



SAFETY DATA SHEET

MSDS 0121

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1. IDENTIFICATION OF THE SUBSTANCES/PREPARATION AND OF THE COMPANY

1.1. Commercial product name: Pathozyme HBsAg Plate
Code: 13197

1.2. Company:
OMEGA DIAGNOSTICS LTD.
Omega House, Hillfoots Business Village
Alva FK12 5DQ, Scotland, United Kingdom
odl@omegadiagnostics.co.uk
www.omegadiagnostics.co.uk

2. COMPOSITION/INFORMATION ON INGREDIENTS

Contains no hazardous substances in reportable quantities

Is to be classified according to EEC directive 88/379, the Chemicals Act and hazardous Goods Regulations as non-hazardous

3. HAZARDS IDENTIFICATION

Warnings:

The usual hygienic measures taken when handling biological materials should be observed

Substance generally non-hazardous to the waste water

4. FIRST AID MEASURES

Eye contact: N/A

Skin contact: N/A

Ingestion: N/A

5. FIRE-FIGHTING MEASURES

Extinguishing media: no restriction

Thermal decomposition : gasses which are damaging to health do not form in dangerous quantities.

SAFETY DATA SHEET

Commercial product name: Pathozyme HBsAg Plate
Code: 13197

6. ACCIDENTAL RELEASE MEASURES

After spillage: N/A
Absorbent material: not necessary
Special measures to limit damage are not necessary

7. HANDLING AND STORAGE

7.1. Handling: no special requirements

7.2. Storage: store in tightly closed containers under cool conditions

Do not store together: no restrictions

8. EXPOSURE CONTROL/PERSONAL PROTECTION

Respiratory protection: none
Hand protection: disposable gloves

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state: Solid
Colour: Clear
Odour: Odourless
pH value: N/A
Boiling point: N/A
Melting point: N/A
Flash point: N/A
Ignition temperature: N/A
Explosion limits: N/A
Vapour pressure: N/A
Density: N/A
Solubility in water: N/A
Viscosity: N/A

10. STABILITY AND REACTIVITY

Hazardous reactions: none known when used appropriately

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Commercial product name: Pathozyme HBsAg Plate
Code: 13197

11. TOXICOLOGICAL INFORMATION

LD50 oral: N/A
LD50: N/A
LD50 skin: N/A
LD50 inhalation: N/A
Toxicological information: N/A

12. ECOLOGICAL INFORMATION

Water hazard class: N/A

13. DISPOSAL CONSIDERATIONS

No special waste-handling cautions needed. Accordance with local regulations should be observed

14. TRANSPORT INFORMATION

This product is not subject to current regulations for transportation of hazardous goods

15. REGULATORY INFORMATION

This product does not require special labelling, in accordance with the appropriate EC directives

16. OTHER INFORMATION

This product is intended for in vitro diagnostic use only. Not for use in humans

The information herein is believed to be correct as of the date hereof and excludes any guarantee related with the final use given to the product, being the recipient the last responsible for observing the local laws applicable in each case



SAFETY DATA SHEET

Omega
D I A G N O S T I C S

MSDS 0119

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1. IDENTIFICATION OF THE SUBSTANCES/PREPARATION AND OF THE COMPANY

1.1. Commercial product name: Pathozyme HBsAg Conjugate
Code: 13147

1.2. Company:
OMEGA DIAGNOSTICS LTD.
Omega House, Hillfoots Business Village
Alva FK12 5DQ, Scotland, United Kingdom
odl@omegadiagnostics.co.uk
www.omegadiagnostics.co.uk

2. COMPOSITION/INFORMATION ON INGREDIENTS

Contains no hazardous substances in reportable quantities

Is to be classified according to Current UK Chemicals (Hazard Information and Packaging for Supply) Regulations and the Chemicals Act as non-hazardous

3. HAZARDS IDENTIFICATION

Warnings:

The usual hygienic measures taken when handling biological materials should be observed

Substance generally non-hazardous to the waste water

4. FIRST AID MEASURES

Eye contact: wash eyes immediately with plenty of water

Skin contact: wash with plenty of water

Ingestion: requires medical control

5. FIRE-FIGHTING MEASURES

Extinguishing media: no restriction

Thermal decomposition: gases which are damaging to health do not form in dangerous quantities

SAFETY DATA SHEET

Commercial product name: Pathozyme HBsAg Conjugate
Code: 13147

6. ACCIDENTAL RELEASE MEASURES

After spillage: can be washed off with plenty of water
Absorbent material: not necessary
Special measures to limit damage are not necessary

