

# SAFETY DATA SHEET

## Calprotectin Flexi reagents

### SECTION 1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

#### 1.1 Product identifier

**Product name:** Calprotectin, Flexi

**Product description** The following reagents:

- Capture
- Detection
- Diluent
- Calibrator
- Low Control
- High Control

**Product code** FX1348, FX1349, FX1353, FX1350, FX1351, FX1352

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

**Use of the product** Reagents for research use.

#### 1.3 Details of the Supplier of the safety data sheet

**Company** Svar Life Science AB  
**Address** Lundvägen 151  
**Zip code/Place** SE-212 24 Malmö, Sweden  
**Telephone** +46 40 53 76 00  
**Website** [www.svarlifescience.com](http://www.svarlifescience.com)  
**E-mail** [info@svarlifescience.com](mailto:info@svarlifescience.com)

#### 1.4 Emergency telephone number

**Emergency telephone number** (Sweden) Acute: 112 – Ask for "Giftinformation". If less acute call: +46 010 4566700.  
 (UK) NHS (England or Wales): Dial 111 or 0845 4647 NHS 24  
 (Scotland): 08454 24 24 24

### SECTION 2. HAZARDS IDENTIFICATION

#### 2.1 Classification of the substance or mixture

Classification according to the Regulation (EC) No. 1272/2008 (CLP):

Not classified as dangerous.

#### 2.2 Label elements

**Diluent, Calibrator, High Control, Low Control**

**EUH208** Contains "Reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC no. 220-239-6] (3:1)" May produce an allergic reaction.

**EUH210:** Safety data sheet available on request.

The remaining reagents require no CLP labelling.

## 2.3 Other hazards

**Other hazards which do not result in classification** None

**Substance meets the criteria for PBT under Regulation EC No. 1907/2006, appendix XIII** PBT: No

**Substance meets the criteria for PBT under Regulation EC No. 1907/2006, appendix XIII** vPvB: No

**Endocrine disrupting properties** The substances are not identified as having endocrine disrupting properties in accordance with the criteria set out in Regulation 2017/2100 or Regulation 2018/605.

## SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

### 3.1 Substances

Not applicable.

### 3.2 Mixtures

The products listed under section 1.1 contain the following declarable preservative unless specified otherwise.

Product/ingredient name	EC-number	CAS-number	REACH registration number	Conc. (weight-%)	Classification Regulation (EC) No. 1272/2008 [CLP]
<b>Diluent, Calibrator, High Control, Low Control</b>					
CMI/MI* (Index No.: 613-167-00-5)	-	55965-84-9	-	<0.0015	Acute Tox. 3; H301 (ATE = 100mg/kg) Acute Tox. 2; H310 (ATE = 50mg/kg) Acute Tox. 3; H331 (ATE = 0,05mg/l/4H) Eye Dam. 1; H318 Skin Corr. 1C; H314 SCL: Skin Corr. 1C; H314: C ≥ 0,6% Eye Dam. 1; H318: C ≥ 0,6% Eye Irrit. 2; H319: 0,06% < C < 0,6% Skin Irrit. 2; H315: 0,06% < C < 0,6% Skin Sens. 1A; H317 (SCL = 0.0015%) Aquatic Acute 1; H400 (M = 100) Aquatic Chronic 1; H410 (M = 100)

\* CMI/MI = 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)

The remaining reagents reagents contain no declarable substances.

See section 16 for the full text of the classifications declared above.

## SECTION 4. FIRST AID MEASURES

### 4.1 Description of first aid measures

<b>Inhalation:</b>	Remove to fresh air, rest. Call a physician if the complaints persist.
<b>Skin contact:</b>	Remove contaminated clothing and footwear. Wash the skin properly with soap and water.
<b>Eye contact:</b>	Keep eyelids well apart. Rinse with water for a couple of minutes. Call a physician if the complaints persist.
<b>Ingestion</b>	Wash mouth properly with water. If victim is conscious and alert, give 2-4 cupfuls of milk/water to dilute the substance in stomach. Call a physician if the complaints persist.

#### 4.2 Most important symptoms and effects, both acute and delayed

##### Potential acute health effects

<b>Inhalation:</b>	Exposure to high airborne concentrations of the reagents in this kit may cause irritation in the respiratory tract, dizziness and sickness.
<b>Skin contact:</b>	Exposure to the skin may cause an allergic skin reaction.
<b>Eye contact:</b>	May cause mild eye irritation.
<b>Ingestion:</b>	Ingestion of larger amounts may cause sickness and vomiting.

