SAFETY DATA SHEET

According to Regulations
(EC) No. 1272/2008 and (EU) No. 453/2010

FMH QuickQuant

1. Identification

1.1 Product Identifier

Product Name: FMH QuickQuant
Product Number: QQF-100
EDMA Code: 13.01.02.02
REACH No.: A registration number is not available for this mixture as the mixture or its uses are exempted from registration, the annual tonnage does not require a registration or the registration is envisaged for a later registration deadline.

CAS No.:

Sodium chloride	Cas. No. 7647-14-5
Potassium chloride	Cas. No. 7447-40-7
Sodium Phosphate dibasic	Cas. No. 7558-79-4
Potassium Phosphate monobasic	Cas. No. 7778-77-0
Sodium azide	Cas. No. 26628-22-8
Bovine serum albumin (BSA)	Cas. No. 9048-46-8
Propidium Iodide	Cas. No. 25535-16-4
Triton X-100	Cas. No. 9002-93-1
Purified immunoglobulins or fluorochrome-conjugated Immunoglobulins	CAS-No. None assigned

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

FMH QuickQuant is available as a 100 tests kit for use on multiparametric flow cytometers. The product is composed of a set of reagents, i.e. Antibody Reagent, Permeabilization solution and Buffer Concentrate. All reagents are liquid containing the ingredients as presented above. The specific intended use is the quantitative enumeration of fetal red cells in maternal or post-natal blood samples for the assessment of fetomaternal hemorrhage, as a stand-alone test. This product is an *in vitro* diagnostic test used only by trained qualified personnel. Not for use in humans. Not for *in vivo* use.

1.3 Details of the supplier of the safety data sheet

Company: IQ PRODUCTS BV
Adress: Rozenburglaan 13a
9727 DL GRONINGEN
THE NETHERLANDS
Telephone: +31-50-5757000
Fax: +31-50-5757002
E-mail address: marketing@iqproducts.nl
Website: www.iqproducts.nl

1.4 Emergency telephone numbers

Emergency Phone # 112

2. Hazard Identification

2.1 Classification of the substance or mixture

The product does not contain a dangerous substance which is classified as hazardous according to EC Regulation No. 1272/2008. There are no reported further health hazards for the product in the current formulation and applications.

2.2 Label elements

Hazard Pictograms (GHS-US): Not applicable
Signal Word (GHS-US): Not applicable
Hazard Statements (GHS-US): Not applicable
Precautionary Statements (GHS-US): Not applicable

General

P270-Do not eat, drink or smoke when using this product;
P262-Do not get in eyes, on skin, or on clothing;
P337+P313- If eye irritation persists: Get medical advice/attention;
P280 – Wear protective gloves/protective clothing/eye protection/face protection.

2.3 Other Hazards

All reagents should be handled in accordance with good laboratory practices using appropriate precautions. In addition, handle all patient samples with appropriate precautions as described in "Biosafety in Microbial and Biomedical Laboratories", 2nd ed., 1988. HHS Publication No. (CDC) 88-8395, Centers for Disease Control.

There are no reported further health hazards for the product in the current formulation and applications. The product contain substances that may be hazardous when available in significant amounts and should be treated as potentially biohazardous. No toxic effects are to be expected when the product is handled appropriately. The product may enter the body through inhalation, ingestion, skin contact and eye contact.

Sodium azide forms explosive compounds with heavy metals. Components of this product contain azide < 0,1% (w/v). Repeated contact of these components with lead and copper, commonly found in plumbing drains, should be avoided as this may result in the buildup of shock-sensitive compound. On disposal, flush with large amounts of water to prevent azide build-up.

3. Composition/Information on ingredients

3.1 Substances

Not applicable.

3.2 Mixtures

Composition of the product:

1 ml	**Antibody Reagent** – containing sodium azide
40 ml	**Permeabilization solution**
40 ml	**Buffer solution** – containing sodium azide

Information on ingredients:

Sodium chloride	Cas. No. 7647-14-5
Potassium chloride	Cas. No. 7447-40-7
Sodium Phosphate dibasic	Cas. No. 7558-79-4
Potassium Phosphate monobasic	Cas. No. 7778-77-0
Sodium azide	Cas. No. 26628-22-8
Bovine serum albumin (BSA)	Cas. No. 9048-46-8
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Triton X-100	Cas. No. 9002-93
Purified immunoglobulins or fluorochrome-conjugated Immunoglobulins	CAS-No. None assigned

4. First-aid Measures

4.1 Description of first aid measures

Inhalation:	Expose to fresh air. If breathing problems persist seek medical advice.
Skin Contact:	Wash with plenty of water for 15 minutes. Remove contaminated clothing. Seek medical advice.
Eye Contact:	Rinse with water for 15 minutes and seek medical advice.
Ingestion:	Rinse mouth with water for 15 minutes and seek medical advice.

