

ISE S.r.l. <small>CUSTOMISED SOLUTIONS FOR YOUR LABORATORY</small>	EN	Calprotectin Reagent Calprotectin Calibrator Calprotectin Control			SDS	 IVD	<small>Rev. B – 20/10/2023</small>			
		<small>R3330000059 (Reagent)</small>								
		<small>REF R3330000065 (Calibrator)</small>								
		<small>R3330000069 (Control)</small>								

Safety Data Sheet (According to 1272/2008/EC)

Trade name: **Calprotectin Reagent, Calibrator, Control**
Article number: **R3330000059, R3330000065, R3330000069**

1 Identification of the substance / preparation and the company

1.1 Product identifiers

Product REF: Refer to the Header
Product Description: Refer to the Header

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

Relevant identified uses: Calprotectin Combo is a latex turbidimetric assay for the quantitative detection of calprotectin in human stool samples.

Calprotectin Turbilatex Calibrators must be used only for the calibration of the Calprotectin Turbilatex Combo assay. Calprotectin Turbilatex C1 & C2 controls must be used only to verify the performance of the Calprotectin Turbilatex. For professional in vitro diagnostic use only.

Calprotectin Turbilatex Reagent 1 (R1): buffer and sodium azide <0.1%.

Calprotectin Turbilatex Latex Reagent (R2): suspension of latex particles coated with antibodies anti-calprotectin.

Calprotectin diluted Calibrators: Protein in solution with preservatives.

Calprotectin Turbilatex Control C1: Protein solution with preservatives.

Calprotectin Turbilatex Control C2: Protein solution with preservatives.

Uses advised against: No information available.

1.3 Details of the supplier of the safety data sheet

Identification company: I.S.E. S.r.l.
Via delle Driadi, 45
00133 Roma - Italia
Tel. +39 0774+ 579365; FAX +39 0774 579305
E-mail: info@logotech-ise.com www.logotech-ise.com

Additional information from: I.S.E. S.r.l. - Regulatory Affairs E-mail: info@logotech-ise.com

1.4 Emergency telephone number

Emergency information: As above or call
Policlinico A. Gemelli - Largo Agostino Gemelli, 8 - Roma - Italy - Tel. + 39 063054343

2 Hazards identification

2.1 Classification of the substance or mixture: Non-hazardous preparation (Regulation 1272/2008/EC).

Classification according to EC regulation 1272/2008: Non-hazardous.

Classification according to Directive 1999/45/EC: Non-hazardous.

Additional information: See SECTION 16.



I.S.E. S.r.l.

Via Delle Driadi, 45 – 00133 Rome - Italy

Tel.+39 0774579365 FAX +39 0774579305 www.logotech-ise.com E-mail: info@logotech-ise.com

ISE S.r.l. <hr/> CUSTOMISED SOLUTIONS FOR YOUR LABORATORY	EN	Calprotectin Reagent Calprotectin Calibrator Calprotectin Control			SDS	 	Rev. B – 20/10/2023
		REF	R3330000059 (Reagent)				
			R3330000065 (Calibrator)				
			R3330000069 (Control)				

2.2 Label elements

Signal Word: None

2.3 Other hazards

No hazards know

3 Composition / information on ingredients

3.1 Substances

No information available..

3.2 Mixtures

Mixture description: Calprotectin Turbilatex R1 contains buffer and <0.1% of sodium azide as preservative. Calprotectin Turbilatex R2 contains latex coated particles and buffer. Diluted Calibrators contains protein, buffer and preservatives. Calprotectin Turbilatex Control C1 contains buffer and preservatives. Calprotectin Turbilatex Control C2 contains buffer and preservatives.

Hazardous components: **Note:** Calprotectin Turbilatex Combo components are not dangerous preparation (Regulation (EC) No 1272/2008 [CLP]). Calprotectin diluted Calibrators is a protein solution containing buffer, detergent and <0.1% of sodium azide as preservative. Calprotectin Turbilatex Controls are a protein solution with <0.1% of sodium azide as preservative.

Additional information: For full text of H-phrases: see SECTION 16

4 First aid measures

4.1 Description of first aid measures

After inhalation: Ensure sufficient ventilation of workplace. Consult a physician.

After skin contact: Wash off immediately with soap and plenty of water. Consult a physician.

After eye contact: Rinse thoroughly with plenty of water for at least 15 minutes. Consult a physician.

After ingestion: Clean mouth with water and drink afterwards plenty of water. Consult a physician.

4.2 Most important symptoms and effects, both acute and delayed

No information available.



I.S.E S.r.l.

Via Delle Driadi, 45 – 00133 Rome - Italy

Tel.+39 0774579365 FAX +39 0774579305 www.logotech-ise.com E-mail: info@logotech-ise.com

ISE S.r.l. <hr/> CUSTOMISED SOLUTIONS FOR YOUR LABORATORY	EN	Calprotectin Reagent Calprotectin Calibrator Calprotectin Control	SDS	 IVD	Rev. B – 20/10/2023
		R3330000059 (Reagent)			
		REF R3330000065 (Calibrator)			
		R3330000069 (Control)			

4.3 Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

5 Fire fighting measures

5.1 Extinguishing media

Suitable Extinguishing Media: Water or CO₂. Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

5.2 Special hazards arising from the substance or mixture

Special hazard caused by the Thermal decomposition can lead to release of irritating gases and vapors. material, its products of combustion or flue gases:

5.3 Advice for firefighters

As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear.

