



Material Safety Data Sheet

Parvovirus B 19 IgM ELISA

Catalog Number: 20-PBMHU-E01

ALPCO Diagnostics

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Trade Name and Article number: Refer to page 1 !	Kit Components: <i>Sample Diluent</i> <i>Pos. Control, Neg. Control,</i> <i>Cut-off Control, Standard</i> <i>Enzyme Conjugate</i> <i>Wash Solution</i>
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1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING

1.1 Identification of the substance or preparation

Trade name: refer to page 1 Article number: refer to page 1

Kit Components: *Sample Diluent*
Pos. Control, Neg. Control, Cut-off Control
Standard
Enzyme Conjugate
Wash Solution

1.2 Use of the substance/preparation

Components of an *in-vitro* diagnostic device

1.3 Company/undertaking identification

Manufacturer/Supplier: _____

DRG Instruments GmbH	Tel.: +49-(0)6421 / 1700-0
Frauenbergstrasse 18	Fax: +49-(0)6421 / 1700-50
D-35039 Marburg	E-Mail: drg@drg-diagnostics.de
Germany	http: //www.drg-diagnostics.de

2. COMPOSITION/INFORMATION ON INGREDIENTS

Chemical characterization: Preparation

Description: Mixture of substances listed below with nonhazardous additions.

Hazardous ingredient	EC No	CAS No	Symbol and R phrases	Concentration
Mixture of CIT/MIT with the proportion 3:1 *	-	55965-84-9	T, N R23/24/25 – 34 – 43 - 50/53	< 0.0015 %

* Proclin 300 is a mixture of substances where two of the components, 5-chloro-2-methyl-2H-isothiazol-3-one (CIT) (EG-nr 247-500-7) and 2-methyl-2H-isothiazol-3-one (MIT) (EG-nr 220-239-6), in a mixture with the proportion 3:1 has a CAS No 55965-84-9 with the classification as stated above.

(For the full text of the R phrases refer to section 16.)

3. HAZARDS IDENTIFICATION

Due to the low concentration of hazardous ingredients none of the listed kit components of the DRG ELISA kits may be classified as dangerous according to Directive 1999/45/EC.

The usual precautionary measures are to be adhered to when handling chemicals.

4. FIRST AID MEASURES

General information: No special measures required.

After inhalation: Supply fresh air; consult doctor in case of complaints.

After skin contact: Wash with plenty amounts of water.

After eye contact: Rinse opened eye for several minutes under running water.

After swallowing: If symptoms persist consult doctor.

Trade Name and Article number: Refer to page 1 !	Kit Components: <i>Sample Diluent Pos. Control, Neg. Control, Cut-off Control, Standard Enzyme Conjugate Wash Solution</i>
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5. FIRE-FIGHTING MEASURES

- suitable extinguishing media:
CO₂, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
- special protective equipment for fire-fighters:
No special measures required.

6. ACCIDENTAL RELEASE MEASURES

- personal precautions: Not required.
- environmental precautions: Dilute with plenty of water.
Do not allow to enter surface or ground water.
- methods for cleaning up: use of absorbent material (e.g. sand, diatomaceous earth, acid binder, universal binder, sawdust, etc.), reduction of gases/fumes with water, dilution.

7. HANDLING AND STORAGE

7.1 Handling

No special measures required.
Use all reagents in accordance with the relevant package insert.

7.2 Storage

No special requirements.
Store all reagents as directed in the relevant package insert.

7.3 Specific use(s)

For in-vitro Diagnostic use only.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Exposure limit values

The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.

8.2 Exposure controls

8.2.1 Occupational exposure controls

The usual precautionary measures are to be adhered to when handling chemicals.

- 8.2.1.1 **Respiratory protection:** Not required.
- 8.2.1.2 **Hand protection.** Protective gloves.
- 8.2.1.3 **Eye protection:** Goggles recommended during refilling.
- 8.2.1.4 **Skin protection:** Lab coat.

Trade Name and Article number:

Refer to page 1 !

Kit Components: *Sample Diluent
Pos. Control, Neg. Control,
Cut-off Control, Standard
Enzyme Conjugate
Wash Solution***9. PHYSICAL AND CHEMICAL PROPERTIES****9.1 General information**

Appearance: – physical state: liquid (has no influence to the properties of the preparation)
– colour: diverse (has no influence to the properties of the preparation)

Odour: odourless

9.2 Important health, safety and environmental information

pH-value at 20°C: 7.2 ± 0.2

Density: ~ 1.0

Flash point: Not applicable

Self-igniting: Product is not selfigniting

Danger of explosion: Product does not present an exploding hazard

10. STABILITY AND REACTIVITY**10.1 Conditions to avoid**

No conditions known.

