

# SAFETY DATA SHEET

## Calprotectin Flexi

### 1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND THE COMPANY/UNDERTAKING

#### 1.1 Product identifier

<b>PRODUCT NAME:</b>	<b>Calprotectin Flexi</b>
<b>Product description</b>	<b>Calprotectin Flexi is consisting of the following reagents:</b> <ul style="list-style-type: none"> <li>• Calprotectin Flexi Capture antibody</li> <li>• Calprotectin Flexi Detection antibody</li> <li>• Calprotectin Flexi Diluent</li> <li>• Calprotectin Flexi Calibrator stock</li> <li>• Calprotectin Flexi High control</li> <li>• Calprotectin Flexi Low control</li> </ul>
<b>Product code</b>	FX1348 FX1349 FX1353 FX1350 FX1351 FX1352

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

<b>Use of the product</b>	Reagents are for and research use.
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#### 1.3 Details of the supplier of the safety data sheet

<b>Company</b>	Svar Life Science AB
<b>Address</b>	Lundavägen 151
<b>Zip code/Place</b>	SE-212 24 Malmö, Sweden
<b>Telephone</b>	+46 40 53 76 00
<b>Internet</b>	<a href="http://www.svarlifescience.com">www.svarlifescience.com</a>
<b>E-mail</b>	<a href="mailto:info@svarlifescience.com">info@svarlifescience.com</a>

#### 1.4 Emergency telephone number

<b>Emergency telephone number</b>	+46-010-456 6700 Poison Information Centre, Sweden
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### 2. HAZARDS IDENTIFICATION

#### 2.1 Classification of the substance or mixture

**Product definition:** Set of reagents to detect Calprotectin, for research use only.

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

Calprotectin Flexi Diluent:	Skin Sens. 1;H317
Remaining components:	Not classified

## 2. HAZARDS IDENTIFICATION - continued

### 2.2 Label elements according the Regulation (EC) No. 1272/2008 (CLP)

#### 2.2.1 Calprotectin Flexi Diluent

Hazard pictogram:



**Warning**

<b>Contains:</b>	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)
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#### Hazard statements

<b>H317</b>	May cause an allergic skin reaction.
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#### Precautionary statements

<b>P264</b>	Wash hands thoroughly after handling.
<b>P280</b>	Wear protective gloves/protective clothing/eye protection/face protection.
<b>P302+352</b>	IF ON SKIN: Wash with plenty of soap and water.
<b>P333+313</b>	If skin irritation or rash occurs: Get medical advice/attention.

#### 2.2.2 Calprotectin Flexi Calibrator stock and Calprotectin Flexi High control and Calprotectin Flexi Low control

Hazard pictogram:



**Warning**

<b>Contains:</b>	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)
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#### Hazard statements

<b>EUH208</b>	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.
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#### 2.2.3 Calprotectin Flexi Capture antibody and Calprotectin Flexi Detection antibody

No labeling requirements.

### 2.3 Other hazards

<b>Other hazards which do not result in classification</b>	None
<b>Substance meets the criteria for PBT under Regulation EC No. 1907/2006, appendix XIII</b>	PBT: No (refers to substances containing)
<b>Substance meets the criteria for PBT under Regulation EC No. 1907/2006, appendix XIII</b>	vPvB: No (refers to substances containing)

## 3. COMPOSITION/INFORMATION ON INGREDIENTS

Aqueous solutions of biological reagents.

### 3.1 Reagents containing following substances classified as dangerous.

No	Product/ingredient name	EC-number	CAS-number	REACH registration number	Conc. (weight-%)	Classification Regulation (EC) No. 1272/2008 [CLP]
<b>Calprotectin Flexi Diluent and Calprotectin Flexi Calibrator stock and Calprotectin Flexi High control and Calprotectin Flexi Low control</b>						
	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)	--	55965-84-9	--	0.015-0.03	Acute Tox 2, H301 Acute Tox 2, H311 Skin Corr 1B, H314 Skin Sens. 1, H317 Acute tox 2, H331 Aquatic Chronic 1, H410
	Sodium azide	26628-22-8	247-852-1	--	< 0.1	Acute tox. 2; H300 Acute tox. 1; H310 STOT RE 2; H373 Aquatic Acute 1; H400;M-factor 1 Aquatic Chronic 1; H410;M-factor 1 EUH 032
<b>Calprotectin Flexi Capture antibody and Calprotectin Flexi Detection antibody</b>						
	Sodium azide	26628-22-8	247-852-1	--	< 0.1	Acute tox. 2; H300 Acute tox. 1; H310 STOT RE 2; H373 Aquatic Acute 1; H400;M-factor 1 Aquatic Chronic 1; H410;M-factor 1 EUH 032

Sodium azide has an EC limit value.

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

Occupational exposure limits are mentioned under section 8, if such exist.

#### 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>	May cause an allergic skin reaction.
<b>Eye contact:</b>	May cause mild, reversible eye irritation.
<b>Ingestion:</b>	Ingestion of larger amounts may cause sickness and vomiting.

