Document reference number: SDS 502-537A Febrile Antigens

Issue number: REV 2 / SEP 2025

# ACCORDING TO EC-REGULATIONS 1907/2006 (REACH), 1272/2008 (CLP) & 2015/830



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

1.1 Product identifier

Product code(s) & Product Name 502005A Salmonella Typhi H

504005A Salmonella Paratyphi AH
506005A Salmonella Paratyphi BH
508005A Salmonella Paratyphi CH
510005A Salmonella Typhi O
512005A Salmonella Paratyphi AO
514005A Salmonella Paratyphi BO
516005A Salmonella Paratyphi CO
518005A Brucella Abortus
520005A Brucella Melitensis
522005A Proteus OX2

526005A Proteus OXK 532042A Febrile Antigen Kit + Controls 536001A Febrile Positive Control 537001A Febrile Negative Control

524005A Proteus OX19

CAS No. Mixture EINECS No. Mixture

Product Description Antigen suspension of of killed bacteria, stained to enhance reading of

agglutination tests. Blue stained antigens are specific to somatic 'O' antigen. Red stained antigens are specific to flagellar 'H' antigens. pH 8

- 8.4, to which is added a preservative

1.2 Relevant identified uses of the substance or mixture

and uses advised against

Identified Use(s)

A slide and tube agglutination test for the qualitative and semi-quantitative

detection of Anti-Salmonella, Brucella and Rickettsia antibodies in human serum. Stained bacterial suspensions will agglutinate (clump) in the presence of the

corresponding antibody

Uses Advised Against

Anything other than the above

1.3 Details of the supplier of the safety data sheet

Company Identification Lorne Laboratories Ltd

Unit 1 Cutbush Park Industrial Estate

Danehill Lower Earley Berkshire RG6 4UT United Kingdom

 Telephone
 +44(0) 0118 921 2264

 Fax
 +44(0) 0118 986 4518

 E-Mail (competent person)
 Info@lornelabs.com

**1.4** Emergency telephone number +44(0) 0118 921 2264

Available 0900 - 1700 (GMT)

Languages spoken English

### 2. SECTION 2: HAZARDS IDENTIFICATION

# 2.1 Classification of the substance or mixture Classification according to Regulation (EC) No. 1272/2008 [CLP]

Skin sensitisation, Category 1 H3

Full text of H- and EUH-statements: see section 16

Adverse physicochemical, human health and environmental effects

No additional information available

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#### 2.2 Label elements

Labelling according to Regulation (EC) No. 1272/2008 [CLP]

Hazard pictograms (CLP)



Signal Word (CLP) Warning

Contains (CLP) Formaldehyde

2-Methyl-2H-isothiazol-3-one (Proclin 950)

Hazard Statement (CLP) EUH208 – May produce an allergic reaction

H317 - May cause an allergic skin reaction

Precautionary Statement (CLP) P261 - Avoid breathing vapours

P272 - Contaminated work clothing should not be allowed out of the workplace P501 - Dispose of contents/container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation

2.3 Other hazards Contains material from animal origin. No known test method can guarantee that

products derived from human or animal sources will not transmit infectious agents. It is recommended that this product and assay material are handled as a

potential biohazard

Contains no PBT/vPvB substances ≥ 0.1% assessed in accordance with REACH Annex XIII

The mixture does not contain substance(s) included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or is not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at a concentration equal to or greater than 0,1 %

### 3. SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

#### 3.1 Substances

Not Applicable

#### 3.2 Mixtures

Name	Product identifier	Conc. (%)	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Sodium Azide	CAS-No: 26628-22-8 EC No: 247-852-1	0.095	Acute Tox. 2; H300 Aquatic Acute 1; H400 Aquatic Chronic 1; H410