10.2 Materials to avoid

No materials known.

10.3 Hazardous decomposition products

No dangerous decomposition products known.

11. TOXICOLOGICAL INFORMATIONAcute toxicity:

Primary irritant effect: on the skin: No irritant effect.
on the eye: No irritant effect.

Sensitization: No sensitizing effects known.

Additional toxicological information:

The product is not subject to classification according to the calculation method of the General EU Classification Guidelines for Preparations as issued in the latest version.

When used and handled according to specifications, the product does not have any harmful effects to our experience and the information provided to us.

12. ECOLOGICAL INFORMATION

The product does not effect the environment.

13. DISPOSAL CONSIDERATIONS**Product:**

Recommendation: Dispose of waste according to applicable local, state, and federal regulations.

Uncleaned packaging:

Recommendation: Dispose of waste according to applicable local, state, and federal regulations.

Recommended cleansing agents: Water, if necessary together with cleansing agents.

Trade Name and Article number:

Refer to page 1 !

Kit Components: *Sample Diluent
Pos. Control, Neg. Control,
Cut-off Control, Standard
Enzyme Conjugate
Wash Solution***14. TRANSPORT INFORMATION**

No hazardous material as defined by the transport regulations.

Land transport ADR/RID: No

Maritime transport IMDG: No

Air transport ICAO-TI and IATA-DGR: No

This product is part of a kit. Information in this section refers to the kit as a whole.

15. REGULATORY INFORMATION**Labelling according to EU guidelines:**

This product is classified and labelled in accordance with directives 1999/45/EC and 91/155/EEC as modified in 2001/58/EC.

The preparations are not classified as hazardous due to the low concentration of hazardous ingredients.

National regulations:

Germany; VwVwS: Water hazardous class 1 (WGK 1) (self-assessment): slightly hazardous for water.

16. OTHER INFORMATION

Valid EC directives: Directive 67/548/EEC
Directive 1999/45/EC
Directive 91/155/EEC as modified in Directive 2001/58/EC

R-phrases of ingredients

These R-phrases refer to the classification of the single components/ingredients (pure substance 100%) and not to the classification of the preparation.

R 34 Causes burns.

R 43 May cause sensitization by skin contact.

R 23/24/25 Toxic by inhalation, in contact with skin and if swallowed.

R 50/53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment

Department issuing MSDS: Product Management

The information in this document is believed to be accurate and represents the best information currently available to us. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

Trade Name and Article number: Refer to page 1 !	Kit Components: Substrate Solution
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1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING**1.1 Identification of the substance or preparation**

Trade name: refer to page 1 *Article number:* refer to page 1

Kit Component: Substrate Solution

1.2 Use of the substance/preparation

Component of an *in-vitro* diagnostic device.

1.3 Company/undertaking identification**Manufacturer/Supplier:**

DRG Instruments GmbH	Tel.: +49-(0)6421 / 1700-0
Frauenbergstrasse 18	Fax: +49-(0)6421 / 1700-50
D-35039 Marburg	E-Mail: drg@drg-diagnostics.de
Germany	http: //www.drg-diagnostics.de

2. COMPOSITION/INFORMATION ON INGREDIENTS

Chemical characterization: Preparation
Description: Aqueous mixture of specific ingredients.

Hazardous ingredients : None identified.

3. HAZARDS IDENTIFICATION

The usual precautionary measures are to be adhered to when handling chemicals.
When used and handled according to specifications, the product does not have any harmful effects to our experience and the information provided to us.

4. FIRST AID MEASURES

General information: No special measures required.
After inhalation: Supply fresh air; consult doctor in case of complaints.
After skin contact: Wash with soap and water.
After eye contact: Rinse opened eye for several minutes under running water.
After swallowing: If symptoms persist consult doctor.

Trade Name and Article number:

Refer to page 1 !

Kit Components: Substrate Solution**5. FIRE-FIGHTING MEASURES**

- suitable extinguishing media:
CO₂, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
- special protective equipment for fire-fighters:
No special measures required.

6. ACCIDENTAL RELEASE MEASURES

- personal precautions: Wear protective equipment. Keep unprotected persons away.
- environmental precautions: Dilute with plenty of water.
Do not allow to enter surface or ground water.
- methods for cleaning up: Absorb with liquid-binding material (sand, universal binders).
Use neutralizing agent.