4.2 Most important symptoms and effects, both acute and delayed

Not available.

4.3 Indication of any immediate medical attention and special treatment needed

Notes to Physician: All treatments should be based on observed signs and symptoms of distress in the patient. Consideration should be given to the possibility that over exposure to materials other than this product may have occurred. Also see above under section 4.1.

5. Fire-fighting Measures

5.1 Extinguishing media

Extinguishing Media:	Use carbon dioxide, dry chemical extinguisher or water.
Protective Equipment:	An approved self-contained breathing apparatus and protective clothing should be used.
Special Fire and Explosion Hazards:	No special hazards determined.
Hazard Combustion Products:	Due to the composition and volume of this product, combustion products generated from it are not expected to present a significant hazard.

5.2 Special hazards arising from the substance or mixture

No special hazards determined.

5.3 Advice for firefighters

This product does not cause special protective equipment to be required. In the event of a large laboratory fire, wear full protective clothing and NIOSH-approved self-contained breathing apparatus with full-face piece operated in the pressure demand or other positive pressure mode. Water spray may be used to keep fire-exposed containers cool. Poisonous gases may be produced in fires.

6. Accidental Release Measures

6.1 Personal Precautions, Protective Equipment and Emergency Procedures

Use universal precautions, appropriate personal protective equipment and standard safe laboratory practices to clean up spilled substance promptly. Absorb spill onto an appropriate material. Avoid contact with eyes, skin and clothing. Wear safety glasses and protective gloves.

6.2 Environmental Precautions

No known environmental precautions. Avoid release to the environment.

6.3 Methods and Material for Containment and Cleaning Up

Soak up spills with an appropriate absorbent material. Consult local, state, or federal regulations for proper disposal.

6.4 Reference to Other Sections

Follow protective measures provided in Sections 7 and 8.

7. Handling and storage

7.1 Precautions for safe handling

All reagents should be handled in accordance with good laboratory practices using appropriate precautions:

- No eating, drinking, or smoking in work areas
- Wash hands after use
- Remove contaminated clothing and protective equipment before leaving work area
- Avoid inhaling, ingesting, and contact with eyes and skin.

In addition, this product should be handled as though capable of transmitting infectious diseases. Universal precautions should be followed when using this product.

7.2 Conditions for Safe Storage, Including Any Incompatibilities

All components of the FMH QuickQuant kit are stable if stored according to appropriate conditions until the expiration date as indicated on the label and on each component provided. Storage conditions recommended: 2 to 8 °C. Protect the kit from temperatures above 30°C and from prolonged time at room temperature. Do not freeze. Avoid direct sunlight.

7.3 Specific End Use(s)

The intended use is mentioned in section 1.2 no other specific uses are stipulated.

8. Exposure controls/personal protection

8.1 Control parameters

The product does not contain any materials that need to be monitored at the workplace.

8.2 Exposure controls

Universal precautions should be followed when using this product.

Wear appropriate personal protective equipment and follow safe laboratory practices.

Pictograms: 

Respiratory: None required when product is used as recommended
Hands: Wear protective gloves according to EN 166
Eye / Face: Wear safety glasses according to EN 374
Skin / Body: None required

9. Physical and chemical properties

9.1 Information on basic physical and chemical properties

	Antibody Reagent	Permeabilization solution	Buffer Solution
Physical State	Liquid	Liquid	Liquid
Appearance	Clear, colorless to light pink liquid	Clear, colorless to light yellow viscous liquid	Clear, colorless to light or medium yellow liquid
Odor	None	None	None
Odor Threshold	Not applicable	Not applicable	Not applicable
pH	Neutral	Neutral	Neutral
Melting point/freezing point	No data available	No data available	No data available
Initial boiling point and boiling range	No data available	No data available	No data available
Flash point	Not applicable	Not applicable	Not applicable
Evaporation rate	No data available	No data available	No data available
Flammability	Not applicable	Not applicable	Not applicable
Upper/lower Flammability or explosive limits	Not applicable	Not applicable	Not applicable
Vapor pressure	Not applicable	Not applicable	Not applicable
Vapor density	Not applicable	Not applicable	Not applicable
Relative density	No data available	No data available	No data available
Water solubility	Fully miscible in water	Fully miscible in water	Fully miscible in water
Partition coefficient: n-octanol/water	No data available	No data available	No data available
Auto-ignition temperature	Not self-igniting	Not self-igniting	Not self-igniting
Decomposition temperature	Not applicable	Not applicable	Not applicable
Viscosity	No data available	No data available	No data available
Explosive properties	Product is not explosive	Product is not explosive	Product is not explosive
Oxidizing properties	Product is not oxidizing	Product is not oxidizing	Product is not oxidizing

9.2 Other information

No other information available.