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Name	Product identifier	Conc. (%)	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Formaldehyde substance with a Community workplace exposure limit	CAS-No.: 50-00-0 EC-No.: 200-001-8 EC Index-No.: 605-001-00-5	< 0.1	Acute Tox. 3 (Oral), H301 Acute Tox. 3 (Dermal), H311 Acute Tox. 3 (Inhalation:dust,mist), H331 Skin Corr. 1B, H314 Skin Sens. 1, H317 Muta. 2, H341 Carc. 1B, H350 STOT SE 3, H335
2-methylisothiazol-3(2H)-one (PROCLIN 950)	CAS-No.: 2682-20-4 EC-No.: 220-239-6 EC Index-No.: 613-326-00-9	< 0.1	Acute Tox. 3 (Oral), H301 Acute Tox. 3 (Dermal), H311 Acute Tox. 2 (Inhalation), H330 Skin Corr. 1B, H314 Eye Dam. 1, H318 Skin Sens. 1A, H317 Aquatic Acute 1, H400 Aquatic Chronic 1, H410

Specific concentration limits:			
Name	Product identifier	Specific concentration limits	
Formaldehyde	CAS-No.: 50-00-0 EC-No.: 200-001-8 EC Index-No.: 605-001- 00-5	( 0.2 ≤C < 100) Skin Sens. 1, H317 ( 5 ≤C < 100) STOT SE 3, H335 ( 5 ≤C < 25) Eye Irrit. 2, H319 ( 5 ≤C < 25) Skin Irrit. 2, H315 ( 25 ≤C < 100) Skin Corr. 1B, H314	
2-methylisothiazol-3(2H)-one (PROCLIN 950)	CAS-No.: 2682-20-4 EC-No.: 220-239-6 EC Index-No.: 613-326- 00-9	( 0.0015 ≤C ≤ 100) Skin Sens. 1A, H317	

Full text of H- and EUH-statements: see section 16

### 4. SECTION 4: FIRST AID MEASURES



#### 4.1 Description of first aid measures

First-aid measures general: Never give anything by mouth to an unconscious person. If you feel unwell, seek

medical advice (show the label where possible)

Inhalation: Allow affected person to breathe fresh air. Allow the victim to rest

Skin Contact: Remove affected clothing and wash all exposed skin area with mild soap and

water, followed by warm water rinse

Eye Contact: Rinse immediately with plenty of water. Obtain medical attention if pain, blinking

or redness persists

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Ingestion: Rinse mouth. Do NOT induce vomiting. Obtain emergency medical attention

4.2 Most important symptoms and effects, both acute

and delayed

Not expected to present a significant hazard under anticipated conditions of

normal use

4.3 Indication of any immediate medical attention and

special treatment needed

No additional information available

#### 5. SECTION 5: FIRE-FIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing Media Foam. Dry powder. Carbon dioxide. Water spray. Sand

Unsuitable extinguishing Media Do not use a heavy water stream

5.2 Special hazards arising from the substance or

mixture

No additional information available

5.3 Advice for fire-fighters

Firefighting instructions

Use water spray or fog for cooling exposed containers. Exercise caution when

fighting any chemical fire. Prevent firefighting water from entering the

environment

Protection during firefighting Do not enter fire area without proper protective equipment, including respiratory

protection

### 6. SECTION 6: ACCIDENTAL RELEASE MEASURES

# 6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel Evacuate unnecessary personnel

For emergency responders

Protective equipment Equip cleanup crew with proper protection

Emergency procedures Ventilate area

**6.2 Environmental precautions** Prevent entry to sewers and public waters. Notify authorities if liquid enters

sewers or public waters

6.3 Methods and material for containment and cleaning

up

Soak up spills with inert solids, such as clay or diatomaceous earth as soon as

possible. Collect spillage. Store away from other materials

**6.4 Reference to other sections** See Section: 8, 13

# 7. SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling Wash hands and other exposed areas with mild soap and water before eating,

drinking or smoking and when leaving work. Provide good ventilation in process

area to prevent formation of vapour

7.2 Conditions for safe storage, including any

incompatibilities

Storage conditions Keep only in the original container in a cool, well-ventilated place away from :

