

# SAFETY DATA SHEET



This safety data sheet was created pursuant to the requirements of:  
Regulation (EC) No. 1907/2006 and Regulation (EC) No. 1272/2008

Assay Diluent (Protein-Free) (SM01)

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

### 1.1. Product identifier

Product Code(s) SM01  
Product Name Assay Diluent (Protein-Free)  
Pure substance/mixture Mixture

Contains 3(2H)-Isothiazolone, 2-methyl-

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

Recommended use For laboratory use  
Uses advised against No information available

### 1.3. Details of the supplier of the safety data sheet

#### Manufacturer

Surmodics, Inc.  
9924 West 74th Street  
Eden Prairie, MN 55344 USA  
Telephone: 952-500-7000  
For further information, please contact

### 1.4. Emergency telephone number

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

Emergency Telephone - §45 - (EC)1272/2008

Europe 112

## SECTION 2: Hazards identification

### 2.1. Classification of the substance or mixture

Regulation (EC) No 1272/2008

Skin sensitization Category 1 - (H317)

### 2.2. Label elements

Contains 3(2H)-Isothiazolone, 2-methyl-



Signal word

Assay Diluent (Protein-Free) (SM01)

Warning

#### Hazard statements

H317 - May cause an allergic skin reaction

EUH071 - Corrosive to the respiratory tract

#### Precautionary Statements - EU (§28, 1272/2008)

P261 - Avoid breathing dust/fume/gas/mist/vapors/spray

P280 - Wear protective gloves

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

P362 + P364 - Take off contaminated clothing and wash it before reuse

P501 - Dispose of contents/ container to an approved waste disposal plant

### 2.3. Other hazards

No information available.

## **SECTION 3: Composition/information on ingredients**

### 3.1 Substances

Not applicable

### 3.2 Mixtures

Chemical name	Weight-%	REACH registration number	EC No	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Specific concentration limit (SCL)	M-Factor	M-Factor (long-term)
Sodium chloride 7647-14-5	0.1 - <1	No data available	231-598-3	No data available	-	-	-
3(2H)-Isothiazolone, 2-methyl- 2682-20-4	<0.1	No data available	220-239-6	Acute Tox. 3 (H301) Acute Tox. 3 (H311) Acute Tox. 2 (H330) Skin Corr. 1B (H314) Eye Dam. 1 (H318) Skin Sens. 1A (H317) Aquatic Acute 1 (H400) Aquatic Chronic 1 (H410) (EUH071)	Skin Sens. 1A :: C>=0.0015%	10	1

Full text of H- and EUH-phrases: see section 16

#### Acute Toxicity Estimate

No information available

This product does not contain candidate substances of very high concern at a concentration  $\geq 0.1\%$  (Regulation (EC) No. 1907/2006 (REACH), Article 59)

## **SECTION 4: First aid measures**

### 4.1. Description of first aid measures

**General advice**

Show this safety data sheet to the doctor in attendance.

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<b>Inhalation</b>	Remove to fresh air.
<b>Eye contact</b>	Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids. Consult a physician.
<b>Skin contact</b>	Wash with soap and water. May cause an allergic skin reaction. In the case of skin irritation or allergic reactions see a physician.
<b>Ingestion</b>	Rinse mouth.

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

**Symptoms** Itching. Rashes. Hives.

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

**Note to physicians** May cause sensitization in susceptible persons. Treat symptomatically.

### **SECTION 5: Firefighting measures**

#### **5.1. Extinguishing media**

**Suitable Extinguishing Media** Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

**Large Fire** CAUTION: Use of water spray when fighting fire may be inefficient.

**Unsuitable extinguishing media** Do not scatter spilled material with high pressure water streams.

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

**Specific hazards arising from the chemical** Product is or contains a sensitizer. May cause sensitization by skin contact.

#### **5.3. Advice for firefighters**

**Special protective equipment and precautions for fire-fighters** Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Use personal protection equipment.