7. HANDLING AND STORAGE**7.1 Handling**

No special measures required.

Use all reagents in accordance with the relevant package insert.

7.2 Storage

Store protected from direct UV light.

Store all reagents as directed in the relevant package insert.

7.3 Specific use(s)

For in-vitro Diagnostic use only.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION**8.1 Exposure limit values**

The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.

8.2 Exposure controls**8.2.1 Occupational exposure controls**

The usual precautionary measures are to be adhered to when handling chemicals.

- 8.2.1.1 **Respiratory protection:** Not required.
- 8.2.1.2 **Hand protection.** Protective gloves.
- 8.2.1.3 **Eye protection:** Goggles recommended during refilling.
- 8.2.1.4 **Skin protection:** Lab coat.

Trade Name and Article number:

Refer to page 1 !

Kit Components: Substrate Solution**9. PHYSICAL AND CHEMICAL PROPERTIES****9.1 General information**

Appearance: – physical state: liquid
 – colour: colourless to very light yellow
Odour: odourless

9.2 Important health, safety and environmental information

pH-value 3.7
Density: ~ 1.0
Flash point: Not applicable
Self-igniting: Product is not selfigniting
Danger of explosion: Product does not present an exploding hazard

10. STABILITY AND REACTIVITY**10.1 Conditions to avoid**

Protect from direct UV light, avoid elevated temperatures

10.2 Materials to avoid

No materials known.

10.3 Hazardous decomposition products

No dangerous decomposition products known.

11. TOXICOLOGICAL INFORMATION**Acute toxicity:**

Primary irritant effect: on the skin: No irritant effect.
 on the eye: No irritant effect.

Sensitization: No sensitizing effects known.

Additional toxicological information:

The product is not subject to classification according to the calculation method of the General EU Classification Guidelines for Preparations as issued in the latest version.

When used and handled according to specifications, the product does not have any harmful effects to our experience and the information provided to us.

12. ECOLOGICAL INFORMATION

No data available.

Trade Name and Article number:

Refer to page 1 !

Kit Components: Substrate Solution**13. DISPOSAL CONSIDERATIONS****Product:**

Recommendation: Dispose of waste according to applicable local, state, and federal regulations.

Uncleaned packaging:

Recommendation: Dispose of waste according to applicable local, state, and federal regulations.

Recommended cleansing agents: Water, if necessary together with cleansing agents.

14. TRANSPORT INFORMATION

No hazardous material as defined by the transport regulations.

Land transport ADR/RID: No

Maritime transport IMDG: No

Air transport ICAO-TI and IATA-DGR: No

This product is part of a kit. Information in this section refers to the kit as a whole.

15. REGULATORY INFORMATION**Labelling according to EU guidelines:**

This product is classified and labelled in accordance with directives 1999/45/EC and 91/155/EEC as modified in 2001/58/EC.

The preparation is not classified as hazardous due to the low concentration of hazardous ingredients.

16. OTHER INFORMATION**Valid EC directives:** Directive 67/548/EEC
Directive 1999/45/EC
Directive 91/155/EEC as amended on Directive 2001/58/EC**R-phrases of ingredients**

These R-phrases refer to the classification of the single components/ingredients (pure substance 100%) and not to the classification of the preparation.

Not applicated.

Department issuing MSDS: Product Management

The information in this document is believed to be accurate and represents the best information currently available to us. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

Trade Name and Article number: Refer to page 1 !	Kit Component: Stop Solution
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1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING**1.1 Identification of the substance or preparation**

Trade name: refer to page 1 *Article number:* refer to page 1

Kit Component: Stop Solution

1.2 Use of the substance/preparation

Component of an In-vitro diagnostic device

1.3 Company/undertaking identification**Manufacturer/Supplier:**

DRG Instruments GmbH Frauenbergstrasse 18 D-35039 Marburg Germany	Tel.: +49-(0)6421 / 1700-0 Fax: +49-(0)6421 / 1700-50 E-Mail: drg@drg-diagnostics.de http: //www.drg-diagnostics.de
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2. COMPOSITION/INFORMATION ON INGREDIENTS

Chemical characterization: Preparation

Description: Aqueous mixture.

Hazardous ingredient	EC No	CAS No	R phrases	Concentration
Sulphuric acid	231-639-5	7664-93-9	C; R: 35	< 5 %

(For the full text of the R phrase refer to section 16.)