10. Stability and Reactivity

10.1 Reactivity

No known reactivity.

10.2 Chemical Stability

The product is stable under ambient storage and handling temperatures and under normal pressures.

10.3 Possibility of Hazardous Reactions

No hazardous reactions known when handled properly.

10.4 Conditions to Avoid

None identified.

10.5 Incompatible Materials

Metals and metallic compounds. Strong acids, strong oxidizing agents, powdered metals and reducing agents. Sodium azide forms explosive compounds with heavy metals. Components of this product contain azide < 0,1% (w/v). Repeated contact of these components with lead and copper, commonly found in plumbing drains, should be avoided as this may result in the buildup of shock-sensitive compound. No hazardous incompatibilities identified.

10.6 Hazardous Decomposition Products

No hazardous decomposition products are known to be formed by this product.

11. Toxicological information

11.1 Information on toxicological effects

Acute Toxicity: No toxic effect known.
Skin Corrosion/Irritation: No irritant effect known.
Serious Eye Damage/Irritation: No irritant effect known.
Respiratory or Skin Sensitization: No sensitizing effect known.
Germ cell mutagenicity: No data available
Carcinogenicity:
IARC: No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.
Reproductive toxicity: No data available
STOT-single exposure: No data available
STOT-repeated exposure: No data available
Aspiration Hazard: Not Classified
Toxicity on Repeated Exposure: No toxic effect known.

12. Ecological information

12.1 Toxicity

Undetermined.

12.2 Persistence and Degradability

Undetermined.

12.3 Bioaccumulative Potential

Undetermined.

12.4 Mobility in Soil

Undetermined.

12.5 Results of PBT and vPvB Assessment

Undetermined.

12.6 Other Adverse Effects

No adverse effects are known when handled and disposed properly.

13. Disposal considerations

13.1 Waste treatment methods

Product:

There are no uniform EC regulations for the disposal of chemicals or residues. Chemical residues generally count as special waste. The disposal of the latter is regulated in the EC member countries through corresponding laws and regulations. We recommend that you contact either the authorities in charge or approved waste disposal companies which will advice you on how to dispose of special waste.

Contaminated Packaging:

Disposal in compliance with official regulations. Handle contaminated packaging in the same way as the substance itself. If not officially specified differently, non-contaminated packaging may be treated like household waste or recycled.

14. Transport information

14.1 UN Number

Not determined.

14.2 UN Proper Shipping Name

Not determined.

14.3 Transport Hazard Class

Not determined.

14.4 Packing Group

Not classified.

14.5 Environmental Hazards

Not classified.

14.6 Special Precautions for Users

See subsections 6-8.

14.7 Transport in Bulk According to Annex II of MARPOL73/78 and the IBC Code

This product is provided only in non-bulk containers.

15. Regulatory information

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

SARA Section 311/312 Hazard Classes are not applicable. This product is not classified. To the best of our knowledge, safety, health, and environmental regulations according to Regulation (EC) No. 1907/2006-REACH are not applicable.

15.2 Chemical safety assessment

No chemical safety assessment has been carried out.

16. Other information

Changes to the previous version

This document has been prepared in accordance with the SDS requirements of the OSHA Hazard Communication Standard 29 CFR 1910:1200 and complies with Regulation (EC) 453/2010.

Literature References

Regulation (EC) No. 1272 / 2008
Regulation (EU) No. 453 / 2010
Regulation (EC) No. 1907 / 2006

Disclaimer/Statement of Liability

The information presented in this Safety Data Sheet is based on the present state of our knowledge. The product should be used according to the instructions provided by the manufacturer, see "Instructions for use" as presented in the package insert accompanying every product. We make no warranty, express or implied, with respect to such information, and we assume no liability resulting from its use. Users should make their own investigations to determine the suitability of the information for their particular purposes. The product should be used according to the instructions provided by the manufacturer, see "instructions for use" as presented in the Package Insert accompanying every product. *IQ Products BV* nor any distributors thereof shall not be held liable for any claims, losses, or damages resulting from handling or from contact with the product.

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