### **SECTION 6: Accidental release measures**

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

**Personal precautions** Avoid contact with skin, eyes or clothing. Ensure adequate ventilation. Use personal protective equipment as required. Evacuate personnel to safe areas. Keep people away from and upwind of spill/leak.

**For emergency responders** Use personal protection recommended in Section 8.

#### **6.2. Environmental precautions**

**Environmental precautions** See Section 12 for additional Ecological Information.

#### **6.3. Methods and material for containment and cleaning up**

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<b>Methods for containment</b>	Prevent further leakage or spillage if safe to do so.
<b>Methods for cleaning up</b>	Take up mechanically, placing in appropriate containers for disposal.
<b>Prevention of secondary hazards</b>	Clean contaminated objects and areas thoroughly observing environmental regulations.

#### **6.4. Reference to other sections**

**Reference to other sections** See section 8 for more information. See section 13 for more information.

## **SECTION 7: Handling and storage**

### **7.1. Precautions for safe handling**

**Advice on safe handling** Handle in accordance with good industrial hygiene and safety practice. Avoid contact with skin, eyes or clothing. Ensure adequate ventilation. In case of insufficient ventilation, wear suitable respiratory equipment. Do not eat, drink or smoke when using this product. Take off contaminated clothing and wash before reuse.

**General hygiene considerations** Handle in accordance with good industrial hygiene and safety practice.

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

**Storage Conditions** Keep containers tightly closed in a dry, cool, and well-ventilated place.

### **7.3. Specific end use(s)**

**Risk Management Methods (RMM)** The information required is contained in this Safety Data Sheet.

## **SECTION 8: Exposure controls/personal protection**

### **8.1. Control parameters**

#### **Exposure Limits**

Chemical name	European Union	Austria	Belgium	Bulgaria	Croatia
3(2H)-Isothiazolone, 2-methyl-2682-20-4	-	TWA: 0.05 mg/m <sup>3</sup>	-	-	-
Chemical name	France	Germany	Germany MAK	Greece	Hungary
3(2H)-Isothiazolone, 2-methyl-2682-20-4	-	-	TWA: 0.2 mg/m <sup>3</sup> Peak: 0.4 mg/m <sup>3</sup>	-	-
Chemical name	Ireland	Italy	Italy REL	Latvia	Lithuania
Sodium chloride 7647-14-5	-	-	-	TWA: 5 mg/m <sup>3</sup>	TWA: 5 mg/m <sup>3</sup>
Chemical name	Sweden	Switzerland	United Kingdom		
3(2H)-Isothiazolone, 2-methyl-2682-20-4	-	TWA: 0.2 mg/m <sup>3</sup> STEL: 0.4 mg/m <sup>3</sup>	-		

**Biological occupational exposure limits** This product, as supplied, does not contain any hazardous materials with biological limits established by the region specific regulatory bodies.

**Derived No Effect Level (DNEL)** No information available.

**Predicted No Effect Concentration (PNEC)** No information available.

**8.2. Exposure controls**

**Personal protective equipment**

**Eye/face protection** Wear safety glasses with side shields (or goggles).

**Hand protection** Wear suitable gloves.

**Skin and body protection** Wear suitable protective clothing.

**Respiratory protection** No protective equipment is needed under normal use conditions. If exposure limits are exceeded or irritation is experienced, ventilation and evacuation may be required.

**General hygiene considerations** Handle in accordance with good industrial hygiene and safety practice.

**Environmental exposure controls** No information available.

**SECTION 9: Physical and chemical properties**

**9.1. Information on basic physical and chemical properties**

**Physical state** Liquid  
**Appearance** clear  
**Color** colorless  
**Odor** No information available.  
**Odor threshold** No information available

