

CHORUS CALPROTECTIN 3RD GENERATION (REF 86603) Calibrator, Positive Control and Sample Diluent/Negative Control

Version: 1 Version date: 31/01/2024 Language: EN According to Regulation (EC) No. 1907/2006 (amended by Regulation (EU) No. 2020/878)

Safety Data Sheet

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

1.1 Product identifier

Substance name : Calibrator, Positive Control and Sample Diluent/Negative Control containing

ProClin® 300 solution.

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

Relevant identified uses : Professional Use as laboratory reagent.

Calibrator - solution necessary for the calibration of the instrument.

Positive Cotrol - solution used to verify the correctness of the obtained

results and for the subsequent validation of the test.

Sample Diluent/Negative Control: solution used as negative control or

diluent of samples that gave out-of-range results.

Uses advised against : No data available.

1.3 Details of the supplier of the safety data sheet

Supplier : Name: DIESSE Diagnostica Senese S.p.A.

Street: Strada del Laghi 39.

Postal code/City: 53035 Monteriggioni (SI).

Country: Italy.

Telephone: +39 0577 307100. Website: www.diesse.it. E-mail: regaffairs@diesse.it.

1.4 Emergency Telephone Number

European Union:

Malta: 112

Ireland: 01 809 2166. 8am-10pm. 7 days a week.

United Kingdom: +35625454030 +35 (0) 31 837 9964 (medical professionals) +35 (0) 31 809 2166 (public) In England and Wales: dial 111 (NHS 111), In Scotland: dial 111 (NHS 24), In Northern Ireland: Contact your local GP or pharmacist during normal hours. During GP Out-of-Hours (www.gpoutofhours.hscni.net/): Belfast HSC Trust, (North & West) 028 9074 4447, (South & East) 028 9079 6220 South Eastern HSC Trust, (North Down & Ards) 028 9182 2344, (Lisburn & Downpatrick) 028 9260 2204, Dalriada Urgent Care (Northern Trust area) 028 2566 3500, Southern HSC Trust 028 3839 9201, Western Urgent Care 028 7186 5195.



$\frac{5}{8}$ 2 Hazards identification

2.1 Classification of the substance or mixture

Hazards identification:

H317 Skin Sens. 1A May cause an allergic skin reaction.

2.2 Label elements

Labelling

Hazard pictograms



Signal word

Warning

Hazard Statements

H317 May cause an allergic skin reaction.

Precautionary Statements - Prevention

P261 Avoid breathing dust/fume/gas/mist/vapours/spray.

P272 Contaminated work clothing should not be allowed out of the workplace.
P280 Wear protective gloves/protective clothing/eye protection/face protection.

Precautionary Statements - Response

P302+P352 IF ON SKIN: Wash with plenty of water.

P333+P313 If skin irritation or rash occurs: Get medical advice/attention.

P363 Wash contaminated clothing before reuse.

Precautionary Statements - Disposal

P501 Dispose of contents/container to ...

Contains

reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-2H -isothiazol-3-one [EC no. 220-239-6] (3:1);

2.3 Other hazards

According to Regulation (EU) 1907/2006, no substances are assessed as PBT or vPvB.

According to Regulation (EU) 2017/2100 or Regulation (EU) 2018/605, no substances are known to have endocrine disrupting properties.

$\frac{1}{2}$ Composition/information on ingredients

3.1 Substances

In accordance with the product knowledge, no nanomaterials have been identified.

The substance does not contain any substances classified as Substances of Very High Concern (SVHC) by the European CHemicals Agency (ECHA) under article 57 of REACH: http://echa.europa.eu/fr/candidate-list-table.

Substance	Concentration (%)	Specific concentration limits	Classification	
reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-2H -isothiazol-3-one [EC no. 220-239-6] (3:1);				
CAS N° 55965-84-9 EC N° IDX N° 613-167-00-5	C< 0.06%	Skin Corr. 1C; : C ≥ 0,6 % Skin Irrit. 2; H315: 0,06 % ≤ C < 0,6 % Eye Dam. 1; : C ≥ 0,6 % Eye Irrit. 2; H319: 0,06 % ≤ C < 0,6 % Skin Sens. 1A; : C ≥ 0,0015 % M=100	H301 Toxic if swallowed. H310 Fatal in contact with skin. H314 Causes severe skin burns and eye damage H317 May cause an allergic skin reaction. H318 Causes serious eye damage H330 Fatal if inhaled. H400 Very toxic to aquatic life. H410 Very toxic to aquatic life with long lasting effects.	