##### 4.2 Indication of any immediate medical attention and special treatment needs

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

#### 5. FIRE-FIGHTING 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>	Promptly isolate the scene by removing all persons from the vicinity of the incident if there is a fire. No action shall be taken involving any personal risk or without suitable training.
<b>Special protective equipment for fire-fighters</b>	Fire-fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full face-piece operated in positive pressure mode. Clothing for fire-fighters (including helmets, protective boots and gloves) conforming to European standard EN 469 will provide a basic level of protection for chemical incidents.
<b>Further information</b>	Not applicable

## 6. ACCIDENTAL RELEASE MEASURES

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

<b>For non-emergency personnel</b>	No action shall be taken involving any personal risk or without suitable training. Evacuate surrounding areas. Keep unnecessary and unprotected personnel from entering. Do not touch or walk through spilt material. Put on appropriate personal protective equipment – see section 8.
<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. Wipe up spillage etc. with paper towels. Use wet towels to finish cleaning up. Follow the laboratory's general decontamination procedure for infectious waste. Flush area of decontamination with water. Further handling of spillage – see section 13.
<b>Large spill</b>	Stop leak if without risk. Move containers from spill area. Prevent entry into sewers,

	water courses, basements or confined areas. Contain and collect spillage with absorbent material such as vermiculite. Further handling of spillage – see section 13.
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#### 6.4 Reference to other sections

<b>Reference to other sections</b>	See Section 8 for information on appropriate personal protective equipment. See Section 13 for additional waste treatment information.
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### 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.
<b>Further information:</b>	Not applicable

#### 7.3 Specific end use(s)

Reagents for Research Use Only.

### 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

#### 8.1 Control parameters

Occupational exposure limits

Ingredient name	CAS nr.	Range	ppm	mg/m <sup>3</sup>	Year	Remarks
Sodium Azide	26628-22-8	--	--	0,1	--	--

<b>Recommended monitoring procedures</b>	Not relevant
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#### Derived effect levels

Product/ingredient name	Type	Exposure	Value	Population	Effects
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<b>Predicted effect concentrations</b>	Not available
<b>PNEC Summary</b>	Not available

## 8.2 Exposure controls

<b>Appropriate engineering controls</b>	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.
<b>Hygiene measures</b>	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.
<b>Respiratory protection</b>	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 exposure controls</b>	Not applicable

## 9. PHYSICAL AND CHEMICAL PROPERTIES

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

<b>Physical state</b>	Liquid
<b>Colour</b>	Not applicable
<b>Odour</b>	Odourless
<b>Odour threshold</b>	Not applicable
<b>Solubility(ies)</b>	Soluble in Water
<b>pH (product)</b>	7,4-8,0
<b>Melting point/freezing point</b>	Not determined
<b>Initial boiling point and boiling range</b>	Approx. 100 °C
<b>Flash point</b>	> 100°C
<b>Evaporation rate (butyl acetate = 1)</b>	< 1
<b>Flammability (solid, gas)</b>	Not applicable
<b>Upper/lower flammability or explosive limits</b>	Not applicable
<b>Combustion rate</b>	Not applicable
<b>Upper/lower flammability or explosive limits</b>	Not applicable
<b>Vapour pressure(at 20°C)</b>	Not determined

<b>Vapour density</b>	Not applicable
<b>Relative density (Water = 1)</b>	Not determined
<b>Partition coefficient: n-octanol/water</b>	Not applicable
<b>Autoignition temperature</b>	Not determined
<b>Decomposition temperature</b>	Not determined
<b>9.1.1 Information on basic physical and chemical properties of the reagents - continued</b>	
<b>Viscosity</b>	Not determined
<b>Explosive properties</b>	Not applicable
<b>Oxidising properties</b>	Not applicable

## 9.2 Other information

Not applicable

## 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 Conditions to avoid</b>	Avoid direct sunlight.
<b>10.5 Incompatible materials</b>	Sodium azide develops highly toxic gas (hydrogen azide) on contact with acid.
<b>10.6 Hazardous decomposition products</b>	Carbon monoxide, carbon dioxide and nitrous gases.

## 11. TOXICOLOGICAL INFORMATION

### 11.1 Information on toxicological effects

#### Acute toxicity

Assessment of acute toxicity for the different reagents:

Not harmful if inhaled. Not harmful in contact with skin. Not harmful if swallowed.

Calculated data:

LD50 oral, rat: > 2000 mg/kg

LD50 dermal, rat: > 2000 mg/kg

#### Irritation/Corrosion

Assessment of the irritant effect for the different reagents:

Not irritating to eyes and skin.

Experimental/calculated data:

Corrosive or irritating to the skin, rabbit: Not irritating.

Serious eye damage/eye irritation, rabbit: Not irritating.



### Sensitization by inhalation/skin contact

May cause an allergic skin reaction.

### Germ cell mutagenicity

Assessment of mutagenicity for the different reagents:

The chemical structure of the different reagents doesn't indicate any mutagenic effects.

