Chorus Calprotectin (REF 86600 - 86600/C03) and Chorus Calprotectin K (REF 86601) are immunoenzymatic methods for the quantitative determination of Calprotectin in stools samples.

REF 86600: Each package contains 2 bags with 6 devices each (sufficient for 12 determinations of total).
REF 86600/C03: Each package contains 2 bags with 6 devices each and a bag with 4 devices used for calibration (sufficient for 16 determinations of total).
REF 86601: Each package contains 2 bags with 6 devices each (sufficient for 12 determinations of total).

Each kit consists of:

- **Device:**
  - Position 8: Space for application of bar code label
  - Position 7: Empty
  - Position 6: MICROPLATE WELL
    Coated with polyclonal anti-calprotectin antibodies
  - Position 5: MICROPLATE WELL
    Uncoated.
  - Position 4: TMB SUBSTRATE 0.4 ml.
    The substance is not classified as dangerous according to Regulation 1272/2008 and does not contain hazardous substances and/or with limit values for exposure in concentrations above the established limits.
    For this mixture, according to EC Regulations 1907/2006 and 453/2010, is not necessary to develop a material safety data sheet.
    Contents: Tetramethylbenzidine 0.26 mg/mL and H2O2 0.01% stabilized in 0.05 mol/L citrate buffer (pH 3.8)
  - Position 3: SAMPLE DILUENT 0.45 ml
    The substance is not classified as dangerous according to Regulation 1272/2008 and does not contain hazardous substances and/or with limit values for exposure in concentrations above the established limits.
    For this mixture, according to EC Regulations 1907/2006 and 453/2010, is not necessary to develop a material safety data sheet.
    Contents: Buffer solution at pH 7.9.
  - Position 2: CONJUGATE 0.3 ml
    The substance is not classified as dangerous according to Regulation 1272/2008 and does not contain hazardous substances and/or with limit values for exposure in concentrations above the established limits.
    For this mixture, according to EC Regulations 1907/2006 and 453/2010, is not necessary to develop a material safety data sheet.
    Contents: anti-calprotectin IgG antibodies labeled with horseradish peroxidase, in buffer solution.
  - Position 1: EMPTY WELL
    In which the operator must place the undiluted sample

- **CALIBRATOR:**
  - 1x0.3 ml (REF 86600)
  - 1x0.15 ml (REF 86600/C03)
  - 1x0.3 ml (REF 86601)
    Calprotectin. Ready for use.

- **POSITIVE CONTROL:**
  - 1x0.6 ml (REF 86600)
  - 1x0.25 ml (REF 86600/C03)
  - 1x0.6 ml (REF 86601)
    Calprotectin. Ready for use.
• SAMPLE DILUENT:
  1x1.8 ml (REF 86600 – 86600/C03 – 86601)
  Diluent ready to use.

The mixtures are not classified as dangerous according to Regulation 1272/2008 and do not contain hazardous substances and/or with limit values for exposure in concentrations above the established limits.

For these mixtures, according to EC Regulations 1907/2006 and 453/2010, is not necessary to develop a material safety data sheet. The Material Safety Data Sheet of the product is reported below.
1. IDENTIFICATION OF THE SUBSTANCE/ MIXTURE AND OF THE COMPANY/ UNDERTAKING

1.1 PRODUCT IDENTIFIERS

Product name: CHORUS CALPROTECTIN
CHORUS CALPROTECTIN K

Product number: CHORUS CALPROTECTIN (REF 86600 - REF 86600/ C03)
CHORUS CALPROTECTIN K (REF 86601)

Brand: DIESSE

1.2 RELEVANT IDENTIFIED USES OF THE SUBSTANCES OR MIXTURE AND USES ADVISED AGAINST

Identified use: Immunoenzymatic methods for the quantitative determination of calprotectin in stools samples, using a disposable device applied on the Chorus and Chorus TRIO instruments. Professional use as laboratory reagent.

1.3 DETAILS OF THE SUPPLIER OF THE SAFETY DATA SHEET

Company: DIESSE Diagnostica Senese SpA

Registered office: Via A. Solari 19
20144 Milan, Italy
Tel: +39 02 4859121
Fax: +39 02 48008530

Production plant: Via delle Rose, 10 - Loc. Tognazza
53035 Monteriggioni (SI), Italy
Tel: +39 0577 319560/61
Fax: +39 0577 318763

1.4 EMERGENCY TELEPHONE NUMBER

Emergency number:

Centro Antiveleni, Ospedale Niguarda Ca’ Granda - Milano
Tel: +39 02 66101029

Centro Antiveleni, Azienda Ospedaliera “S.G.Battista” - Molinette di Torino - Torino
Tel: +39 011 6637637

Centro Antiveleni - U.O. Tossicologia Medica, Azienda Ospedaliera Careggi - Firenze
Tel: +39 055 4277238

Centro Antiveleni, Policlinico A. Gemelli - Università Cattolica del Sacro Cuore - Roma
Tel: +39 06 3054343