7. HANDLING AND STORAGE

7.1. Handling: no special requirements

7.2. Storage: store in tightly closed containers under cool conditions

Do not store together: no restrictions

8. EXPOSURE CONTROL/PERSONAL PROTECTION

Respiratory protection: none
Hand protection: disposable gloves

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state: Liquid
Colour: Purple
Odour: Odourless
pH value: 7.0
Boiling point: N/A
Melting point: N/A
Flash point: N/A
Ignition temperature: N/A
Explosion limits: N/A
Vapour pressure: N/A
Density: N/A
Solubility in water: 100%
Viscosity: N/A

10. STABILITY AND REACTIVITY

Hazardous reactions: none known when used appropriately

SAFETY DATA SHEET

Commercial product name: Pathozyme HBsAg Conjugate
Code: 13147

11. TOXICOLOGICAL INFORMATION

LD50 oral: not known
LD50: not known
LD50 skin: not known
LD50 inhalation: not known
Toxicological information: not known

12. ECOLOGICAL INFORMATION

Water hazard class: Not Known

13. DISPOSAL CONSIDERATIONS

No special waste-handling cautions needed. Accordance with local regulations should be observed

14. TRANSPORT INFORMATION

This product is not subject to current regulations for transportation of hazardous goods

15. REGULATORY INFORMATION

This product does not require special labelling, in accordance with the appropriate EC directives

16. OTHER INFORMATION

This product is intended for in vitro diagnostic use only. Not for use in humans

The information herein is believed to be correct as of the date hereof and excludes any guarantee related with the final use given to the product, being the recipient the last responsible for observing the local laws applicable in each case

SAFETY DATA SHEET

MSDS 0120

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1. IDENTIFICATION OF THE SUBSTANCES/PREPARATION AND OF THE COMPANY

1.1. Commercial product name: Pathozyme HBsAg Negative Control
Code: 13167

1.2. Company:
OMEGA DIAGNOSTICS LTD.
Omega House, Hillfoots Business Village
Alva FK12 5DQ, Scotland, United Kingdom
odl@omegadiagnostics.co.uk
www.omegadiagnostics.co.uk

2. COMPOSITION/INFORMATION ON INGREDIENTS

Contains no hazardous substances in reportable quantities
Is to be classified according to Current UK Chemicals (Hazard Information and Packaging for Supply) Regulations and the Chemicals Act as non-hazardous

3. HAZARDS IDENTIFICATION

Warnings:

The usual hygienic measures taken when handling biological materials should be observed

Substance generally non-hazardous to the waste water

Only blood from donors proven to have no antibodies against HIV I, HIV II, HCV and HBsAg, with the FDA-licensed tests, is used in the manufacture of this product. Since, nevertheless, the risk of infection cannot be fully precluded, the product must be handled with the same care as a patient sample.

4. FIRST AID MEASURES

Eye contact: wash eyes immediately with plenty of water.

Skin contact: wash with plenty of water.

Ingestion: requires medical control.

5. FIRE-FIGHTING MEASURES

Extinguishing media: no restriction

Thermal decomposition: gases which are damaging to health do not form in dangerous quantities.

SAFETY DATA SHEET

Commercial product name: Pathozyme HBsAg Negative Control
Code: 13167

6. ACCIDENTAL RELEASE MEASURES

After spillage: can be washed off with plenty of water
Absorbent material: not necessary
Special measures to limit damage are not necessary

7. HANDLING AND STORAGE

7.1. **Handling:** no special requirements

7.2. **Storage:** store in tightly closed containers under cool conditions

Do not store together: no restrictions

8. EXPOSURE CONTROL/PERSONAL PROTECTION

Respiratory protection: none
Eye protection: none
Hand protection: disposable gloves

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state: Liquid
Colour: Blue
Odour: Odourless
pH value: 7.5
Boiling point: N/A
Melting point: N/A
Flash point: N/A
Ignition temperature: N/A
Explosion limits: N/A
Vapour pressure: N/A
Density: N/A
Solubility in water: Very soluble
Viscosity: N/A

10. STABILITY AND REACTIVITY

Hazardous reactions: none known when used appropriately

SAFETY DATA SHEET

Commercial product name: Pathozyme HBsAg Negative Control
Code: 13167

11. TOXICOLOGICAL INFORMATION

LD50 oral: not known
LD50: not known
LD50 skin: not known
LD50 inhalation: not known
Toxicological information: not known

