other hazards

PBT: This product is not identified as a PBT/vPvB substance.

Section 3: Composition/information on ingredients

3.1. Substances

Chemical identity: Pneumo CEL Reagent (RP1)

Reagent (RP1) contained in Pneumo CEL IFA kit

| Reagent (INI I) oon | | | | |
|---------------------|-----------|---------------|---------------|--|
| CAS No. | EC No. | Chemical Name | Concentration | |
| 314-13-6 | 206-242-5 | Evans Blue | 0.005% | |
| 26628-22-8 | 247-852-1 | Sodium Azide | <0.1% | |

Contains: Contains no hazardous substances in reportable quantities under the CLP.

Section 4: First aid measures

4.1. Description of first aid measures

Skin contact: Wash immediately with plenty of soap and water.

Eye contact: Rinse cautiously with water for several minutes. Remove contact lenses, if present and

easy to do so. Continue rinsing. If eye irritation persists, seek medical advice/attention.

Ingestion: Do not induce vomiting. Wash mouth with water and give plenty of water to drink

immediately. Obtain medical attention if necessary and show label on container.

Inhalation: Irritation is unlikely to occur but in the event of discomfort, provide plenty of fresh air and if

necessary seek medical assistance.

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

Skin contact: There may be mild irritation at the site of contact.

Eye contact: There may be irritation and redness.

Ingestion: There may be irritation of the throat.

Inhalation: No symptoms.

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

Immediate / special treatment: Not applicable.

Section 5: Fire-fighting measures



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5.1. Extinguishing media

Extinguishing media: Suitable extinguishing media for the surrounding fire should be used. Use water spray

to cool containers.

5.2. Special hazards arising from the substance or mixture

Exposure hazards: No known specific hazards

5.3. Advice for fire-fighters

Advice for fire-fighters: Do not enter fire without proper protective equipment, including respiratory protection.

Section 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Personal precautions: Refer to section 8 of MSDS for personal protection details.

Turn leaking containers leak-side up to prevent the escape of liquid.

6.2. Environmental precautions

Environmental precautions: Do not discharge into drains or rivers.

6.3. Methods and material for containment and cleaning up

Clean-up procedures: For small spills, clean up with paper/cloth, or mop up, and dispose of safely.

Clean area of spillage down with plenty of water.

6.4. Reference to other sections

Reference to other sections: Refer to section 8 of MSDS.

Section 7: Handling and storage

7.1. Precautions for safe handling

Handling requirements: No special requirements.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions: Store in original container between 2°C and 8°C. Keep container tightly closed.

Suitable packaging: Must only be kept in original packaging.

7.3. Specific end use(s)

Specific end use(s): No data available.

Section 8: Exposure controls/personal protection

8.1. Control parameters

Workplace exposure limits: No data available.

DNEL/PNEC Values

DNEL / PNEC No data available.

8.2. Exposure controls



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 Engineering measures:
 N/A.

 Respiratory protection:
 Respiratory protection not required.

 Hand protection:
 Protective gloves.

 Eye protection:
 Use eye protection eg. Safety glasses

 Skin protection:
 Protective clothing as per good laboratory practices. Eg. Laboratory coat, enclosed shoes

Section 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

State: Liquid Colour: Blue Odour: Odourless Solubility in water: Soluble Viscosity: Non-viscous Boiling point/range°C: >35 Flash point°C: >93 Vapour pressure: No data available. pH: 7.2

Melting point/range°C: No data available. Autoflammability°C: No data available. Relative density: 1.0

9.2 Other information

Other information: No data available.

Section 10: Stability and reactivity

10.1. Reactivity

Reactivity: Stable under recommended transport or storage conditions.

10.2. Chemical stability

Chemical stability: Stable under normal conditions.

10.3. Possibility of hazardous reactions

Hazardous reactions: Hazardous reactions will not occur under normal transport or storage conditions.

10.4. Conditions to avoid

Conditions to avoid: No known specific conditions to avoid

10.5. Incompatible materials

Materials to avoid: None known.

10.6. Hazardous decomposition products

Section 11: Toxicological information

11.1. Information on toxicological effects



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Toxicity values: No data available.

Symptoms / routes of exposure

Skin contact: There may be mild irritation at the site of contact.

Eye contact: There may be irritation and redness.

Ingestion: There may be irritation of the throat.

Inhalation: No symptoms.

Section 12: Ecological information

12.1. Toxicity

Ecotoxicity values: No data available for reagent solution although Sodium Azide is toxic to fish at mortality LC50 – *Pimephales promelas* – 5.46m/L 96 h(OECD Test Guideline 203). Toxic to algea at static test EC50 – *Pseudokirchneriella subcapitata* – 0.35 mg/L 96 h (OECD Test Guideline 201)

12.2. Persistence and degradability

Persistence and degradability: Biodegradable.

12.3. Bioaccumulative potential

Bioaccumulative potential: No bioaccumulation potential.

12.4. Mobility in soil

Mobility: Readily absorbed into soil.

12.5. Results of PBT and vPvB assessment

PBT identification: This product is not identified as a PBT/vPvB substance.

12.6. Other adverse effects

Other adverse effects: Negligible ecotoxicity.

Section 13: Disposal considerations

13.1. Waste treatment methods

Disposal operations: Dispose of in accordance with current legislation and local authority regulation. Comply with

local waste disposal regulations.

NB: The user's attention is drawn to the possible existence of regional or national regulations regarding disposal.

Section 14: Transport information

14.1. UN number

UN number: N/A

14.2. UN proper shipping name

Shipping name: This product is not covered by international regulation on the transport of dangerous goods (IMDG, IATA, ADR/RID) Non-hardous for rail/road, sea and air transport



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Marine pollutant: Yes

14.3. Transport hazard class(es)

14.4. Packing group

14.5. Environmental hazards

Environmentally hazardous: possible hazards

14.6. Special precautions for user

Special precautions: No special precautions.

Section 15: Regulatory information

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

Specific regulations: Standard for the Uniform Scheduling of Medicines and Poisons GHS, REACH, ECHA, 1272/2008 CLP Regulation

15.2. Chemical Safety Assessment

This product is labelled as follows:Pneumo CEL IFADanger Classification:Contains Evans Blue & Soduim Azide in quantities below the limit concentrations.

Section 16: Other information

Other information

Other information: This safety data sheet is prepared in accordance with Commission Regulation (EU) No 453/2010.

Legal disclaimer: The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. This company shall not be held liable for any damage resulting from handling or from contact with the above product.