3.3 Remark

Text phrases and H-EUH-: see section 16.

First aid measures

4.1 Description of first aid measures

General information:

In case of accident or unwellness, seek medical advice immediately (show directions for use or safety data sheet if possible).

Do not leave affected person unattended. Remove victim out of the danger area.

Keep affected person warm, still and covered.

Following inhalation:

Remove person to fresh air and keep comfortable for breathing.

Following skin contact:

Remove contaminated, saturated clothing immediately.

After contact with skin, wash immediately with plenty of water and soap.

Take off contaminated clothing.

In case of skin reactions, consult a physician.

Following eye contact:

In case of eye irritation consult an ophthalmologist.

Rinse immediately carefully and thoroughly with eye-bath or water.

Following ingestion:

Never give anything by mouth to an unconscious person or a person with cramps.

IF SWALLOWED: Rinse mouth.

Do NOT induce vomiting.

Self-protection of the first aider:

First aider: Pay attention to self-protection!.

4.2 Most important symptoms and effects, both acute and delayed

The most important known symptoms and effects are described in the labelling (see section 2.2) and/or in section 11.

4.3 Indication of any immediate medical attention and special treatment needed

Notes for the doctor:

Treat symptomatically.

ទ្ចី **5** Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media:

Foam.

Extinguishing powder.

Carbon dioxide (CO2).

Sand.

Unsuitable extinguishing media:

None

5.2 Special hazards arising from the substance or mixture

Formation of toxic gases is possible during heating or in case of fire.

5.3 Advice for firefighters

Wear a self-contained breathing apparatus and chemical protective clothing.

5.4 Additional information

Do not inhale vapors and fumes.



Co-ordinate fire-fighting measures to the fire surroundings.

Move undamaged containers from immediate hazard area if it can be done safely.

Use caution when applying carbon dioxide in confined spaces. carbon dioxide can displace oxygen.

Use water spray jet to protect personnel and to cool endangered containers.

Collect contaminated fire extinguishing water separately. Do not allow entering drains or surface water.

$\frac{5}{8}$ 6 Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Use personal protection equipment. Remove persons to safety.

6.2 Environmental precautions

Ensure that waste is collected and contained.

In case of gas escape or of entry into waterways, soil or drains, inform the responsible authorities. Contain leaks or spills within cabinets with removable trays.

6.3 Methods and material for containment and cleaning up

Treat the recovered material as prescribed in the section on waste disposal.

Collect in closed and suitable containers for disposal.

Clean contaminated objects and areas thoroughly observing environmental regulations.

Absorb with liquid-binding material (e.g. sand, diatomaceous earth, acid- or universal binding agents). Wipe up with absorbent material (eg. cloth, fleece).

6.4 Reference to other sections

Safe handling: see section 7.

Disposal: see section 13.

Personal protection equipment: see section 8.

6.5 Additional information

Not available

$^{rac{5}{8}}7$ Handling and Storage

7.1 Precautions for safe handling

PROTECTIVE MEASURES:

Avoid contact with skin, eyes and clothes.

Wear personal protective clothing (see section 8).

Sewers and ducts must be protected against the entry of the product.

Avoid breathing gas/fumes/vapour/spray.

Advices on general occupational hygiene:

Wash hands before breaks and after work.

Street clothing should be stored seperately from work clothing.

Wash contaminated clothing before reuse.

Remove contaminated, saturated clothing immediately.

7.2 Conditions for safe storage, including any incompatibilities

Keep container tightly closed in a dry, cool, and well-ventilated place.

Keep container in upright position in order to prevent leakage.

Keep container at 2-8°C.

Advice on joint storage:

Keep away from food, drink and animal feedingstuffs.

7.3 Specific end uses

Apart from the uses mentioned in section 1.2 no other specific uses are stipulated.

8

Exposure controls/personal protection

8.1 Control parameters

Occupational exposure limits:

Does not contain substances above concentration limits fixing an occupational exposure limit.

Biological limit values:

Not available

Exposure limits at intended use:

Not available

Remark:

Not available

8.2 **Exposure controls**

Appropriate engineering controls:

Technical measures and the application of suitable work processes have priority over personal protection equipment. Individual protection measures, such as personal protective equipment:



Eye/face protection

Suitable eye protection:

No data available.