12. ECOLOGICAL INFORMATION

Water hazard class: irrelevant

13. DISPOSAL CONSIDERATIONS

No special waste-handling cautions needed. Accordance with local regulations should be observed

14. TRANSPORT INFORMATION

This product is not subject to current regulations for transportation of hazardous goods

15. REGULATORY INFORMATION

This product does not require special labelling, in accordance with the appropriate EC directives

16. OTHER INFORMATION

This product is intended for in vitro diagnostic use only. Not for use in humans

The information herein is believed to be correct as of the date hereof and excludes any guarantee related with the final use given to the product, being the recipient the last responsible for observing the local laws applicable in each case

SAFETY DATA SHEET

MSDS 0122



Page 1 of 3

1. IDENTIFICATION OF THE SUBSTANCES/PREPARATION AND OF THE COMPANY

1.1. Commercial product name: Pathozyme HBsAg Positive Control
Code: 13157

1.2. Company:
OMEGA DIAGNOSTICS LTD.
Omega House, Hillfoots Business Village
Alva FK12 5DQ, Scotland, United Kingdom
odl@omegadiagnostics.co.uk
www.omegadiagnostics.co.uk

2. COMPOSITION/INFORMATION ON INGREDIENTS

Contains no hazardous substances in reportable quantities

Is to be classified according to Current UK Chemicals (Hazard Information and Packaging for Supply) Regulations and the Chemicals Act as non-hazardous

3. HAZARDS IDENTIFICATION

Warnings:

The usual hygienic measures taken when handling biological materials should be observed

Substance generally non-hazardous to the waste water

Only Serum from donors proven to have no antibodies against HIV I, HIV II, with the FDA-licenced tests, and heated at 60°C for 10 hours is used in the manufacture of this product. Since, nevertheless, the risk of infection cannot be fully precluded, the product must be handled with the same care as a patient sample.

4. FIRST AID MEASURES

Eye contact: wash eyes immediately with plenty of water

Skin contact: wash with plenty of water

Ingestion: requires medical control

5. FIRE-FIGHTING MEASURES

Extinguishing media: no restriction

Thermal decomposition: gases which are damaging to health do not form in dangerous quantities

SAFETY DATA SHEET

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Commercial product name: Pathozyme HBsAg Positive Control
Code: 13157

6. ACCIDENTAL RELEASE MEASURES

After spillage: can be washed off with plenty of water
Absorbent material: not necessary
Special measures to limit damage are not necessary

7. HANDLING AND STORAGE

7.1. **Handling:** no special requirements

7.2. **Storage:** store in tightly closed containers under cool conditions

Do not store together: no restrictions

8. EXPOSURE CONTROL/PERSONAL PROTECTION

Respiratory protection: none
Eye protection: none
Hand protection: disposable gloves

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state: Liquid
Colour: Red
Odour: Odourless
pH value: 7.4
Boiling point: N/A
Melting point: N/A
Flash point: N/A
Ignition temperature: N/A
Explosion limits: N/A
Vapour pressure: N/A
Density: N/A
Solubility in water: Very soluble
Viscosity: N/A

10. STABILITY AND REACTIVITY

Hazardous reactions: none known when used appropriately

SAFETY DATA SHEET

Commercial product name: Pathozyme HBsAg Positive Control
Code: 13157

11. TOXICOLOGICAL INFORMATION

LD50 oral: not known
LD50: not known
LD50 skin: not known
LD50 inhalation: not known
Toxicological information: not known

12. ECOLOGICAL INFORMATION

Water hazard class: irrelevant

13. DISPOSAL CONSIDERATIONS

No special waste-handling cautions needed. Accordance with local regulations should be observed

14. TRANSPORT INFORMATION

This product is not subject to current regulations for transportation of hazardous goods

15. REGULATORY INFORMATION

This product does not require special labelling, in accordance with the appropriate EC directives

16. OTHER INFORMATION

This product is intended for in vitro diagnostic use only. Not for use in humans

The information herein is believed to be correct as of the date hereof and excludes any guarantee related with the final use given to the product, being the recipient the last responsible for observing the local laws applicable in each case

SAFETY DATA SHEET

MSDS 0282

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1. IDENTIFICATION OF THE SUBSTANCES/PREPARATION AND OF THE COMPANY

- 1.1. Commercial product name: Pathozyme Single Step Substrate
Code: 13037
- 1.2. Company:
OMEGA DIAGNOSTICS LTD.
Omega House, Hillfoots Business Village
Alva FK12 5DQ, Scotland, United Kingdom
odl@omegadiagnostics.co.uk
www.omegadiagnostics.co.uk

