

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Product form : Mixture
 Trade name : StabilCoat® Immunoassay Stabilizer SC01
 5X StabilCoat® Immunoassay Stabilizer SC05
 StabilGuard® Immunoassay Stabilizer (BSA-Free) SG01
 StabilBlock® Immunoassay Stabilizer ST01
 Product code : SC01, SC05, SG01, ST01

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

1.2.1. Relevant identified uses

Use of the substance/mixture : For further manufacture.

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

Surmodics, Inc.
 9924 West 74th Street
 Eden Prairie, MN 55344 USA
 Phone: (952) 500-7000
 Fax: (952) 500-7001

1.4. Emergency telephone number

Emergency number : CHEMTREC: 1-800-424-9300 (US and Canada) / 1-703-527-3887 (International shipments)

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP]
 Not classified

Adverse physicochemical, human health and environmental effects

No additional information available

2.2. Label elements

Labeling according to Regulation (EC) No. 1272/2008 [CLP]
 No labelling applicable

2.3. Other hazards

Other hazards not contributing to the classification : None under normal conditions.

SECTION 3: Composition/information on ingredients

3.1. Substance

Not applicable

3.2. Mixture

This mixture does not contain any substances to be mentioned according to the criteria of section 3.2 of REACH Annex II

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures general : If exposed or concerned, get medical attention/advice. Show this safety data sheet to the doctor in attendance. Wash contaminated clothing before re-use. Never give anything to an unconscious person.
 First-aid measures after inhalation : IF INHALED: Remove to fresh air and keep at rest in a comfortable position for breathing.
 First-aid measures after skin contact : IF ON SKIN (or clothing): Remove affected clothing and wash all exposed skin with water for at least 15 minutes.
 First-aid measures after eye contact : IF IN EYES: Immediately flush with plenty of water for at least 15 minutes. Remove contact lenses if present and easy to do so. Continue rinsing.

StabilCoat® and StabilGuard® Immunoassay Stabilizers

Safety Data Sheet (EU)

First-aid measures after ingestion : IF SWALLOWED: rinse mouth thoroughly. Do not induce vomiting without advice from poison control center or medical professional. Get medical attention if you feel unwell.

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

Symptoms/injuries : Not expected to present a significant hazard under anticipated conditions of normal use.
Symptoms/injuries after inhalation : May cause respiratory irritation.
Symptoms/injuries after skin contact : May cause skin irritation.
Symptoms/injuries after eye contact : May cause slight temporary irritation.
Symptoms/injuries after ingestion : May cause gastrointestinal irritation.

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

No additional information available

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media : Foam. Dry powder. Carbon dioxide. Water spray. Sand.

5.2. Special hazards arising from the substance or mixture

Fire hazard : No data available.
Explosion hazard : No data available.

5.3. Advice for firefighters

Firefighting instructions : Use water spray or fog for cooling exposed containers. Exercise caution when fighting any chemical fire. Do not dispose of fire-fighting water in the environment.
Protection during firefighting : Do not enter fire area without proper protective equipment, including respiratory protection.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General measures : Evacuate area. Keep upwind. Ventilate area. Spill should be handled by trained clean-up crews properly equipped with respiratory equipment and full chemical protective gear (see Section 8).

6.1.1. For non-emergency personnel

Protective equipment : Wear Protective equipment as described in Section 8.
Emergency procedures : Evacuate unnecessary personnel.

6.1.2. For emergency responders

Protective equipment : Wear suitable protective clothing, gloves and eye or face protection. Approved supplied-air respirator, in case of emergency.

6.2. Environmental precautions

Prevent entry to sewers and public waters. Notify authorities if liquid enters sewers or public waters. Avoid release to the environment.

6.3. Methods and material for containment and cleaning up

For containment : Contain any spills with dikes or absorbents to prevent migration and entry into sewers or streams.
Methods for cleaning up : Place in a suitable container for disposal in accordance with the waste regulations (see Section 13). Wash spill area thoroughly with plenty of soap and water.

6.4. Reference to other sections

No additional information available

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : Do not handle until all safety precautions have been read and understood. Use appropriate personal protection equipment (PPE) Keep away from sources of ignition - No smoking. Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Keep container tightly closed. Store in a dry, cool and well-ventilated place. Avoid elevated temperatures.
Storage temperature : Refrigerated or room temperature.

7.3. Specific end use(s)

No additional information available

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

No additional information available

StabilCoat® and StabilGuard® Immunoassay Stabilizers

Safety Data Sheet (EU)

8.2. Exposure controls

Appropriate engineering controls	: Ensure adequate ventilation, especially in confined areas.
Personal protective equipment	: Gloves. Protective goggles or safety glasses.
Hand protection	: Use gloves chemically resistant to this material when prolonged or repeated contact could occur. Gloves should be classified under Standard EN 374 or ASTM F1296. Suggested glove materials are: Neoprene, Nitrile/butadiene rubber, Polyethylene, Ethyl vinyl alcohol laminate, PVC or vinyl.
Eye protection	: Chemical goggles or safety glasses
Skin and body protection	: Wear suitable protective clothing. Wear long sleeves
Respiratory protection	: Where excessive vapour, mist, or dust may result, use NIOSH approved respiratory protection equipment.



SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Liquid
Appearance	: Clear
Colour	: Golden (SC01, SC05) Colorless (SG01, ST01)
odour	: No data available
Odour threshold	: No data available
pH	: Neutral
Relative evaporation rate (butylacetate=1)	: No data available
Melting point	: No data available
Freezing point	: No data available
Boiling point	: 100 °C
Flash point	: No data available
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
Flammability (solid, gas)	: No data available
Vapour pressure	: No data available
Relative vapour density at 20 °C	: No data available
Relative density	: No data available
Solubility	: Water: Complete
Log Pow	: No data available
Viscosity, kinematic	: No data available
Viscosity, dynamic	: No data available
Explosive properties	: Product is not explosive.
Oxidising properties	: Not an Oxidizer.
Explosive limits	: No data available

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

No dangerous reactions known under normal conditions of use.

10.2. Chemical stability

Stable under recommended handling and storage conditions (see section 7).

10.3. Possibility of hazardous reactions

None known.

StabilCoat® and StabilGuard® Immunoassay Stabilizers

Safety Data Sheet (EU)

10.4. Conditions to avoid

None known.

10.5. Incompatible materials

None known.

10.6. Hazardous decomposition products

Thermal decomposition generates : Carbon oxides (CO, CO₂). Nitrogen oxides. Other toxic fumes.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity	: Not classified No data available
Irritation	: Not classified No data available pH: Neutral
Corrosivity	: Not classified pH: Neutral
Sensitisation	: Not classified No data available
Repeated dose toxicity	: Not classified No data available
Carcinogenicity	: Not classified No data available
Mutagenicity	: Not classified No data available
Toxicity for reproduction	: Not classified No data available

SECTION 12: Ecological information

12.1. Toxicity

Ecology - general : No data available.

12.2. Persistence and degradability

No additional information available

12.3. Bioaccumulative potential

No additional information available

12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

No additional information available

12.6. Other adverse effects

No additional information available

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste treatment methods	: Obtain the consent of pollution control authorities before discharging to wastewater treatment plants.
Waste disposal recommendations	: Dispose in a safe manner in accordance with local/national regulations. Do not allow the product to be released into the environment.

SECTION 14: Transport information

In accordance with ADR / RID / IMDG / IATA / ADN

14.1. UN number

Not hazardous for transport

14.2. UN proper shipping name

Proper Shipping Name (ADR)	: Not applicable
Proper Shipping Name (IMDG)	: Not applicable
Proper Shipping Name (IATA)	: Not applicable
Proper Shipping Name (ADN)	: Not applicable
Proper Shipping Name (RID)	: Not applicable

14.3. Transport hazard class(es)

ADR

Transport hazard class(es) (ADR) : Not applicable

StabilCoat® and StabilGuard® Immunoassay Stabilizers

Safety Data Sheet (EU)

IMDG

Transport hazard class(es) (IMDG) : Not applicable

IATA

Transport hazard class(es) (IATA) : Not applicable

ADN

Transport hazard class(es) (ADN) : Not applicable

RID

Transport hazard class(es) (RID) : Not applicable

14.4. Packing group

Packing group (ADR) : Not applicable

Packing group (IMDG) : Not applicable

Packing group (IATA) : Not applicable

Packing group (ADN) : Not applicable

Packing group (RID) : Not applicable

14.5. Environmental hazards

Dangerous for the environment : No

Marine pollutant : No

Other information : No supplementary information available

14.6. Special precautions for user

14.6.1. Overland transport

Not applicable

14.6.2. Transport by sea

Not applicable

14.6.3. Air transport

Not applicable

14.6.4. Inland waterway transport

Carriage prohibited (ADN) : No

Not subject to ADN : No

14.6.5. Rail transport

Carriage prohibited (RID) : No

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

Not applicable

SECTION 15: Regulatory information

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

15.1.1. EU-Regulations

Contains no substances with Annex XVII restrictions

Contains no substance on the REACH Candidate List

Contains no REACH Annex XIV substances.

15.1.2. National regulations

All chemical substances in this product are listed in the EPA (Environment Protection Agency) TSCA (Toxic Substances Control Act) Inventory

Germany

Water hazard class (WGK) : 1 - low hazard to waters

15.2. Chemical safety assessment

No additional information available

StabilCoat® and StabilGuard® Immunoassay Stabilizers

Safety Data Sheet (EU)

SECTION 16: Other information

Indication of changes:

Revision 01: Section 1.2.

Revision 02: Periodic review.

Other information : Author: DRH.

Surmodics Custom SDS EU (REACH Annex II)

The above product information is believed to be correct, but Surmodics, Inc. makes no representation of its accuracy or completeness. Persons receiving this information must exercise their independent judgment in determining the product's safety and suitability for its intended use. SURMODICS, INC. MAKES NO REPRESENTATIONS OR WARRANTIES, EXPRESSED OR IMPLIED, OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE AND WILL NOT BE RESPONSIBLE FOR DAMAGES RESULTING FROM USE OF THE PRODUCT OR RELIANCE UPON THIS INFORMATION.