Side Shields Safety Goggles compliant with EN 166.

Skin protection

Hand protection: Suitable gloves type: Wear protective gloves. Recommended glove articles:

Chemical-resistant gloves, compliant with EN 374.

Additional hand protection measures:

Do not wear gloves near machines and rotating tools.

Use gloves only once.

Remark:

When handling with chemical substances, protective gloves must be worn

with the CE-label including the four control digits.

The quality of the protective gloves resistant to chemicals must be chosen as a function of the specific working place concentration and quantity of

hazardous substances.

For special purposes, it is recommended to check the resistance to chemicals of the protective gloves mentioned above together with the supplier of these gloves.

Breakthrough times and swelling properties of the material must be taken

into consideration. Body protection:

Suitable protective clothing:

Lab coat.

Respiratory protection Respiratory protection necessary at:

Not required under normal work activities. Suitable respiratory protection apparatus:

No data available.

Environmental exposure controls:

Do not discard residuals in the environment.

Consumer exposure controls:

Not available

8.3 Additional information

Not available

Physical and chemical Properties

9.1 Information on basic physical and chemical properties





Physical state Liquid Colour Colorless Odour Odorless Odour threshold Not available Not available Melting point/freezing point Not available Initial boiling point and boiling range Not available Flash point Not available **Evaporation rate** Not available Flammability Not available Upper/lower flammability or explosive Not available

Vapour pressure Not available Vapour density Not available Relative density Not available Solubility(ies) Not available Partition coefficient n-octanol/water (log Not available

Not available Auto-ignition temperature Decomposition temperature Not available Kinematic viscosity Not available **Explosive properties** Not available Oxidising properties Not available Solubility in other Solvents Not available Log Kow Not available Particle characteristics Not available

9.2 Other safety information

Not available

Stability and Reactivity

10.1 Reactivity

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

10.2 Chemical stability

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

10.3 Possibility of hazardous reactions

The mixture could react with the basic and/or oxidizing substances.

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

When heated or in case of fire, vapors potentially dangerous to health may be produced.

Additional information 10.7

Not available

Toxicological information



11.1 Acute oral toxicity

The product is not classified.

Data for mixture:

Not available

Substances:

Not available

11.2 Acute dermal toxicity

The product is not classified.

Data for mixture:

Not available

Substances:

Not available

11.3 Acute inhalation toxicity

The product is not classified.

Data for mixture:

Not available

Substances:

Not available

11.4 Skin corrosion/irritation

The product is not classified.

Data for mixture:

Not available

Substances:

Not available

11.5 Serious eye damage/irritation

The product is not classified.

Data for mixture:

Not available

Substances:

Not available

11.6 Skin sensitisation

The product is classified Skin Sens. 1A according to the referenced regulation. May cause an allergic skin reaction.

Data for mixture:

Not available

Substances:

Not available

11.7 Specific target organ toxicity (repeated exposure)

The product is not classified.

Data for mixture:

Not available

Substances:

Not available

11.8 Specific target organ toxicity (single exposure)

The product is not classified.

Data for mixture:

Not available

Substances:

Not available

11.9 Carcinogenicity

The product is not classified.



Data for mixture:

Not available

Substances:

Not available

11.10 Reproductive toxicity

The product is not classified.

Data for mixture:

Not available

Substances:

Not available

11.11 Germ cell mutagenicity

The product is not classified.

Data for mixture:

Not available

Substances:

Not available

11.12 Sensitisation to the respiratory tract

The product is not classified.

Data for mixture:

Not available

Substances:

Not available

11.13 Additional information

Not available

11.14 Information on other hazards

Endocrine disrupting properties:

According to Regulation (EU) 2017/2100 or Regulation (EU) 2018/605, no substances are known to have endocrine disrupting properties.

$\frac{1}{2}$ Ecological information

12.1 Toxicity

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

Data for mixture:

Not available

Substances:

Not available

12.2 Persistence and degradability

The product has not been tested.

Data for mixture:

Not available

Substances:

Not available

12.3 Bioaccumulative potential

The product has not been tested.

Data for mixture:

Not available

Substances:

Not available

12.4 Mobility in soil



The product has not been tested.