Centro Antiveleni, Azienda Ospedaliera A. Cardarelli - Napoli
Tel: +39 081 7472870


2. HAZARDS IDENTIFICATION

2.1 CLASSIFICATION OF THE SUBSTANCES OR MIXTURE

Classification according to Regulation (EC) No. 1272/ 2008:
The mixtures are not classified as dangerous according to Regulation 1272/2008

Hazard statement: None

2.2 LABEL ELEMENTS

Pictograms: None

Signal word: None

Hazard statement(s): None

Precautionary statement(s): None
2.3 Other hazards

None

3. COMPOSITION/ INFORMATION ON INGREDIENTS

3.1 Substances

Not applicable

3.2 Mixtures

The products contain no mixtures and substances classified as hazardous to health and/or the environment in concentrations exceeding the limits according to Regulation 1272/2008.

4. FIRST AID MEASURES

4.1 Description of first aid measures

General advice: Move the person from the exposure to open air. Consult a physician immediately and show this Material Safety Datasheet.

Skin contact: Wear off the contaminated clothes and wash with copious amounts of water.

Eye contact: If present, remove immediately contact lenses. Wash with plenty of water at least 15 minutes, keeping eyelids opened. Consult an oculist if the irritation persists.

Inhalation: Move the person from the exposure to open air. Consult a physician.

Ingestion: Rinse mouth immediately and drink a copious amounts of water. Call a physician immediately. Do not cause vomiting.

4.2 Most important symptoms and effects

No data available.

4.3 Indication of any immediate medical attention and special treatment needed

No data available, other than point 4.1.

5. FiRPERTIES MEASURES

5.1 Extinguishing media

Suitable extinguishing media: Use extinguishing measures (CO₂, foam, powder) that are appropriate to local circumstances and the surrounding environment.

Not Suitable extinguishing media: None

5.2 Special hazards arising from the substance or mixture

The mixture is not flammable, however in case of fire may release irritating and/or toxic gases.

5.3 Advice for firefighters

In case of fire wear self-contained breathing apparatus. Avoid that fire extinguishing water contaminates surface water and/or groundwater.

6. ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

Keep people not involved in the intervention operations away. Ensure an adequate ventilation of the affected area. Do not handle damaged containers or the leaked product before wearing appropriate protective outfit.

6.2 Environmental precautions

Avoid the contamination of surface water, soil and the dispersion in the air. Do not let product enter into drains. Discharge into the environment must be avoided.

SAFETY INFORMATION

Chorus Calprotectin (REF: 86600 – 86600/C03)
Chorus Calprotectin K (REF: 86601)
6.3 METHODS AND MATERIALS FOR CONTAINMENT AND CLEANING UP

Contain the leakages with earth and sand. Collect the spilled material and store it in suitable containers for disposal. Use water only to remove residuals, to avoid the danger of spill of product into the sewers.

6.4 REFERENCE TO OTHER SECTIONS

For further information see section 8 and 13.

7. HANDLING AND STORAGE

7.1 PRECAUTION FOR SAFE HANDLING

Work in well ventilated areas and in the presence of ventilation systems or personal protective equipment. Do not inhale vapors or mists. Calibrator and Positive Control have to be handled as potentially infected materials. In presence of skin lesions the handling has to be avoided.

7.2 CONDITION FOR SAFE STORAGE, INCLUDING ANY INCOMPATIBILITIES

Keep the containers at 2-8°C in a cool, well-ventilated area, away from heat sources and humidity. Close accurately the containers and keep them vertically avoiding the possibility of falls and leakage.

7.3 SPECIFIC END USE

None

8. EXPOSURE CONTROL/ PERSONAL PROTECTION

8.1 CONTROL PARAMETERS

Applicable exposure limits: None

8.2 EXPOSURE CONTROLS

Work and handle according to the usual precautionary measures for handling chemicals.

Do not eat, drink or smoke while handling the product; wash hands thoroughly with soap and water before meals and after the work shift. Immediately remove all contaminated clothing.

Appropriate engineering controls: Ensure an adequate ventilation of the working area.

Personal Protective Equipment:

The suggestions on the use of specific PPE are indicative. Their choice should be made according to the use of the product and the instructions given by the supplier of the device.

Hand protections:

Chemical-resistant gloves, compliant with EN 374.

Eye protections:

Side Shields Safety Goggles compliant with EN 166

Body protections:

Work outfits

Respiratory protections:

Work using chemical cabinet and, if necessary, masks (EN 143).