2. COMPOSITION/INFORMATION ON INGREDIENTS

Contains no hazardous substances in reportable quantities

Is to be classified according to Current UK Chemicals (Hazard Information and Packaging for Supply) Regulations and the Chemicals Act as non-hazardous

3. HAZARDS IDENTIFICATION

Warnings:

Substance generally non-hazardous to the waste water

4. FIRST AID MEASURES

Eye contact: wash eyes immediately with plenty of water
Skin contact: wash with plenty of water
Ingestion: requires medical control

5. FIRE-FIGHTING MEASURES

Extinguishing media: no restriction
Thermal decomposition: gases which are damaging to health do not form in dangerous quantities

SAFETY DATA SHEET

Commercial product name: Pathozyme Single Step Substrate
Code: 13037

6. ACCIDENTAL RELEASE MEASURES

After spillage: can be washed off with plenty of water
Absorbent material: not necessary
Special measures to limit damage are not necessary

7. HANDLING AND STORAGE

7.1. Handling: no special requirements

7.2. Storage: store in tightly closed containers under cool conditions

Do not store together: no restrictions

8. EXPOSURE CONTROL/PERSONAL PROTECTION

Respiratory protection: None
Hand protection: disposable gloves
Eye Protection: None

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state: Liquid
Colour: Clear / Slightly Yellow
Odour: Odourless
pH value: 7.0
Boiling point: N/A
Melting point: >100°C
Flash point: N/A
Ignition temperature: N/A
Explosion limits: N/A
Vapour pressure: N/A
Density: N/A
Solubility in water: 100%
Viscosity: N/A

10. STABILITY AND REACTIVITY

Hazardous reactions: none known when used appropriately

SAFETY DATA SHEET

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Commercial product name: Pathozyme Single Step Substrate
Code: 13037

11. TOXICOLOGICAL INFORMATION

LD50 oral: not known
LD50: not known
LD50 skin: not known
LD50 inhalation: not known
Toxicological information: not known

12. ECOLOGICAL INFORMATION

Water hazard class: Not Known

13. DISPOSAL CONSIDERATIONS

No special waste-handling cautions needed. Accordance with local regulations should be observed

14. TRANSPORT INFORMATION

This product is not subject to current regulations for transportation of hazardous goods

15. REGULATORY INFORMATION

This product does not require special labelling, in accordance with the appropriate EC directives

16. OTHER INFORMATION

This product is intended for in vitro diagnostic use only. Not for use in humans

The information herein is believed to be correct as of the date hereof and excludes any guarantee related with the final use given to the product, being the recipient the last responsible for observing the local laws applicable in each case

SAFETY DATA SHEET

MSDS 0288



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1. IDENTIFICATION OF THE SUBSTANCES/PREPARATION AND OF THE COMPANY

1.1. Commercial product name: Pathozyme Stop Solution
Code: 13027

1.2. Company:
OMEGA DIAGNOSTICS LTD.
Omega House, Hillfoots Business Village
Alva FK12 5DQ, Scotland, United Kingdom
odl@omegadiagnostics.co.uk
www.omegadiagnostics.co.uk

2. COMPOSITION/INFORMATION ON INGREDIENTS

Contains no hazardous substances in reportable quantities

Is to be classified according to Current UK Chemicals (Hazard Information and Packaging for Supply) Regulations and the Chemicals Act as non-hazardous

3. HAZARDS IDENTIFICATION

Warnings:

The usual hygienic measures taken when handling biological materials should be observed

Substance generally non-hazardous to the waste water

4. FIRST AID MEASURES

Eye contact: wash eyes immediately with plenty of water

Skin contact: wash with plenty of water

Ingestion: requires medical control

5. FIRE-FIGHTING MEASURES

Extinguishing media: no restriction

Thermal decomposition : gasses which are damaging to health do not form in dangerous quantities.