Heat sources. Keep container closed when not in use

Incompatible products Strong bases. Strong acids

Incompatible materials Sources of ignition. Direct sunlight

7.3 Specific end use(s) See Section: 1.2

### 8. SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

#### 8.1 Control parameters

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National occupational exposure and biological limit values

Sodium azide (26628-22-8)	
EU - Indicative Occupational Exposure Limit (IOEL)	
Local name	Sodium azide
IOEL TWA	0.1 mg/m³
IOEL STEL	0.3 mg/m³
Remark	Skin

Formaldehyde (50-00-0)		
EU - Indicative Occupational Exposure Limit (IOEL)		
Local name	Formaldehyde	
IOEL TWA [ppm]	0.2 ppm	
IOEL STEL [ppm]	0.4 ppm	
Remark	skin sensitiser. SCOEL Recommendations (2008/Ongoing)	

Methanol (CH3OH) (67-56-1)		
EU - Indicative Occupational Exposure Limit (IOEL)		
Local name	Methanol	
IOEL TWA	260 mg/m³	
IOEL TWA [ppm]	200 ppm	
Remark	skin	

Recommended monitoring procedures

No additional information available

# 8.2 Exposure controls

Appropriate engineering controls:

No additional information available

Personal protective equipment:

Avoid all unnecessary exposure

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### Personal protective equipment symbol(s):

Eye/face protection Chemical goggles or safety glasses



Skin protection Wear protective gloves



Respiratory protection Wear appropriate mask



Thermal hazards No additional information available

Environmental Exposure Controls: Do not eat, drink or smoke during use

### 9. SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

### 9.1 Information on basic physical and chemical properties

Appearance Liquid

Colour

Salmonella Typhi H Red Salmonella Paratyphi AH Red Salmonella Paratyphi BH Red Salmonella Paratyphi CH Red Salmonella Typhi O Blue Salmonella Paratyphi AO Blue Salmonella Paratyphi BO Blue Salmonella Paratyphi CO Blue Brucella Abortus Blue Brucella Melitensis Blue Proteus OX2 Blue Proteus OX19 Blue Proteus OXK Blue Febrile Positive Control Yellowish

Febrile Negative Control Colourles or Yellowish

Odour Odourless
Odour threshold Not available
Melting point Not available
Freezing point Not available

Boiling point  $96-98~^{\circ}\text{C}$  Applies only to formol

Flammability

Explosive limits

Lower explosion limit

Upper explosion limit

Not available

Not available

Not available

Flash point 62 °C Applies only to formol

Auto-ignition temperature

Decomposition temperature

pH

8 - 8.4

Viscosity, kinematic

Solubility

Partition coefficient n-octanol/water (Log Kow)

Vapour pressure

Not available

Not available

Not available

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Vapour pressure at 50°C

Density

Not available

Relative density

Relative vapour density at 20°C

Particle characteristics

Not available

Not available

Not available

9.2 Other information No additional information available

### 10. SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity No additional information available

10.2 Chemical stability
 10.3 Possibility of hazardous reactions
 Not established
 Not established

10.4 Conditions to avoid Direct sunlight. Extremely high or low temperatures

**10.5** Incompatible materials Not known when used appropriately

10.6 Hazardous decomposition product(s) No hazardous decomposition products known

#### 11. SECTION 11: TOXICOLOGICAL INFORMATION

# 11.1 Information on toxicological effects (Substances in preparations / mixtures) Acute toxicity

Acute toxicity (oral)

Acute toxicity (dermal)

Acute toxicity (inhalation)

Not classified

Not classified

Skin corrosion/irritation Not classified pH: 8 – 8.4

Additional information Based on available data, the classification criteria are not met

Serious eye damage/irritation Not classified pH: 8 – 8.4

Additional information Based on available data, the classification criteria are not met