8.3 ENVIRONMENTAL EXPOSURE CONTROLS:

Do not discard residuals in the environment.
9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 INFORMATION ON BASIC PHYSICAL AND CHEMICAL PROPERTIES

- **Appearance**: Liquid
- **Odor**: Odorless
- **Odor threshold**: Not pertinent
- **PH**: See it at the first page
- **Melting point/freezing point**: No data available
- **Initial boiling point and boiling range**: No data available
- **Flash point**: Not pertinent
- **Evaporation rate**: Not pertinent
- **Flammability**: Not pertinent
- **Upper/lower flammability or explosive limit**: Not pertinent
- **Vapor pressure**: No data available
- **Vapor density**: No data available
- **Relative density**: No data available
- **Water solubility**: Soluble in water
- **Partition coefficient: n-octano/water**: No data available
- **Autoignition temperature**: Not pertinent
- **Decomposition temperature**: Not pertinent
- **Viscosity**: No data available
- **Explosive properties**: Not explosive
- **Oxidizing properties**: No data available

9.2 OTHER SAFETY INFORMATION

None

10. STABILITY AND REACTIVITY

10.1 REACTIVITY

In the normal condition, no risk of reactivity are present.

10.2 CHEMICAL STABILITY

Stable until the expire date under the recommended transport, handling and storage conditions

10.3 POSSIBILITY OF HAZARDOUS REACTIONS

No hazardous situations are undelined.

10.4 CONDITIONS TO AVOID

Avoid the storage at temperature different from that are advised.

10.5 INCOMPATIBLE MATERIALS

Strong oxidizing and reducing agents.

10.6 HAZARDOUS DECOMPOSITION PRODUCTS

The heating decomposition could cause the production of toxic fumes.

11. TOXICOLOGICAL INFORMATION

11.1 INFORMATION ON TOXICOLOGICAL EFFECTS

There are no known information on toxicological effects from exposure to the mixtures. However it’s recommended to operate according to the good operational practices. Nevertheless the mixture can cause mild health effects on sensitive people by inhalation, cutaneous absorption, contact with eyes or on ingestion.

- **Acute toxicity**: No data available
- **Skin irritation/corrosion**: No data available
- **Eye lesions/severe eye irritation**: No data available
- **Respiratory/skin sensitization**: No data available
- **Mutagenicity for germ cells**: No data available
SAFETY INFORMATION
Chorus Calprotectin (REF: 86600 – 86600/C03)
Chorus Calprotectin K (REF: 86601)

12. ECOLOGICAL INFORMATION

12.1 TOXICITY
Use according to the good working practices, avoiding the disposal in the environment. In case the product reach waterways or sewers or contaminate soil or vegetation, inform the competent authorities.

12.2 PERSISTENCE AND DEGRADABILITY
No data available

12.3 BIOACCUMULATIVE POTENTIAL
No data available

12.4 MOBILITY IN SOIL
No data available

12.5 RESULTS OF PBT AND vPvB ASSESSMENT
No data available

12.6 OTHER ADVERSE EFFECTS
No data available

13. DISPOSAL CONSIDERATIONS

13.1 WASTE TREATMENT METHODS
The product and its containers should be considered special waste.
Their transport and disposal should be performed by authorized specialized companies according to the law.

14. TRANSPORT INFORMATION

Not hazardous good according to the transport regulations.

15. REGULATORY INFORMATION

15.1 SAFETY, HEALTH AND ENVIRONMENTAL REGULATIONS/ LEGISLATION SPECIFIC FOR THE SUBSTANCE OR MIXTURE
Hazard classification and labeling under directives 1272/2008 (EC) and its subsequent amendments.

Legislative Decree 81/2008:
The use of this chemical entails the obligation of "Risk Assessment" by the employer in accordance with the provisions of the Decree April 9, 2008 n. 81 and subsequent amendments. Workers exposed to this chemical agent must not undergo health checks whether the results of the risk assessment show that, depending on the type and quantity of chemical agent and the method and frequency of exposure to this agent, there is only one "Low risk to the safety and irrelevant to the health" of the workers and the measures provided for in the same Decree are sufficient to reduce the risk

European Standard 1907/2006/EC:
Not applicable

Directive 96/82/EC (Seveso Directive):
Not applicable

15.2 CHEMICAL SAFETY ASSESSMENT
Not performed for the product
16. OTHER INFORMATION

This product has to be used for diagnostic use only by personnel who is qualified and trained on the hazards shown in this safety sheet.

REFERENCES:
1. Directive 67/548/EEC and following amendments and technical adjustments
2. Regulation (EC) 1907/2006 of the European Parliament (REACH) as amended
5. ECHA European Chemicals Agency www.echa.europa.eu
6. The Merck Index.
7. Handling Chemical Safety
8. NIOSH - Registry of Toxic Effects of Chemical Substances
9. INRS - Fiche Toxicologique

DIESSE Diagnostica Senese SpA declares that the information contained in this data sheet is based on the knowledge available to us on the date of the last version. Users must verify the suitability and accuracy of the provided information according to the specific use of the product. The document has not be accepted as a guarantee of any specific product property. Because of the use of this product is not subject to our direct control, the users, under their own responsibility, must observe the laws and regulations relating to health and safety. We accept no responsibility for improper use.

This data sheet supersedes each previous edition.