6 Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Prevent contact with skin, eyes and clothes. Use personal protective equipment. Ensure adequate ventilation.

6.2 Environmental precautions

Measures for environmental protection: Given the way dispensation there is no possibility of accidental spillage in sufficient quantity to be dangerous. Avoid release to the environment.

6.3 Methods and material for containment and cleaning up

Measures for cleaning/collecting: Soak up with inert absorbent material. Clean contaminated surface thoroughly.

6.4 Reference to other sections

: If appropriate Sections 8 and 13 shall be referred to.

7 Handling and storage



I.S.E S.r.l.

Via Delle Driadi, 45 – 00133 Rome - Italy

Tel.+39 0774579365 FAX +39 0774579305 www.logotech-ise.com E-mail: info@logotech-ise.com

ISE S.r.l. <small>CUSTOMISED SOLUTIONS FOR YOUR LABORATORY</small>	EN	Calprotectin Reagent Calprotectin Calibrator Calprotectin Control			SDS	 IVD	<small>Rev.B – 20/10/2023</small>			
		<small>R3330000059 (Reagent)</small>								
		<small>REF R3330000065 (Calibrator)</small>								
		<small>R3330000069 (Control)</small>								

7.1 Precautions for safe handling

Precautions for safe handling: Good Laboratory Practices (disposal gloves). Not to eat, drink and smoke in work areas. Avoid contact and contamination with skin, eyes and clothes. Use disposal gloves. Specimens should be handled as potentially infectious materials.

7.2 Conditions for safe storage, including any incompatibilities

Store in a dry place at +2°C to +8°C, protect from the light.

7.3 Specific end use(s)

Only use these reagents with other Calprotectin Turbilatex reagents (Latex reagents and Calibrator)

8 Exposure controls / personal protection

8.1 Control parameters

Any specific protection and prevention measures should not be taken during use of the product

Exposure limits: Based upon the available data, the classification criteria are not met.

8.2 Exposure controls

All the specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.

Appropriate engineering controls: No relevant for this material.

Personal protective equipment: Handle with disposable gloves (EN 374). Wear appropriate protective safety eyewear and clothing, such as a lab coat.

Environmental Exposure Controls: No special measures are required.

9 Physical and chemical properties

9.1 Information on basic physical and chemical properties

General information

Appearance/Physical State Calprotectin Turbilatex Reagent 1 (R1): Slightly yellowish solution
 Calprotectin Turbilatex Latex Reagent (R2): White colored solution
 Diluted calibrators (Cal 0-5): Transparent solution
 Calprotectin Turbilatex Control C1: Transparent solution
 Calprotectin Turbilatex Control C2: Transparent solution

The following table applies to R1 & R2, Calprotectin diluted Calibrator and Controls C1&C2



I.S.E S.r.l.

Via Delle Driadi, 45 – 00133 Rome - Italy

Tel.+39 0774579365 FAX +39 0774579305 www.logotech-ise.com E-mail: info@logotech-ise.com

ISE S.r.l. <small>CUSTOMISED SOLUTIONS FOR YOUR LABORATORY</small>	EN	Calprotectin Reagent Calprotectin Calibrator Calprotectin Control			SDS	 IVD	<small>Rev.B – 20/10/2023</small>			
		R3330000059 (Reagent)								
		REF R3330000065 (Calibrator)								
		R3330000069 (Control)								

Odor	Odourless	Explosion Limits	Not applicable
pH	7.5-8.5	Vapor Density	Not determined
Boiling Point	Similar to water (100°C)	Relative density	Similar to water (1g/cm ³)
Flash Point	Not applicable	Solubility	Soluble
Vapor Pressure	Similar to water (23hPa)	Flammability	Not applicable
Melting Point	Similar to water (0°C)	Viscosity	Not determined
Autoignition Temperature	Not determined	Explosive Properties	Not explosive
Partition Coefficient (n-octanol/water)	Not determined	Oxidizing Properties	Not determined

10 Stability and reactivity

10.1 Reactivity

No hazardous reactivity known.

10.2 Chemical stability

Under storage at normal ambient temperatures the product is stable. No known hazardous reactions.

10.3 Possibility of hazardous reactions

Thermal decomposition can lead to release of irritating gases and vapors.

10.4 Conditions to avoid

Direct contact with a flame. Temperatures outside the range of 2-8 °C. Avoid storing in places with high humidity and protect from light.

10.5 Incompatible products

The stool sample should be treated only with buffer that is provided with the product before testing.

10.6 Hazardous decomposition products

No known hazardous decomposition products.