#### 4.3 Indication of any immediate medical attention and special treatment needed

<b>Ingestion:</b>	Treat symptomatically.
<b>Specific treatments:</b>	No specific treatment.

### SECTION 5. FIREFIGHTING MEASURES

#### 5.1 Extinguishing media

<b>Suitable extinguishing media</b>	Dry chemical, foam, water spray or carbon dioxide.
<b>Unsuitable extinguishing media</b>	Waterjet

#### 5.2 Special hazards arising from the substance or mixture

<b>Hazards from the substance or mixture</b>	None
<b>Hazardous thermal decomposition products</b>	Decomposition products may include the following materials: carbon monoxide, carbon dioxide and nitrous gases.

#### 5.3 Advice for firefighters

<b>Special protective actions for fire-fighters</b>	Not relevant. The product will not burn.
<b>Special protective equipment for fire-fighters</b>	Not Applicable.
<b>Further information</b>	Not applicable

### SECTION 6. ACCIDENTAL RELEASE MEASURES

#### 6.1 Personal precautions, protective equipment and emergency procedures

<b>For non-emergency personnel</b>	Keep non-emergency personnel away from the spillage area.
<b>For emergency responders</b>	If specialized clothing is required to deal with the spillage, take note of any information in Section 8 on suitable and unsuitable materials. See also Section 8 for additional information on hygiene measures.

#### 6.2 Environmental precautions

Do not empty into drains – see section 12. Inform appropriate authorities in accordance with local regulations.

#### 6.3 Methods and materials for containment and cleaning up

<b>Small spill</b>	Stop leak if without risk. Move containers from spill area. Dilute with water and mop up if water-soluble. Alternatively, or if water-insoluble, absorb with an inert dry material and place in an appropriate waste disposal container. Dispose of via a licensed waste disposal contractor.
<b>Large spill</b>	The kit only contains small amounts of each reagent.

#### 6.4 Reference to other sections

See Section 8 for information on appropriate personal protective equipment.  
See Section 13 for additional waste treatment information.

## SECTION 7. HANDLING AND STORAGE

### 7.1 Precautions for safe handling

<b>Protective measures</b>	Put on appropriate personal protective equipment (see Section 8).
<b>Advice on general occupational hygiene</b>	Eating, drinking and smoking should be prohibited in areas where this material is handled, stored and processed. Workers should wash hands and face before eating, drinking and smoking. Remove contaminated clothing and protective equipment before entering eating areas. See also Section 8 for additional information on hygiene measures.

### 7.2 Conditions for safe storage, including any incompatibilities

<b>Storage:</b>	Store in original container protected from direct sunlight in a dry, cool and well-ventilated area, away from incompatible materials (see section 10), food and drink. Keep container tightly closed and sealed until ready for use. Containers that have been opened must be carefully resealed and kept upright to prevent leakage.
<b>Further information:</b>	Not applicable

### 7.3 Specific end use(s)

Reagents for in vitro diagnostic and research use.

## SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

### 8.1 Control parameters

#### Occupational exposure limits

Chemical name	EU	United Kingdom	France	Spain	Germany
CMI/MI (CAS No. 55965-84-9)	None.	None.	None.	None.	None.
Chemical name	Italy	Portugal	Netherlands	Finland	Denmark
CMI/MI (CAS No. 55965-84-9)	None.	None.	None.	None.	None.
Chemical name	Austria	Switzerland	Poland	Norway	Ireland
CMI/MI (CAS No. 55965-84-9)	None.	None.	None.	None.	None.

**Recommended monitoring procedure** Not relevant

#### Derived effect levels

Product/ingredient name	Type	Exposure	Value	Population	Effects
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**Predicted effect concentrations** Not available

**PNEC Summary** Not available

### 8.2 Exposure controls

**Appropriate engineering controls** Good general ventilation should be sufficient to control worker exposure to airborne contaminants. Otherwise, use local exhaust ventilation or other engineering controls to keep worker exposure below any recommended or statutory limits.

**Hygiene measures** Wash hands, forearms and face thoroughly after handling chemical products, before eating, smoking and using the lavatory and at the end of the working period. Appropriate techniques should be used to remove potentially contaminated clothing. Wash contaminated clothing before reusing. Ensure that eyewash stations and safety showers are close to the workstation location.