Respiratory or skin sensitization

Germ cell mutagenicity

Not classified. Based on available data, the classification criteria are not met
Not classified. Based on available data, the classification criteria are not met
Not classified. Based on available data, the classification criteria are not met
Reproductive toxicity

Not classified. Based on available data, the classification criteria are not met
Not classified. Based on available data, the classification criteria are not met

STOT - single exposure

Formaldehyde (50-00-0) May cause respiratory irriation

STOT - repeated exposure Not classified. Based on available data, the classification criteria are not met Aspiration hazard Not classified. Based on available data, the classification criteria are not met

11.2 Information on other hazards

Endocrine disrupting properties No additional information available

Potential adverse human health effects and symptoms Based on available data, the classification criteria are not met

### 12. SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

Hazardous to the aquatic environment, short–term Not classified

(acute)

Hazardous to the aquatic environment, long-term Not classified

(chronic)

12.2 Persistence and degradability

Salmonella Typhi H Not established Salmonella Paratyphi AH Not established

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Salmonella Paratyphi BH Not established Salmonella Paratyphi CH Not established Salmonella Typhi O Not established Salmonella Paratyphi AO Not established Salmonella Paratyphi BO Not established Salmonella Paratyphi CO Not established Brucella Abortus Not established Brucella Melitensis Not established Proteus OX2 Not established Proteus OX19 Not established Proteus OXK Not established Febrile Antigen Kit + Controls Not established Febrile Positive Control Not established Not established Febrile Negative Control

12.3 Bioaccumulative potential Not established

 12.4
 Mobility in soil
 No additional information available

 12.5
 Results of PBT and VPVB assessment
 No additional information available

 12.6
 Endocrine disrupting properties
 No additional information available

 12.7
 Other adverse effects
 Avoid release to the environment

### 13. SECTION 13: DISPOSAL CONSIDERATIONS

#### 13.1 Waste treatment methods

Product/Packaging disposal recommendations Ecological waste information Dispose in a safe manner in accordance with local/national regulations

Avoid release to the environment

### 14. SECTION 14: TRANSPORT INFORMATION

 $Not \ classified \ according \ to \ the \ United \ Nations \ `Recommendations \ on \ the \ Transport \ of \ Dangerous \ Goods'.$ 

In accordance with ADR / IMDG / IATA / ADN / RID

#### 14.1 UN number

UN-No. (ADR)

UN-No. (IMDG)

UN-No. (IATA)

UN-No. (ADN)

UN-No. (RID)

Not applicable

Not applicable

Not applicable

#### 14.2 UN proper shipping name

Proper Shipping Name (ADR)

Proper Shipping Name (IMDG)

Proper Shipping Name (IATA)

Proper Shipping Name (ADN)

Proper Shipping Name (ADN)

Proper Shipping Name (RID)

Not applicable

Not applicable

#### 14.3 Transport hazard class(es)

Transport hazard class(es) (ADR)

Transport hazard class(es) (IMDG)

Not applicable

Transport hazard class(es) (IATA)

Transport hazard class(es) (ADN)

Transport hazard class(es) (RID)

Not applicable

Not applicable

#### 14.4 Packing group

Packing group (ADR)
Packing group (IMDG)
Packing group (IATA)
Packing group (ADN)
Not applicable
Not applicable

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Packing group (RID) Not applicable

14.5 Environmental hazards

Dangerous for the environment No Marine pollutant No

Other information No supplementary information available

14.6 Special precautions for user

Overland transport Not applicable
Transport by sea Not applicable
Air transport Not applicable
Inland waterway transport Not applicable
Rail transport Not applicable
Roil transport Not applicable

14.7 Maritime transport in bulk according to IMO

instruments

Not applicable

# 15. SECTION 15: REGULATORY INFORMATION

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

#### **EU-Regulations**

#### **REACH Annex XVII (Restriction List)**

Contains no substance(s) listed on REACH Annex XVII (Restriction Conditions)