<u>Property</u>	<u>Values</u>	<u>Remarks • Method</u>
<b>Melting point / freezing point</b>	No data available	None known
<b>Initial boiling point and boiling range</b>	No data available	None known
<b>Flammability</b>	No data available	None known
<b>Flammability Limit in Air</b>		None known
<b>Upper flammability or explosive limits</b>	No data available	
<b>Lower flammability or explosive limits</b>	No data available	
<b>Flash point</b>	No data available	None known
<b>Autoignition temperature</b>	No data available	None known
<b>Decomposition temperature</b>		None known
<b>pH</b>	No data available	Neutral
<b>pH (as aqueous solution)</b>	No data available	None known
<b>Kinematic viscosity</b>	No data available	None known
<b>Dynamic viscosity</b>	No data available	None known
<b>Water solubility</b>	Completely soluble	None known
<b>Solubility(ies)</b>	No data available	None known
<b>Partition coefficient</b>	No data available	None known
<b>Vapor pressure</b>	No data available	None known
<b>Relative density</b>	No data available	None known
<b>Bulk density</b>	No data available	
<b>Liquid Density</b>	No data available	
<b>Relative vapor density</b>	No data available	None known
<b>Particle characteristics</b>		
<b>Particle Size</b>	No information available	

**Particle Size Distribution** No information available

## **9.2. Other information**

### **9.2.1. Information with regard to physical hazard classes**

Not applicable

### **9.2.2. Other safety characteristics**

No information available

## **SECTION 10: Stability and reactivity**

### **10.1. Reactivity**

**Reactivity** No information available.

### **10.2. Chemical stability**

**Stability** Stable under normal conditions.

#### **Explosion data**

**Sensitivity to mechanical impact** None.

**Sensitivity to static discharge** None.

### **10.3. Possibility of hazardous reactions**

**Possibility of hazardous reactions** None under normal processing.

### **10.4. Conditions to avoid**

**Conditions to avoid** None known based on information supplied.

### **10.5. Incompatible materials**

**Incompatible materials** None known based on information supplied.

### **10.6. Hazardous decomposition products**

**Hazardous decomposition products** None known based on information supplied.

## **SECTION 11: Toxicological information**

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

#### **Information on likely routes of exposure**

##### **Product Information**

**Inhalation** Specific test data for the substance or mixture is not available.

**Eye contact** Specific test data for the substance or mixture is not available.

**Skin contact** May cause sensitization by skin contact. Specific test data for the substance or mixture is not available. Repeated or prolonged skin contact may cause allergic reactions with susceptible persons. (based on components).

**Ingestion** Specific test data for the substance or mixture is not available.

**Symptoms related to the physical, chemical and toxicological characteristics****Symptoms** Itching. Rashes. Hives.**Acute toxicity****Numerical measures of toxicity**

No information available

**Component Information**

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Sodium chloride	= 3 g/kg ( Rat )	> 10000 mg/kg ( Rabbit )	> 42 mg/L ( Rat ) 1 h
3(2H)-Isothiazolone, 2-methyl-	232 - 249 mg/kg ( Rat ) = 120 mg/kg ( Rat )	= 200 mg/kg ( Rabbit )	= 0.11 mg/L ( Rat ) 4 h

**Delayed and immediate effects as well as chronic effects from short and long-term exposure****Skin corrosion/irritation** No information available.**Serious eye damage/eye irritation** No information available.**Respiratory or skin sensitization** May cause sensitization by skin contact.**Germ cell mutagenicity** No information available.**Carcinogenicity** No information available.**Reproductive toxicity** No information available.**STOT - single exposure** No information available.**STOT - repeated exposure** No information available.**Aspiration hazard** No information available.**11.2. Information on other hazards****11.2.1. Endocrine disrupting properties****Endocrine disrupting properties** No information available.**11.2.2. Other information**

**Other adverse effects** No information available.**SECTION 12: Ecological information****12.1. Toxicity****Ecotoxicity****Unknown aquatic toxicity** Contains 0 % of components with unknown hazards to the aquatic environment.