### Carcinogenicity

Assessment of carcinogenicity for the different reagents:

The chemical structure of the different reagents doesn't indicate any carcinogenic effects.

### Reproduction toxicity

Assessment of reproduction toxicity for the different reagents:

The chemical structure of the different reagents doesn't indicate any reproduction toxic effects.

### Developmental toxicity

Assessment of teratogenicity for the different reagents:

The chemical structure of the different reagents doesn't indicate any teratogenic effects.

### Specific target organ toxicity (single exposure)

STOT assessment single dos toxicity:

Based on available information an organ specific toxicity is not expected for the different reagents.

### Repeated dose toxicity and specific organ toxicity (repeated exposure)

Based on available information an organ specific toxicity is not expected for the different reagents.

## 12. ECOLOGICAL INFORMATION

### 12.1 Toxicity

#### 12.1.1 Acute toxicity in the aquatic environment of 5-chloro-2-methyl-4-isothiazolin-3-one

Test	Value/unit (mg/l)	Test method	Exp. time (h)	Species
Fish LC50	6,1		96	Brachydanio rerio
Daphnia EC50	4,2		48	Daphnia magna
BCF = 114. Bioaccumulating effects may occur. 39-62% degraded in 29 days OECD 301B. Not readily biodegradable.				

#### 12.1.2 Acute toxicity in the aquatic environment of 2-methyl-4-isothiazolin-3-one

Test	Value/unit (mg/l)	Test method	Exp. time (h)	Species
Daphnia EC50	0,18		48	Daphnia magna
BCF = 114. Log P <sub>ow</sub> : -0,486. Bioaccumulating effects are not expected. 48-54% degraded in 29 days OECD 301B. Not readily biodegradable.				

#### 12.1.3 Acute toxicity in the aquatic environment of sodium azide

Test	Value/unit (mg/l)	Test method	Exp. time (h)	Species
Fish LC50	0,7		96	Lepomis

				macrochirus
Daphnia EC50	4,2		48	Daphnia pulex
Algae EC50	0,35		96	Pseudokirchneriella sub
Log Kow < 1 - No bioaccumulation expected. Methods for determining biodegradability do not apply to inorganic substances.				

#### 12.1.4 Ecotoxicity

The reagents contain low concentration of the above-mentioned substances. These concentrations are below the lowest concentration limit for classification as harmful to aquatic organisms.

#### 12.2 Persistence and degradability

<b>Conclusion/Summary</b>	The reagents as such will be classified as readily biodegradable.
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#### 12.3 Bioaccumulative potential

<b>Conclusion/Summary</b>	The reagents as such will not be classified as bioaccumulative.
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#### 12.4 Mobility in soil

<b>Soil/water partition coefficient (KOC)</b>	Not available
<b>Mobility</b>	Not available

#### 12.5 Results of PBT and vPvB assessment

<b>PBT</b>	Not applicable
<b>vPvB</b>	Not applicable
<b>Conclusion</b>	The reagents contain substances classified as dangerous for the environment. But the concentrations of these substances are very low, so the reagents as such are not classified as dangerous for the environment, according to the EU classification rules in force.

### 13. DISPOSAL CONSIDERATIONS

#### 13.1 Waste treatment methods

##### Product

<b>Method of disposal</b>	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
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	disposed as a hazardous waste.
<b>Hazardous waste</b>	Within the present knowledge of the supplier, this product is regarded as hazardous waste, as defined by EU Directive 2008/98/EU.

**European Waste Catalogue (EWC)**

<b>EWC Waste Code</b>	<b>Type of waste</b>
<b>18 01 06*</b>	Chemicals consisting of or containing dangerous substances
<b>15 01 10*</b>	Packaging containing residues of or contaminated by dangerous substances

**Packaging**

Method of disposal	Incineration.
Special precautions	None.

**14. TRANSPORT INFORMATION**

Product classified as dangerous  Yes  No  Not decided  
goods:

	<b>ADR/RID</b>	<b>ADN/ADNR</b>	<b>IMDG</b>	<b>IATA</b>
<b>14.1 UN 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>Additional information</b>	Used kit is dangerous goods by transportation in class 6.2, UN 3291. Contact the manufacturer for further information.			

**14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code**

Not applicable

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

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

<b>15.3 Other information Tariff Code – harmonized system</b>	Not applicable
<b>The EU Seveso Directive</b>	Not applicable

### International regulations

<b>Chemical Weapons Convention List Schedule I Chemicals</b>	<b>Chemical Weapons Convention List Schedule II Chemicals</b>	<b>Chemical Weapons Convention List Schedule III Chemicals</b>
Not regulated	Not regulated	Not regulated

## 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

<b>No.</b>	<b>H-Statements</b>
H300	Fatal if swallowed.
H301	Toxic if swallowed.
H310	Fatal in contact with skin.
H311	Toxic in contact with skin.
H331	Toxic if inhaled.
H314	Causes severe skin burns and eye damage

H317	May cause an allergic skin reaction.
H373	May cause damage to organs through prolonged or repeated exposure.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.