#### **REACH Annex XIV (Authorisation List)**

Contains no substance(s) listed on REACH Annex XIV (Authorisation List)

#### **REACH Candidate List (SVHC)**

Contains no substance(s) listed on the REACH Candidate List

#### **PIC Regulation (Prior Informed Consent)**

Contains no substance(s) listed on the PIC list (Regulation EU 649/2012 concerning the export and import of hazardous chemicals)

#### **POP Regulation (Persistent Organic Pollutants)**

Contains no substance(s) listed on the POP list (Regulation EU 2019/1021 on persistent organic pollutants)

#### Ozone Regulation (1005/2009)

Contains no substance(s) listed on the Ozone Depletion list (Regulation EU 1005/2009 on substances that deplete the ozone layer)

#### Explosives Precursors Regulation (2019/1148)

Contains no substance(s) listed on the Explosives Precursors list (Regulation EU 2019/1148 on the marketing and use of explosives precursors)

#### Drug Precursors Regulation (273/2004)

Contains no substance(s) listed on the Drug Precursors list (Regulation EC 273/2004 on the manufacture and the placing on market of certain substances used in the illicit manufacture of narcotic drugs and psychotropic substances)

### **National regulations**

No additional information available

### 15.2 Chemical Safety Assessment

No chemical safety assessment has been carried out

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# 16. SECTION 16: OTHER INFORMATION

Indication of changes: Sections 1 - 16

Regulatory information

Data sources

REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

Full text of H- and EUH-s	Full text of H- and EUH-statements:		
Acute Tox. 2 (Inhalation)	Acute toxicity (inhal.), Category 2		
Acute Tox. 3 (Dermal)	Acute toxicity (dermal), Category 3		
Acute Tox. 3 (Inhalation:dust,mist)	Acute toxicity (inhalation:dust,mist) Category 3		
Acute Tox. 3 (Oral)	Acute toxicity (oral), Category 3		
Aquatic Acute 1	Hazardous to the aquatic environment – Acute Hazard, Category 1		
Aquatic Chronic 1	Hazardous to the aquatic environment – Chronic Hazard, Category 1		
Carc. 1B	Carcinogenicity, Category 1B		
EUH208	Contains Formaldehyde. May produce an allergic reaction		
EUH210	Safety data sheet available on request		
Eye Dam. 1	Serious eye damage/eye irritation, Category 1		
Eye Irrit. 2	Serious eye damage/eye irritation, Category 2		
H301	Toxic if swallowed		
H311	Toxic in contact with skin		
H314	Causes severe skin burns and eye damage		
H315	Causes skin irritation		
H317	May cause an allergic skin reaction		
H318	Causes serious eye damage		
H319	Causes serious eye irritation		
H330	Fatal if inhaled		
H331	Toxic if inhaled		

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H335	May cause respiratory irritation
H341	Suspected of causing genetic defects
H350	May cause cancer
H400	Very toxic to aquatic life
H410	Very toxic to aquatic life with long lasting effects
Muta. 2	Germ cell mutagenicity, Category 2
Skin Corr. 1B	Skin corrosion/irritation, Category 1, Sub-Category 1B
Skin Irrit. 2	Skin corrosion/irritation, Category 2
Skin Sens. 1	Skin sensitisation, Category 1 (Using H317 Calculation method)
Skin Sens. 1A	Skin sensitisation, category 1A
STOT SE 3	Specific target organ toxicity – Single exposure, Category 3, Respiratory tract irritation

The classification complies with : ATP 12

#### **Disclaimers**

Customers are urged to ensure that the product is entirely suitable for their own purpose. It is the customers' responsibility to ensure that a suitable and sufficient assessment of the risks created by the use of the product is undertaken. The use of the reagent and the interpretation of results must be carried out by properly trained and qualified personnel in accordance with the requirements of the country where the reagent is in use.

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### **Revision History**

Revision	Date	Description
1	JUL 2013	Issue 1
2	SEP 2025	Issue 2