Data for mixture:

Not available

Substances:

Not available

12.5 Results of PBT and vPvB assessment

No data available.

12.6 Endocrine disrupting properties

No data available.

12.7 Other adverse effects

Not available

12.8 Additional ecotoxicological information

Not available

$\frac{1}{8}$ Disposal considerations

13.1 Waste treatment methods

Product/Packaging disposal:

Waste codes/waste designations according to EWC/AVV:

The allocation of waste identity numbers/waste descriptions must be carried out according to the EEC, specific to the industry and process.

Properties of waste which render it hazardous:

The samples and all the used reagents have to be handled as potentially infected.

Waste treatment options:

The product and its containers should be considered special waste.

Appropriate disposal/Product:

Waste requiring special supervision.

Dispose of waste according to applicable legislation.

Delivery to an approved waste disposal company.

Appropriate disposal/Package:

Non-contaminated packages must be recycled or disposed of.

Handle contaminated packages in the same way as the substance itself.

Dispose of waste according to applicable legislation.

Remark

Collect the waste separately.

Consult the appropriate authorities about waste disposal.

The waste is to be kept separate from other types of waste until its disposal.

13.2 Additional information

Not available

$\frac{1}{2}$ Transport information

14.1 UN number

Not available

14.2 UN proper shipping name

Not available

14.3 Transport hazard class(es)



Not available

14.4 Packing group

Not available

14.5 Environmental hazards

Not available

14.6 Special precautions for user

Not available

14.7 Bulk shipping according to IMO instruments

Not available

14.8 Additional information

Not available

$\frac{1}{2}$ Regulatory information

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

This SDS has been established in accordance with REACH regulation, including its amendments: REACH Regulation (EC) No 1907/2006.

This SDS has been established in accordance with CLP regulation, including its amendments: CLP Regulation EC No. 1272/2008.

15.2 Chemical Safety Assessment

No Chemical Safety Assessment has been carried out for this substance/mixture by the supplier.

15.3 Additional information

Not available

$\frac{1}{2}$ 16 Other information

16.1 Indication of changes

Not applicable (first edition of the MSDS).

16.2 Abbreviations and acronyms

CAS: Chemical Abstract Service Number.

IATA: International Air Transport Association.

IMDG: International Maritime Dangerous Goods Code.

DPD Dangerous Preparation Directive.

UN number: United Nations number.

No EC: European Commission Number.

ADN/ADNR: Regulations concerning the transport of dangerous substances in barges on the waterways.

ADR/RID: European Agreement concerning the International Carriage of Dangerous Goods by Road/Regulations concerning the international carriage of dangerous goods by rail.

CLP: Classification, labeling and packaging.

VPvB: very persistent and very bioaccumulative substances.

16.3 Key literature references and sources for data

No data available.

16.4 Classification for mixtures and used evaluation method according to regulation (EC) 1272/2008 [CLP]



Classification of the mixture is in accordance with the evaluation method described in Regulation (EC) No 1272/2008. Complies with ATP 18, Regulation (EU) $n^{\circ}2022/692$.

16.5 Relevant R-, H- and EUH-phrases (Number and full text)

H301	Acute Tox. 3 ORAL	Toxic if swallowed.
H310	Acute Tox. 2 DERMAL	Fatal in contact with skin.
H314	Skin Corr. 1C	Causes severe skin burns and eye damage
H317	Skin Sens. 1A	May cause an allergic skin reaction.
H318	Eye Dam. 1	Causes serious eye damage
H330	Acute Tox. 2 INHALATION	Fatal if inhaled.
H400	Aquatic Acute 1	Very toxic to aquatic life.
H410	Aquatic Chronic 1	Very toxic to aquatic life with long lasting effects.

16.6 Training advice

Refer to Sections 4, 5, 6, 7 and 8 of this safety data sheet.

16.7 Additional information

Creation date: 31/01/2024 Version date: 31/01/2024 Printing date: 31/01/2024

The information given in this Safety Data Sheet is based on our present knowledge and national regulations. This Safety Data Sheet describes safety requirements relative to identified uses, it doesn't guarantee all the product properties particularly in the case of non identified uses. The product mustn't be used for any uses other than those identified under heading 1. Since the user's working conditions are not known by us, it is the responsability of the user to take all necessary measures to comply with legal requirements for specific uses and avoid negative health effects.