

SAFETY DATA SHEET

According to Regulations

(EC) No. 1907/2006, (EC) No. 1272/2008, (EU) No. 453/2010,
(EU) No. 2015/830, (EU) No. 2020/878, (EU) No. 2024/2865

Fetal Cell Count™ kit

1. Identification of the substance/mixture and of the company/undertaking

1.1 Product Identifier

Product Name: Fetal Cell Count™ kit
Product Number: IQP-363
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.

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

Intended use: This product is intended for *In vitro* diagnostic use.
Uses advised against: Not for use in humans.
Not for *in vivo* use.
Not for use other than those indicated above.

1.3 Details of the supplier of the safety data sheet

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

1.4 Emergency telephone numbers

Emergency Phone # 112

2. Hazard Identification

The Fetal Cell Count™ Kit is available as a 25 tests kit. The product is composed of a set of reagents, i.e. Fetal Cell Count™ Reagent A, B, C, D, E and F. All reagents are liquid containing the ingredients as presented above.

There are no reported further health hazards for the product in the current formulation and applications. Only Reagent B of the product composition does contain a dangerous substance in amounts that need to be hazard labeled according to Regulation (EC) No. 1272/2008. All other components of the product contain substances that may be hazardous when available in significant amounts and should be treated as potentially biohazardous.

Component	Content	Quantity
Reagent A	Fixative solution (A)	2.5 ml
Reagent B	Fixative solution (B);	2.5 ml
Reagent C	Permeabilization solution (C);	2.5 ml
Reagent D	Washing Solution (10xD	50 ml
Reagent E	Monoclonal Antibody - FITC conjugated	1.3 ml
Reagent F	Monoclonal Antibody - R-PE conjugated	1.3 ml


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

Carcinogenicity – category 2 (H351)

Acute Toxicity – category 3 (H331, H311, H301)

Skin Sens. – category 1 (H317)

2.2 Label elements

Pictogram	
Signal word	DANGER
Component	Reagent B

Hazard Statements (GHS_US):

Reagent B:

H301 Toxic if swallowed.

H311 Toxic in contact with skin.

H317 May cause an allergic skin reaction;

H331 Toxic if inhaled.

H351 Suspected of causing cancer;

Precautionary Statements (GHS-US):

Reagent B:

P202 Do not handle until all safety precautions have been read and understood.

P210 Keep away from heat/sparks/open flames/hot surfaces. — No smoking.

P280 Wear protective gloves/protective clothing/eye protection/face protection.

P303 + P361 + P353 IF ON SKIN (or hair): Remove/Take off Immediately all contaminated clothing. Rinse SKIN with water/shower.

P304 + P340, P310 IF INHALED: Remove victim to fresh air and Keep at rest in a position comfortable for breathing and immediately call a POISON CENTER or doctor/ physician.

P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

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;

P501 Dispose of contents/container according to local, regional, national, territorial, provincial, and international regulations.

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", 6th ed., 2020. HHS Publication No. (CDC) 300859, 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:

Composition of the product:			Classification CLP according to Regulation (EC) No 1272/2008 (CLP)	
CAS/EC-no.	Chemical name	Content	Hazard Class and Category Code(s)	Hazard statement
Reagent A				
N/A	Fetal Bovine Serum (FBS)	99.91% (v/v)	N/A	N/A
26628-22-8	Sodium Azide	0.09% (v/v)	Not applicable concentration limit ≥ 1 % according to (EU) No. 2020/878	
Reagent B				
30525-89-4	(Para)Formaldehyde	6.0 % (w/v)	Carc. 2 Acute Tox. 3 * Acute Tox. 3 * Acute Tox. 3 * Skin Corr. 1B ** Skin Sens. 1	H351 H331 H311 H301 H317
14431-43-7	Glucose	5.96 % (w/v)	N/A	N/A
6138-23-4	Trehalose	7.56 % (w/v)	N/A	N/A
1310-73-2	Sodium hydroxide	0.43 % (w/v)	N/A	N/A
10049-21-5	Sodiumdihydrogen phosphate monohydrate (NaH ₂ PO ₄)	1.88 % (w/v)	N/A	N/A
Reagent C				
N/A*	Phosphate buffered Saline (10x)	10.0 % (v/v)	N/A*	N/A*
9005-49-6	Heparin	0.2 % (v/v)	N/A	N/A
151-21-3	Sodium Dodecyl Sulfate	0.3 % (v/v)	Not applicable concentration limit ≥ 1 % according to (EU) No. 2020/878	
Reagent D				
N/A*	Phosphate buffered Saline (10x)	10.0 % (v/v)	N/A*	N/A*
9005-49-6	Heparin	0.2 % (v/v)	N/A	N/A
Reagent E				
N/A*	Phosphate buffered Saline (10x)	10.0 % (v/v)	N/A*	N/A*
N/A	Horse serum	10.0 % (v/v)	N/A	N/A
26628-22-8	Sodium Azide	0.09% (v/v)	Not applicable concentration limit ≥ 1 % according to (EU) No. 2020/878	
Reagent F				
N/A*	Phosphate buffered Saline (10x)	10.0 % (v/v)	N/A*	N/A*
N/A	Horse serum	10.0 % (v/v)	N/A	N/A
26628-22-8	Sodium Azide	0.09% (v/v)	Not applicable concentration limit ≥ 1 % according to (EU) No. 2020/878	

