

SAFETY DATA SHEET

MSDS 0049

Page 1 of 3

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

1.1. Commercial product name: Treponema Pallidum Haemagglutination (TPHA) Test Cells
Code: 13081

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

Page 2 of 3

Commercial product name: Treponema Pallidum Haemagglutination (TPHA) Test Cells
Code: 13081

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: Formalised Chicken Red Blood Cells

Colour: Brown

Odour: Odourless

pH value: 6.6

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

SAFETY DATA SHEET

Commercial product name: Treponema Pallidum Haemagglutination (TPHA) Test Cells
Code: 13081

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 0044

Page 1 of 3

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

- 1.1. Commercial product name: Treponema Pallidum Haemagglutination (TPHA) Control Cells.
Code: 13091
- 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

Page 2 of 3

Commercial product name: Treponema Pallidum Haemagglutination (TPHA) Control Cells.
Code: 13091

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: Formalised Chicken Red Blood Cells

Colour: Brown

Odour: Odourless

pH value: 6.6

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

SAFETY DATA SHEET

Page 3 of 3

Commercial product name: Treponema Pallidum Haemagglutination (TPHA) Control Cells.
Code: 13091

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 0043

Page 1 of 3

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

1.1. Commercial product name: Treponema Pallidum Haemagglutination (TPHA)
Coloured Diluent
Code: 13171

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

Page 2 of 3

Commercial product name: Treponema Pallidum Haemagglutination (TPHA)
Coloured Diluent
Code: 13171

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: Clear Solution

Colour: Yellow

Odour: Odourless

pH value:

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

SAFETY DATA SHEET

Page 3 of 3

Commercial product name: Treponema Pallidum Haemagglutination (TPHA)
Coloured Diluent
Code: 13171

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 0047

Page 1 of 3

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

- 1.1. Commercial product name: Treponema Pallidum Haemagglutination (TPHA) Reactive Control
Code: 13111
- 1.2. Company:
OMEGA DIAGNOSTICS LTD.
Omega House, Hillfoots Business Village
Alva FK12 5DQ, Scotland, United Kingdom
odl@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-licenced 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: Treponema Pallidum Haemagglutination (TPHA) Reactive Control
Code: 13111

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: Opalescent

Odour: Odourless

pH value: 7.2

Boiling point:

Melting point:

Flash point:

Ignition temperature:

Explosion limits:

Vapour pressure:

Density:

Solubility in water: Very soluble

Viscosity:

10. STABILITY AND REACTIVITY

Hazardous reactions: none known when used appropriately

SAFETY DATA SHEET

Page 3 of 3

Commercial product name: Treponema Pallidum Haemagglutination (TPHA) Reactive Control
Code: 13111

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 0046

Page 1 of 3

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

1.1. Commercial product name: Treponema Pallidum Haemagglutination (TPHA) Non-Reactive Control
Code: 13121

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-licenced 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

Page 2 of 3

Commercial product name: Treponema Pallidum Haemagglutination (TPHA) Non-Reactive Control
Code: 13121

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: Opalescent

Odour: Odourless

pH value: 7.2

Boiling point:

Melting point:

Flash point:

Ignition temperature:

Explosion limits:

Vapour pressure:

Density:

Solubility in water: Very soluble

Viscosity:

10. STABILITY AND REACTIVITY

Hazardous reactions: none known when used appropriately

SAFETY DATA SHEET

Page 3 of 3

Commercial product name: Treponema Pallidum Haemagglutination (TPHA) Non-Reactive Control
Code: 13121

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