**Respiratory protection** Not relevant during normal condition.

<b>Eye/face protection</b>	Use safety glasses (according to EN166) when there is risk of splashes.
<b>Hand protection</b>	Wear protective gloves (according to EN374) of butyl rubber or nitrile rubber.
<b>Body protection</b>	Wear suitable protective clothing.
<b>Environmental exposurecontrols</b>	Not applicable

## SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

### 9.1 Information on basic physical and chemical properties of the reagents

TCC, Flexi	Capture	Detection	Diluent	Calibrator	Low Control	High Control
<b>Physical state</b>	Liquid	Liquid	Liquid	Liquid	Liquid	Liquid
<b>Colour</b>	Colourless	Colourless	Red	Colourless	Green	Red
<b>Odour</b>	Odourless	Odourless	Odourless	Odourless	Odourless	Odourless
<b>Melting point/freezing point</b>	n.d	n.d	n.d	n.d	n.d	n.d
<b>Boiling point or initial boiling point and boiling range</b>	n.d	n.d	n.d	n.d	n.d	n.d
<b>Flammability (solid, gas)</b>	n.a	n.a	n.a	n.a	n.a	n.a
<b>Lower and upper explosion limit</b>	n.a	n.a	n.a	n.a	n.a	n.a
<b>Flash point</b>	> 100°C	> 100°C	> 100°C	> 100°C	> 100°C	> 100°C
<b>Auto-ignition temperature</b>	n.d	n.d	n.d	n.d	n.d	n.d
<b>Decomposition temperature</b>	n.d	n.d	n.d	n.d	n.d	n.d
<b>pH</b>	n.d	n.d	n.d	n.d	n.d	n.d
<b>Kinematic viscosity</b>	n.d	n.d	n.d	n.d	n.d	n.d
<b>Solubility (in water)</b>	Soluble	Soluble	Soluble	Soluble	Soluble	Soluble
<b>Partition coefficient n-octanol/water (log value):</b>	n.a	n.a	n.a	n.a	n.a	n.a
<b>Vapour pressure</b>	n.d	n.d	n.d	n.d	n.d	n.d
<b>Density and/or relative density</b>	n.d	n.d	n.d	n.d	n.d	n.d
<b>Relative vapour density:</b>	n.a	n.a	n.a	n.a	n.a	n.a
<b>Particle characteristics:</b>	n.a	n.a	n.a	n.a	n.a	n.a

n.a = not applicable. n.d = not determined

### 9.2 Other information

Not applicable

## SECTION 10. STABILITY AND REACTIVITY

<b>10.1 Reactivity</b>	Non-reactive
<b>10.2 Chemical stability</b>	Stabile under normal conditions of use and storage.
<b>10.3 Possibility of hazardous reactions</b>	Under normal conditions of storage and use, hazardous reactions will not occur.
<b>10.4 Condition to avoid</b>	Avoid direct sunlight.
<b>10.5 Incompatible materials</b>	None
<b>10.6 Hazardous decomposition products</b>	Carbon monoxide, carbon dioxide and nitrous gases.

## SECTION 11. TOXICOLOGICAL INFORMATION

### 11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

#### Acute toxicity

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

Calculated data:

LD<sub>50</sub> oral, rat: > 2000 mg/kg

LD<sub>50</sub> dermal, rat: > 2000 mg/kg

#### Irritation/Corrosion

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

Experimental/calculated data: Corrosive or irritating to the skin, rabbit: Not irritating.

#### Serious eye damage/irritation

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

Experimental/calculated data: Serious eye damage/eye irritation, rabbit: Not irritating.

#### Respiratory or skin sensitization

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

#### Germ cell mutagenicity

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

#### Carcinogenicity

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

#### Reproductive toxicity

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

#### STOT-single exposure

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

#### STOT-repeated exposure

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

#### Aspiration hazard

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

### 11.2. Information on other hazards

None known.

## SECTION 12. ECOLOGICAL INFORMATION

### 12.1 Toxicity

#### Acute toxicity in the aquatic environment for CMI/MI

Test	Value/unit (mg/l)	Test method	Exp. time (h)	Species
Fish LC <sub>50</sub>	0.19	--	96	Salmo gairdneri
Daphnia EC <sub>50</sub>	0.028	--	48	Crassostrea virg.
Algae EC <sub>50</sub>	0.018	--	96	Selenastrum cap.

### 12.2 Persistence and degradability

**Conclusion/Summary** CMI/MI is not rapidly degradable

### 12.3 Bioaccumulative potential

**Conclusion/Summary** CMI/MI: Log Kow > 5 (significant bioaccumulation).

### 12.4 Mobility in soil

**Soil/water partition coefficient (KOC)** Not available

**Mobility** Not available

**12.5 Results of PBT and vPvB assessment**

PBT Not applicable  
 vPvB Not applicable

**12.6 Endocrine disrupting properties**

Conclusion None known.

**12.7 Other adverse effects**

Conclusion None known.