* Phosphate Buffered Saline (10x) is produced in-house - composition of this component is shown here:

CAS/EC-no	Chemical Name	Content [(%) w/v]	Hazard Class and Category Code(s)	Hazard statement
N/A	Demineralized water	89.60	N/A	N/A
7647-14-5	Sodium chloride	8.75	N/A	N/A
10028-24-7	Sodium phosphate dibasic dihydrate	1.41	N/A	N/A
7778-77-0	Potassium dihydrogen phosphate	0.24	N/A	N/A

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.

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, 8 and 13.

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 Fetal Cell Count™ 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 ISO 16321-1:2022

Eye / Face: Wear safety glasses according to EN ISO 374-1:2016

Skin / Body: None required

9. Physical and chemical properties

9.1 Information on basic physical and chemical properties

Reagent A			
Physical state: Liquid, clear	Colour: Light yellow	Odour: No data available	Melting/freezing point: No data available
Initial boiling point and range: Not applicable	Flammability: No data available	Lower and upper explosion limit: No data available	Flash point: Not applicable
Auto-ignition temperature: Not self-igniting	Decomposition temperature: Not applicable	pH: 5,4 - 5,6	Kinematic viscosity: No data available
Solubility: Fully miscible in water	Partition coefficient n-octanol/water: No data available	Vapour pressure: Not applicable	(relative) density: Not applicable
Relative vapour density: Not applicable	Particle characteristics: Not applicable	Explosive properties Not explosive	Oxidizing properties Not oxidizing

Reagent B			
Physical state: Liquid, clear	Colour: Colourless	Odour: No data available	Melting/freezing point: No data available
Initial boiling point and range: Not applicable	Flammability: No data available	Lower and upper explosion limit: No data available	Flash point: Not applicable
Auto-ignition temperature: Not self-igniting	Decomposition temperature: Not applicable	pH: 5,4 - 5,6	Kinematic viscosity: No data available
Solubility: Fully miscible in water	Partition coefficient n-octanol/water: No data available	Vapour pressure: Not applicable	(relative) density: Not applicable
Relative vapour density: Not applicable	Particle characteristics: Not applicable	Explosive properties Not explosive	Oxidizing properties Not oxidizing

Reagent C			
Physical state: Liquid, clear	Colour: Light white	Odour: No data available	Melting/freezing point: No data available
Initial boiling point and range: Not applicable	Flammability: No data available	Lower and upper explosion limit: No data available	Flash point: Not applicable
Auto-ignition temperature: Not self-igniting	Decomposition temperature: Not applicable	pH: 5,4 - 5,6	Kinematic viscosity: No data available
Solubility: Fully miscible in water	Partition coefficient n-octanol/water: No data available	Vapour pressure: Not applicable	(relative) density: Not applicable
Relative vapour density: Not applicable	Particle characteristics: Not applicable	Explosive properties Not explosive	Oxidizing properties Not oxidizing

Reagent D			
Physical state: Liquid, clear	Colour: Colourless	Odour: No data available	Melting/freezing point: No data available
Initial boiling point and range: Not applicable	Flammability: No data available	Lower and upper explosion limit: No data available	Flash point: Not applicable
Auto-ignition temperature: Not self-igniting	Decomposition temperature: Not applicable	pH: No data available	Kinematic viscosity: No data available
Solubility: Fully miscible in water	Partition coefficient n-octanol/water: No data available	Vapour pressure: Not applicable	(relative) density: Not applicable
Relative vapour density: Not applicable	Particle characteristics: Not applicable	Explosive properties Not explosive	Oxidizing properties Not oxidizing