11 Toxicological information

11.1 Information on toxicological effects

Acute toxicity	Product does not present an acute toxicity hazard based on known or supplied information
on the skin:	Based upon the available data, the classification criteria are not met.
on the eye:	Based upon the available data, the classification criteria are not met



ISE S.r.l. <hr/> CUSTOMISED SOLUTIONS FOR YOUR LABORATORY	EN	Calprotectin Reagent Calprotectin Calibrator Calprotectin Control			SDS	 IVD	Rev. B – 20/10/2023			
		REF								
		R3330000059 (Reagent)								
		R3330000065 (Calibrator)								

Respiratory or skin sensitisation Based upon the available data, the classification criteria are not met

Germ cell mutagenicity: : Based upon the available data, the classification criteria are not met

Carcinogenicity A4-Not classifiable as a Human Carcinogen.

Reproductive toxicity: Based upon the available data, the classification criteria are not met.

Summary of evaluation of the CMR properties: Based upon the available data, the classification criteria are not met.

STOT-single exposure: Based upon the available data, the classification criteria are not met.

STOT-repeated exposure: Based upon the available data, the classification criteria are not met.

Aspiration hazard: Based upon the available data, the classification criteria are not met.

12 Ecological information

12.1 Toxicity

Ecotoxicological effects Based upon the available data, the classification criteria are not met. The product should be discarded in a proper biohazard container after testing. Do not allow product to reach ground water, water bodies or sewage system.

12.2 Persistence and degradability

Based upon the available data, the classification criteria are not met.

12.3 Bioaccumulative potential

Based upon the available data, the classification criteria are not met.

12.4 Mobility in soil

Based upon the available data, the classification criteria are not met.

12.5 Results of PBT and vPvB assessment

: No data available for assessment.

12.6 Other adverse effects

: Based upon the available data, the classification criteria are not met.

13 Disposal considerations

13.1 Waste treatment methods



I.S.E S.r.l.

Via Delle Driadi, 45 – 00133 Rome - Italy

Tel.+39 0774579365 FAX +39 0774579305 www.logotech-ise.com E-mail: info@logotech-ise.com

ISE S.r.l. <small>CUSTOMISED SOLUTIONS FOR YOUR LABORATORY</small>	EN	Calprotectin Reagent Calprotectin Calibrator Calprotectin Control	SDS	 IVD	<small>Rev.B – 20/10/2023</small>
		REF	R3330000059 (Reagent)		
			R3330000065 (Calibrator)		
			R3330000069 (Control)		

Waste from Residues: After testing, the product must be disposed of compliance with the respective local, state or national regulations. One option would be possible inactivation of infectious agents in the product after use. Performed in autoclave at a pressure and a certain temperature.

Non-contaminated packaging: The containers can be recycled.

14 Transport information

Maritime transport (IMDG/IMO): Not dangerous preparations not required transport regulations.

Land transport (ADR): Not dangerous preparations not required transport regulations.

Air Transport (IATA) Not dangerous preparations not required transport regulations.

15 Regulatory information

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

This product does not require special labelling, in accordance with the appropriate EC directives. These products are used for in vitro diagnosis, so they must meet the criteria described in Directive 98/79/CE, do not carry the CE marking for marketing outside the EU.

The product is a mixture which is not subject to Regulation (EC) No 1005/2009, (EC) No 850/2004.

National Regulations: Please ask your national/regional authorities

15.2 Chemical Safety Assessment

A Chemical Safety Assessment/Report has not been conducted.

16 Other information

Recommendations: Consult instructions for use prior to product use. Professional use only for in vitro diagnosis

References (previous version): RD 255/2003, of February 28, approving the Regulation on classification, packaging and labeling of dangerous preparations, which incorporates into Spanish law Directive 1999/45/CE, Directive 2001/60/CE and partly Directive 2001/58/CE. Directive 91/155/CE.

Changes: Update in accordance with Regulation (EC) No 1272/2008 and EU No 2015/830 (changes to all sections).



ISE S.r.l. <hr/> CUSTOMISED SOLUTIONS FOR YOUR LABORATORY	EN	Calprotectin Reagent Calprotectin Calibrator Calprotectin Control	SDS	 IVD	Rev. B – 20/10/2023
		REF			
		R3330000059 (Reagent)			

Abbreviations and acronyms:

STOT: Specific Target Organ Toxicity
 PBT: Persistent, Bioaccumulative and Toxic
 vPvB: very Persistent and very Bioaccumulative

Key literature references and sources for data:

see instruction for use, Safety Data sheet and ECHA

Classification and procedure used to derive the classification for mixtures according to Regulation (EC) 1272/2008 [CLP]:

Annex I section 3 and 4; Annex VI Table 3.1 of Regulation (EC) No 1272/2008 was used for the purpose of classification.

Relevant H-statements (number None and full text):

Training advice:

No special training is required.

Contact

E. S.r.l.
 Via delle Driadi, 45
 00133 Roma - Italia
 Tel. +39 0774+ 579365; FAX +39 0774 579305
 E-mail: info@logotech-ise.com www.logotech-ise.com