**SECTION 13. DISPOSAL CONSIDERATIONS**

**13.1 Waste treatment methods**

**Product**

**Method of disposal** The generation of waste should be avoided or minimized wherever possible. This material and its container must be disposed of in a safe way. Dispose of surplus and non-recyclable products via a licensed waste disposal contractor. Disposal of this product, solutions and any by-products should at all times comply with the requirements of environmental protection and waste disposal legislation and any regional local authority requirements.  
 Used kit may be potentially infectious material and shall be disposed as a hazardous waste.

**Hazardous waste** Within the present knowledge of the supplier, this product is not regarded as hazardous waste, as defined by EU Directive 2008/98/EC.  
 Used kit may be potentially infectious material and shall be disposed as a hazardous waste.

**European Waste Catalogue (EWC)**

EWC Waste Code	Type of waste
18 01 07	Product
15 02 03	Absorbents, filter materials, wiping cloths and protective clothing
18 01 03*	Used kit

**Packaging**

Method of disposal Incineration.  
 Special precautions None.

**SECTION 14. TRANSPORT INFORMATION**

Product classified as dangerous goods:  Yes  No  Not decided

	ADR/RID	ADN/ADNR	IMDG	IATA
<b>14.1 UN number or ID number</b>	Not regulated	Not regulated	Not regulated	Not regulated
<b>14.2 UN proper shipping name</b>	--	--	--	--
<b>14.3 Transport hazard class(es)</b>	--	--	--	--
<b>14.4 Packing Group</b>	--	--	--	--
<b>14.5 Environmental hazards</b>	--	--	--	--
<b>14.6 Special precautions for user</b>	Not available	Not available	Not available	Not available
<b>14.7 Maritime transport in bulk according to IMO instruments</b>	Not applicable	Not applicable	Not applicable	Not applicable

**Additional information** Used kit is dangerous goods by transportation in class 6.2, UN 3291. Contact the manufacturer for further information.

## SECTION 15. REGULATORY INFORMATION

### 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture EU Regulation (EC) No. 1907/2006 (REACH)

**REACH Status** In compliance. Pre-registration status: All components are listed or exempted.

#### Annex XIV - List of substances subject to authorization

##### Substances of very high concern

None of the components are listed.

#### Annex XVII - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles

Not applicable.

### 15.2 Chemical safety assessment

The reagents in this kit contain substances for which Chemical Safety Assessments still are required.

### 15.3 Other information

**Tariff Code – harmonized system** Not applicable

**The EU Seveso Directive** Not applicable

#### International regulations

**Chemical Weapons Convention List**

**Schedule I Chemicals**  
Not regulated

**Chemical Weapons Convention List**

**Schedule II Chemicals**  
Not regulated

**Chemical Weapons Convention List**

**Schedule III Chemicals**  
Not regulated

## SECTION 16. OTHER INFORMATION

### Conforms to Regulation (EC) No. 1907/2006 (REACH), Annex II

**Disclaimer:** The above information is based on data available to us and is believed to be correct. Since the information may be applied under conditions beyond our control and with which we may be unfamiliar, we do not assume any responsibility for the results of its use and all persons receiving it must make their own determination of the effects, properties, protections and disposal which pertain to their particular conditions. No representation, warranty, or guarantee, express or implied (including a warranty of fitness or merchantability for a particular purpose), is made with respect to the materials, the accuracy of this information, the results to be obtained from the use thereof, or the hazards connected with the use of the material. Caution should be used in the handling and use of the material. The above information is offered in good faith and with the belief that it is accurate. As of the date of issuance, we are providing all information relevant to the foreseeable handling of the material. However, in the event of an adverse incident associated with this product, this Safety Data Sheet is not, and is not intended to be, a substitute for consultation with appropriately trained personnel.

### THE PRODUCER'S NOTES

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### LIST OF HAZARD STATEMENTS MENTIONED UNDER SECTION 3

No.	H-Statements
H301	Toxic if swallowed.
H310	Fatal if in contact with skin.
H331	Toxic if inhaled.
H314	Causes severe skin burns and eye damage.
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H318	Causes serious eye damage.
H319	Causes serious eye irritation.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.



**DOCUMENT HISTORY**

<b>Version</b>	<b>Valid from (date)</b>	<b>Changes</b>
1.0	28-Feb-2020	New SDS- new RUO Product Calprotectin Flexi according to CR-00224.
2.0	01-Jun-2020	Removal of the word "Kit" as Calprotectin Flexi components will be sold as separate products, according item numbers were added to the document. Biohazard symbol was added to calibrator and control components to align with product labels.
3.0	04-Aug-2023	Review according to CR-00523. Editorial changes.