Reagent E			
Physical state: Liquid, clear	Colour: Light yellow	Odour: No data available	Melting/freezing point: No data available
Initial boiling point and range: Not applicable	Flammability: No data available	Lower and upper explosion limit: No data available	Flash point: Not applicable
Auto-ignition temperature: Not self-igniting	Decomposition temperature: Not applicable	pH: No data available	Kinematic viscosity: No data available
Solubility: Fully miscible in water	Partition coefficient n-octanol/water: No data available	Vapour pressure: Not applicable	(relative) density: Not applicable
Relative vapour density: Not applicable	Particle characteristics: Not applicable	Explosive properties Not explosive	Oxidizing properties Not oxidizing

Reagent F			
Physical state: Liquid, clear	Colour: Light pink	Odour: No data available	Melting/freezing point: No data available
Initial boiling point and range: Not applicable	Flammability: No data available	Lower and upper explosion limit: No data available	Flash point: Not applicable
Auto-ignition temperature: Not self-igniting	Decomposition temperature: Not applicable	pH: No data available	Kinematic viscosity: No data available
Solubility: Fully miscible in water	Partition coefficient n-octanol/water: No data available	Vapour pressure: Not applicable	(relative) density: Not applicable

Relative vapour density: Not applicable	Particle characteristics: Not applicable	Explosive properties Not explosive	Oxidizing properties Not oxidizing
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9.2 Other information

No other physical and chemical parameters are applicable relevant to the safe use the Fetal Cell Count™ kit.

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 hazard classes as defined in Regulation (EC) No. 1272/2008

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:

This product contains formaldehyde (a component of reagent B) that is a Group 1 carcinogenic to humans based on its International Agency for Research on Cancer (IARC) classification.

Reproductive toxicity: No data available

STOT-single exposure: No data available

STOT-repeated exposure: No data available

Aspiration hazard: Not Classified

11.2 Information on other hazards

No other information on adverse health effects are identified relevant to the safe use of the Fetal Cell Count™ kit.

12. Ecological information

12.1 Toxicity

Undetermined.

12.2 Persistence and degradability

Undetermined.

12.3 Bio accumulative potential

Undetermined.

12.4 Mobility in soil

Undetermined.

12.5 Results of PBT and vPvB assessment

Undetermined.

12.6 Endocrine disrupting properties

Undetermined.

12.7 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 advise 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 or ID Number

Not determined.

14.2 UN proper shipping name

Not determined.

14.3 Transport hazard class(es)

Not determined.

14.4 Packing group

Not classified.

14.5 Environmental hazards

Not classified.

14.6 Special precautions for users

See subsections 6-8 and 13.

14.7 Maritime transport in bulk according to IMO instruments

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 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) No. 1272/2008, (EU) No. 453/2010, (EU) No. 2015/830 and (EU) No. 2020/878.

In November 2025 the third revision of this document was published. Changes in this document and corresponding justifications are shown in the table below:

Current version	Revision 3.0, November 2025
Previous version	Revision 2.0, 15June2021
Changes	<ol style="list-style-type: none"> 1. Literature references to Regulations (EC) No 1907/2006, (EC) No 1272/2008, (EU) No 2015/830 and (EU) No 2020/878 added. Replaced EN-166 by EN ISO 16321-1:2022 and EN-374 by EN ISO 374-1:2016. 2. Toxicological information regarding carcinogenicity has been revised. 3. Basic physical and chemical properties (section 9.1) now put in a table per reagent, so that it is more readable 4. Placed label elements (Section 2.2) in a table and enlarged the symbols 5. Corrected hazard symbol 6. Removed EDMA code 7. Minor layout changes
Justification	<ol style="list-style-type: none"> 1. New version of these guidelines were available 2. new CLP analyse introduced and performed 3.-5. Increasing readability 6. EDMA code is not required to be included in the SDS

Literature References

- Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)
- Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures (CLP)
- Regulation (EU) No 453/2010 amending Regulation (EC) No 1907/2006
- Regulation (EU) No 2015/830 amending Regulation (EC) No 1907/2006
- Regulation (EU) No 2020/878 amending Annex II to Regulation (EC) No 1907/2006
- EN ISO 16321-1:2022
- EN ISO 374-1:2016

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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