Chemical name	Algae/aquatic plants	Fish	Toxicity to microorganisms	Crustacea
Sodium chloride	-	LC50: 5560 - 6080mg/L (96h, Lepomis macrochirus) LC50: =12946mg/L (96h, Lepomis macrochirus) LC50: 6020 - 7070mg/L (96h, Pimephales promelas) LC50: =7050mg/L (96h, Pimephales promelas) LC50: 6420 - 6700mg/L (96h, Pimephales promelas) LC50: 4747 - 7824mg/L (96h, Oncorhynchus mykiss)	-	EC50: =1000mg/L (48h, Daphnia magna) EC50: 340.7 - 469.2mg/L (48h, Daphnia magna)

**12.2. Persistence and degradability****Persistence and degradability** No information available.**12.3. Bioaccumulative potential****Bioaccumulation****12.4. Mobility in soil****Mobility in soil** No information available.**12.5. Results of PBT and vPvB assessment****PBT and vPvB assessment**

Chemical name	PBT and vPvB assessment
Sodium chloride	The substance is not PBT / vPvB PBT assessment does not apply
3(2H)-Isothiazolone, 2-methyl-	The substance is not PBT / vPvB

**12.6. Endocrine disrupting properties****Endocrine disrupting properties** No information available.**12.7. Other adverse effects**

No information available.



**SECTION 13: Disposal considerations**

**13.1. Waste treatment methods**

<b>Waste from residues/unused products</b>	Dispose of in accordance with local regulations. Dispose of waste in accordance with environmental legislation.
<b>Contaminated packaging</b>	Do not reuse empty containers.

**SECTION 14: Transport information**

**IATA**

<b>14.1 UN number or ID number</b>	Not regulated
<b>14.2 UN proper shipping name</b>	Not regulated
<b>14.3 Transport hazard class(es)</b>	Not regulated
<b>14.4 Packing group</b>	Not regulated
<b>14.5 Environmental hazards</b>	Not applicable
<b>14.6 Special precautions for user</b>	
<b>Special Provisions</b>	None

**IMDG**

<b>14.1 UN number or ID number</b>	Not regulated
<b>14.2 UN proper shipping name</b>	Not regulated
<b>14.3 Transport hazard class(es)</b>	Not regulated
<b>14.4 Packing group</b>	Not regulated
<b>14.5 Environmental hazards</b>	Not applicable
<b>14.6 Special precautions for user</b>	
<b>Special Provisions</b>	None
<b>14.7 Maritime transport in bulk according to IMO instruments</b>	No information available

**RID**

<b>14.1 UN number or ID number</b>	Not regulated
<b>14.2 UN proper shipping name</b>	Not regulated
<b>14.3 Transport hazard class(es)</b>	Not regulated
<b>14.4 Packing group</b>	Not regulated
<b>14.5 Environmental hazards</b>	Not applicable
<b>14.6 Special precautions for user</b>	
<b>Special Provisions</b>	None

**ADR**

<b>14.1 UN number or ID number</b>	Not regulated
<b>14.2 UN proper shipping name</b>	Not regulated
<b>14.3 Transport hazard class(es)</b>	Not regulated
<b>14.4 Packing group</b>	Not regulated
<b>14.5 Environmental hazards</b>	Not applicable
<b>14.6 Special precautions for user</b>	
<b>Special Provisions</b>	None

**SECTION 15: Regulatory information**

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

**National regulations**

France

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### Occupational Illnesses (R-463-3, France)

Chemical name	French RG number
Sodium chloride 7647-14-5	RG 78

### European Union

Take note of Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work.

### Authorizations and/or restrictions on use:

This product contains one or more substance(s) subject to restriction (Regulation (EC) No. 1907/2006 (REACH), Annex XVII)

Chemical name	Restricted substance per REACH Annex XVII	Substance subject to authorization per REACH Annex XIV
3(2H)-Isothiazolone, 2-methyl- - 2682-20-4	75.	-

### Persistent Organic Pollutants

Not applicable

### Ozone-depleting substances (ODS) regulation (EC) 1005/2009

Not applicable

### EU - Plant Protection Products (1107/2009/EC)

Chemical name	EU - Plant Protection Products (1107/2009/EC)
Sodium chloride - 7647-14-5	Plant protection agent