SAFETY DATA SHEET

Commercial product name: Pathozyme Stop Solution
Code: 13027

6. ACCIDENTAL RELEASE MEASURES

After spillage: can be washed off with plenty of water
Absorbent material: not necessary
Special measures to limit damage are not necessary

7. HANDLING AND STORAGE

7.1. **Handling:** no special requirements

7.2. **Storage:** store in tightly closed containers under cool conditions

Do not store together: no restrictions

8. EXPOSURE CONTROL/PERSONAL PROTECTION

Respiratory protection: none
Hand protection: disposable gloves

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state: Liquid
Colour: Clear
Odour: Odourless
pH value: N/A
Boiling point: N/A
Melting point: N/A
Flash point: N/A
Ignition temperature: N/A
Explosion limits: N/A
Vapour pressure: N/A
Density: N/A
Solubility in water: 100%
Viscosity: N/A

10. STABILITY AND REACTIVITY

Hazardous reactions: none known when used appropriately

SAFETY DATA SHEET

Commercial product name: Pathozyme Stop Solution
Code: 13027

11. TOXICOLOGICAL INFORMATION

LD50 oral: not known
LD50: not known
LD50 skin: not known
LD50 inhalation: not known
Toxicological information: not known

12. ECOLOGICAL INFORMATION

Water hazard class: Not Known

13. DISPOSAL CONSIDERATIONS

No special waste-handling cautions needed. Accordance with local regulations should be observed

14. TRANSPORT INFORMATION

This product is not subject to current regulations for transportation of hazardous goods

15. REGULATORY INFORMATION

This product does not require special labelling, in accordance with the appropriate EC directives

16. OTHER INFORMATION

This product is intended for in vitro diagnostic use only. Not for use in humans

The information herein is believed to be correct as of the date hereof and excludes any guarantee related with the final use given to the product, being the recipient the last responsible for observing the local laws applicable in each case

SAFETY DATA SHEET

MSDS 0290



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1. IDENTIFICATION OF THE SUBSTANCES/PREPARATION AND OF THE COMPANY

1.1. Commercial product name: Pathozyme Wash Buffer
Code: 13317

1.2. Company:
OMEGA DIAGNOSTICS LTD.
Omega House, Hillfoots Business Village
Alva FK12 5DQ, Scotland, United Kingdom
odl@omegadiagnostics.co.uk
www.omegadiagnostics.co.uk

2. COMPOSITION/INFORMATION ON INGREDIENTS

Contains no hazardous substances in reportable quantities

Is to be classified according to Current UK Chemicals (Hazard Information and Packaging for Supply) Regulations and the Chemicals Act as non-hazardous

3. HAZARDS IDENTIFICATION

Warnings:

The usual hygienic measures taken when handling biological materials should be observed

Substance generally non-hazardous to the waste water

4. FIRST AID MEASURES

Eye contact: wash eyes immediately with plenty of water

Skin contact: wash with plenty of water

Ingestion: requires medical control

5. FIRE-FIGHTING MEASURES

Extinguishing media: no restriction

Thermal decomposition : gasses which are damaging to health do not form in dangerous quantities.

SAFETY DATA SHEET

Commercial product name: Pathozyme Wash Buffer
Code: 13317

6. ACCIDENTAL RELEASE MEASURES

After spillage: can be washed off with plenty of water
Absorbent material: not necessary
Special measures to limit damage are not necessary

7. HANDLING AND STORAGE

7.1. **Handling:** no special requirements

7.2. **Storage:** store in tightly closed containers under cool conditions

Do not store together: no restrictions

8. EXPOSURE CONTROL/PERSONAL PROTECTION

Respiratory protection: none
Hand protection: disposable gloves

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state: Liquid
Colour: Clear
Odour: Odourless
pH value: 7.5
Boiling point: N/A
Melting point: N/A
Flash point: N/A
Ignition temperature: N/A
Explosion limits: N/A
Vapour pressure: N/A
Density: N/A
Solubility in water: 100%
Viscosity: N/A

10. STABILITY AND REACTIVITY

Hazardous reactions: none known when used appropriately

SAFETY DATA SHEET

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Commercial product name: Pathozyme Wash Buffer
Code: 13317

11. TOXICOLOGICAL INFORMATION

LD50 oral: not known
LD50: not known
LD50 skin: not known
LD50 inhalation: not known
Toxicological information: not known

12. ECOLOGICAL INFORMATION

Water hazard class: Not Known

13. DISPOSAL CONSIDERATIONS

No special waste-handling cautions needed. Accordance with local regulations should be observed

14. TRANSPORT INFORMATION

This product is not subject to current regulations for transportation of hazardous goods

15. REGULATORY INFORMATION

This product does not require special labelling, in accordance with the appropriate EC directives

16. OTHER INFORMATION

This product is intended for in vitro diagnostic use only. Not for use in humans

The information herein is believed to be correct as of the date hereof and excludes any guarantee related with the final use given to the product, being the recipient the last responsible for observing the local laws applicable in each case