3. HAZARDS IDENTIFICATION

Due to the low concentration of the hazardous ingredient the listed kit component of the DRG ELISA kits may not be classified as dangerous according to Directive 1999/45/EC.

The usual precautionary measures are to be adhered to when handling chemicals.

4. FIRST AID MEASURES

General information No special measures required.

After inhalation: Supply fresh air; consult doctor in case of complaints.

After skin contact: Wash with plenty amounts of water.

After eye contact: Rinse opened eye for several minutes under running water.

After swallowing: If symptoms persist consult doctor.

Trade Name and Article number:

Refer to page 1 !

Kit Component: Stop Solution**5. FIRE-FIGHTING MEASURES**

- suitable extinguishing media:
CO₂, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
- special protective equipment for fire-fighters:
No special measures required.

6. ACCIDENTAL RELEASE MEASURES

- personal precautions: Wear protective equipment. Keep unprotected persons away.
- environmental precautions: Do not allow to enter surface or ground water.
- methods for cleaning up: Absorb with liquid-binding material (sand, universal binders).
Use neutralizing agent.
Wash with plenty of water.
Dispose contaminated material as waste according to item 13.

7. HANDLING AND STORAGE

Ensure adequate ventilation.

7.1 Handling

No special measures required.

Use all reagents in accordance with the relevant package insert.

7.2 Storage

No special requirements.

Store all reagents as directed in the relevant package insert.

7.3 Specific use(s)

For in-vitro Diagnostic use only.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION**8.1 Exposure limit values**

The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.

8.2 Exposure controls**8.2.1 Occupational exposure controls**

The usual precautionary measures are to be adhered to when handling chemicals.

- 8.2.1.1 **Respiratory protection:** Not required.
- 8.2.1.2 **Hand protection.** Protective gloves.
- 8.2.1.3 **Eye protection:** Goggles recommended during refilling.
- 8.2.1.4 **Skin protection:** Lab coat.

Trade Name and Article number:

Refer to page 1 !

Kit Component: Stop Solution**9. PHYSICAL AND CHEMICAL PROPERTIES****9.1 General information**

Appearance: – physical state: liquid
– colour: colourless

Odour: odourless

9.2 Important health, safety and environmental information

pH-value at 20°C: < 1.0

Density: ~ 1.0

Flash point: Not applicable

Self-igniting: Product is not selfigniting

Danger of explosion: Product does not present an exploding hazard

10. STABILITY AND REACTIVITY**10.1 Conditions to avoid**

No conditions known.

10.2 Materials to avoid

No materials known.

10.3 Hazardous decomposition products

No dangerous decomposition products known.

11. TOXICOLOGICAL INFORMATION**Acute toxicity:**

Primary irritant effect: on the skin: No irritant effect.

on the eye: No irritant effect.

Sensitization: No sensitizing effects known.

Additional toxicological information:

The product is not subject to classification according to the calculation method of the General EU Classification Guidelines for Preparations as issued in the latest version.

12. ECOLOGICAL INFORMATION

Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water.

Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.

Trade Name and Article number:

Refer to page 1 !

Kit Component: Stop Solution**13. DISPOSAL CONSIDERATIONS****Product:**

Recommendation: Dispose of waste according to applicable local, state, and federal regulations.

Uncleaned packaging:

Recommendation: Dispose of waste according to applicable local, state, and federal regulations.

Recommended cleansing agents: Water, if necessary together with cleansing agents.

14. TRANSPORT INFORMATION

No hazardous material as defined by the transport regulations.

Land transport ADR/RID: No

Maritime transport IMDG: No

Air transport ICAO-TI and IATA-DGR: No

This product is part of a kit. Information in this section refers to the kit as a whole.

15. REGULATORY INFORMATION**Labelling according to EU guidelines:**

This product is classified and labelled in accordance with directives 1999/45/EC and 91/155/EEC as modified in 2001/58/EC.

The preparation is not classified as hazardous due to the low concentration of hazardous ingredients.

National regulations:

Germany; VwVwS: Water hazardous class 1 (WGK 1) (self-assessment): slightly hazardous for water.

16. OTHER INFORMATION**Valid EC directives:** Directive 67/548/EEC
Directive 1999/45/EC
Directive 91/155/EEC as amended on Directive 2001/58/EC**R-phrases of ingredients**

These R-phrases refer to the classification of the single components/ingredients (pure substance 100%) and not to the classification of the preparation.

R 35 Causes severe burns.

Department issuing MSDS: Product Management

The information in this document is believed to be accurate and represents the best information currently available to us. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.