### Biocidal Products Regulation (EU) No 528/2012 (BPR)

### International Inventories

TSCA	Contact supplier for inventory compliance status
DSL/NDSL	Contact supplier for inventory compliance status
EINECS/ELINCS	Contact supplier for inventory compliance status
ENCS	Contact supplier for inventory compliance status
IECSC	Contact supplier for inventory compliance status
KECL	Contact supplier for inventory compliance status
PICCS	Contact supplier for inventory compliance status
AIIC	Contact supplier for inventory compliance status
NZIoC	Contact supplier for inventory compliance status

### Legend:

TSCA	- United States Toxic Substances Control Act Section 8(b) Inventory
DSL/NDSL	- Canadian Domestic Substances List/Non-Domestic Substances List
EINECS/ELINCS	- European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances
ENCS	- Japan Existing and New Chemical Substances
IECSC	- China Inventory of Existing Chemical Substances
KECL	- Korean Existing and Evaluated Chemical Substances
PICCS	- Philippines Inventory of Chemicals and Chemical Substances
AIIC	- Australian Inventory of Industrial Chemicals
NZIoC	- New Zealand Inventory of Chemicals

### 15.2. Chemical safety assessment

**Chemical Safety Report** No information available

**SECTION 16: Other information**

**Key or legend to abbreviations and acronyms used in the safety data sheet**

**Full text of H-Statements referred to under section 3**

- EUH071 - Corrosive to the respiratory tract
- H301 - Toxic if swallowed
- H311 - Toxic 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

**Legend**

SVHC: Substances of Very High Concern for Authorization:

**Legend Section 8: Exposure controls/personal protection**

TWA                      TWA (time-weighted average)                      STEL                      STEL (Short Term Exposure Limit)  
 Ceiling                      Maximum limit value                      \*                      Skin designation

Classification procedure	
Classification according to Regulation (EC) No. 1272/2008 [CLP]	Method Used
Acute oral toxicity	Calculation method
Acute dermal toxicity	Calculation method
Acute inhalation toxicity - gas	Calculation method
Acute inhalation toxicity - vapor	Calculation method
Acute inhalation toxicity - dust/mist	Calculation method
Skin corrosion/irritation	Calculation method
Serious eye damage/eye irritation	Calculation method
Respiratory sensitization	Calculation method
Skin sensitization	Calculation method
Mutagenicity	Calculation method
Carcinogenicity	Calculation method
Reproductive toxicity	Calculation method
STOT - single exposure	Calculation method
STOT - repeated exposure	Calculation method
Acute aquatic toxicity	Calculation method
Chronic aquatic toxicity	Calculation method
Aspiration hazard	Calculation method
Ozone	Calculation method

**Key literature references and sources for data used to compile the SDS**

- Agency for Toxic Substances and Disease Registry (ATSDR)
- U.S. Environmental Protection Agency ChemView Database
- European Food Safety Authority (EFSA)
- European Chemicals Agency (ECHA) Committee for Risk Assessment (ECHA\_RAC)
- European Chemicals Agency (ECHA) (ECHA\_API)
- EPA (Environmental Protection Agency)
- Acute Exposure Guideline Level(s) (AEGL(s))
- U.S. Environmental Protection Agency Federal Insecticide, Fungicide, and Rodenticide Act
- U.S. Environmental Protection Agency High Production Volume Chemicals
- Food Research Journal
- Hazardous Substance Database
- International Uniform Chemical Information Database (IUCLID)
- National Institute of Technology and Evaluation (NITE)
- Australia National Industrial Chemicals Notification and Assessment Scheme (NICNAS)

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NIOSH (National Institute for Occupational Safety and Health)

National Library of Medicine's ChemID Plus (NLM CIP)

National Library of Medicine's PubMed database (NLM PUBMED)

National Toxicology Program (NTP)

New Zealand's Chemical Classification and Information Database (CCID)

Organization for Economic Co-operation and Development Environment, Health, and Safety Publications

Organization for Economic Co-operation and Development High Production Volume Chemicals Program

Organization for Economic Co-operation and Development Screening Information Data Set

World Health Organization

**Revision date**

08-Dec-2022

**This material safety data sheet complies with the requirements of Regulation (EC) No. 1907/2006**

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**End of Safety Data Sheet**