

Safety Data Sheet

acc. to OSHA HCS

Printing date 03/16/2016

Reviewed on 03/16/2016

1 Identification

- **Product identifier**
- **Trade name:** Amplichek STI, Negative
- **Catalog or product number:** 12000991, 12000993
- **Relevant identified uses of the substance or mixture and uses advised against**
- **Sector of Use** SU20 Health services
- **Application of the substance / the mixture** In-vitro laboratory reagent or component
- **Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**
Bio-Rad Laboratories, Diagnostic Group
9500 Jeronimo Road
Irvine, California 92618-2017
1(949) 598-1200
- **Information department:** Technical services, customer support
- **Emergency telephone number:**
1(800) 424-9300 Use only in the event of a CHEMICAL EMERGENCY involving a SPILL, LEAK, FIRE, EXPLOSION, or ACCIDENT.

2 Hazard(s) identification

- **Classification of the substance or mixture**
Flam. Liq. 2 H225 Highly flammable liquid and vapor.
Carc. 1A H350 May cause cancer.
STOT SE 2 H371 May cause damage to organs.
- **Label elements**
- **GHS label elements** The product is classified and labeled according to the Globally Harmonized System (GHS).
- **Hazard pictograms**
 
GHS02 GHS08
- **Signal word** Danger
- **Hazard-determining components of labeling:**
ethanol
methanol
propan-2-ol
- **Hazard statements**
H225 Highly flammable liquid and vapor.
H350 May cause cancer.
H371 May cause damage to organs.
- **Precautionary statements**
P210 Keep away from heat/sparks/open flames/hot surfaces. No smoking.
P260 Do not breathe dust/fume/gas/mist/vapors/spray.
P280 Wear protective gloves/protective clothing/eye protection/face protection.
P303+P361+P353 If on skin (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower.
- **Emergency overview:**
- **Routes of exposure:**
Ingestion

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- Inhalation
Skin
- **Classification system**
 - **NFPA ratings (scale 0-4)**
Health = 2
Fire = 3
Reactivity = 0
 - **Special Hazards** Contains human sourced and/or potentially infectious components.
 - **Other hazards**
 - **Results of PBT and vPvB assessment**
 - **PBT:** Not applicable.
 - **vPvB:** Not applicable.

3 Composition/information on ingredients

- **Chemical characterization: Mixtures**
- **Description:** Mixture of the substances listed below with non-hazardous additions.

- **Listing of dangerous and non-hazardous components:**

	Proprietary Reagent MK5	Flam. Liq. 2, H225 Carc. 1A, H350	20-35%
	Proprietary Reagent MK6	Flam. Liq. 2, H225 Eye Irrit. 2, H319; STOT SE 3, H336	2.5-5%
	Proprietary Reagent MK7	Flam. Liq. 2, H225 Acute Tox. 2, H330 STOT SE 1, H370	2.5-5%
CAS: 67-68-5 EINECS: 200-664-3	dimethyl sulfoxide		0.1-1.0%
CAS: 7732-18-5 EINECS: 231-791-2	water		50-100%

- **Additional information**
Contains human sourced and/or potentially infectious components.
Contains added constituents of animal origin.

4 First-aid measures

- **Description of first aid measures**
- **General information** No special measures required.
- **After inhalation**
Supply fresh air. If required, provide artificial respiration. Keep patient warm. Consult doctor if symptoms persist.
- **After skin contact**
Immediately wash with water and soap and rinse thoroughly.
Generally the product does not irritate the skin.
- **After eye contact** Rinse opened eye for several minutes under running water. Then consult a doctor.
- **After swallowing**
Immediately call a doctor.
Rinse mouth with water. Seek medical attention and appropriate follow-up.
- **Information for doctor**
- **Most important symptoms and effects, both acute and delayed** Eye irritation

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· **Indication of any immediate medical attention and special treatment needed** No further relevant information available.

5 Fire-fighting measures

- **Extinguishing media**
- **Suitable extinguishing agents**
CO₂, extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
- **Special hazards arising from the substance or mixture** No further relevant information available.
- **Advice for firefighters**
- **Protective equipment:** Mount respiratory protective device.

6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures** Handle as potentially infectious.
- **Environmental precautions:**
Do not allow to enter sewers/ surface or ground water.
Keep contaminated washing water and dispose of appropriately.
- **Methods and material for containment and cleaning up:**
Absorb liquid components with liquid-binding material.
Pick up mechanically.
Clean the affected area carefully; suitable cleaners are:
Disinfectant
- **Reference to other sections** See Section 13 for disposal information.

7 Handling and storage

- **Handling**
- **Precautions for safe handling** No special measures required.
- **Information about protection against explosions and fires:**
Keep ignition sources away - Do not smoke.
Protect against electrostatic charges.
- **Conditions for safe storage, including any incompatibilities**
- **Storage**
- **Requirements to be met by storerooms and receptacles:** Store in a cool location.
- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:**
Keep receptacle tightly sealed.
Refer to package insert for additional information regarding storage conditions.
- **Specific end use(s)** No further relevant information available.

8 Exposure controls/personal protection

- **Additional information about design of technical systems:** No further data; see item 7.

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· **Control parameters**· **Components with limit values that require monitoring at the workplace:****Proprietary Reagent MK5**

PEL (United States)	Long-term value: 1900 mg/m ³ , 1000 ppm
REL (United States)	Long-term value: 1900 mg/m ³ , 1000 ppm
TLV (United States)	Short-term value: 1880 mg/m ³ , 1000 ppm

Proprietary Reagent MK6

PEL (United States)	Long-term value: 980 mg/m ³ , 400 ppm
REL (United States)	Short-term value: 1225 mg/m ³ , 500 ppm Long-term value: 980 mg/m ³ , 400 ppm
TLV (United States)	Short-term value: 984 mg/m ³ , 400 ppm Long-term value: 492 mg/m ³ , 200 ppm BEI

67-68-5 dimethyl sulfoxide

WEEL (United States)	Long-term value: 250 ppm
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· **Ingredients with biological limit values:****Proprietary Reagent MK6**

BEI (United States)	40 mg/L Medium: urine Time: end of shift at end of workweek Parameter: Acetone (background, nonspecific)
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· **Additional information:** The lists that were valid during the creation were used as basis.· **Exposure controls**· **Personal protective equipment**· **General protective and hygienic measures**

The usual precautionary measures for handling chemicals should be followed.

Follow the usual biosafety practices for handling potentially infectious materials.

· **Breathing equipment:**

In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use respiratory protective device that is independent of circulating air.

· **Protection of hands:** Protective gloves.· **Material of gloves**

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

Synthetic gloves

· **Penetration time of glove material**

The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

· **Eye protection:** Safety glasses· **Body protection:** Protective work clothing.

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9 Physical and chemical properties

· Information on basic physical and chemical properties

· General Information

· Appearance:

Form: Liquid

Color: Clear

· Odor: Mild

· pH-value: Not determined.

· Change in condition

Melting point/Melting range: undetermined

Boiling point/Boiling range: 78 °C

· Flash point: <21 °C

· Flammability (solid, gaseous) Not applicable.

· Ignition temperature: 425 °C

· Danger of explosion: Product is not explosive. However, formation of explosive air/vapor mixtures are possible.

· Explosion limits:

Lower: 3.5 Vol %

Upper: 15.0 Vol %

· Vapor pressure at 20 °C: 59 hPa

· Density: Not determined

· Solubility in / Miscibility with

Water: Fully miscible

· Solvent content:

Organic solvents: 25-50 %

Water: 50-100 %

· Other information No further relevant information available.

10 Stability and reactivity

· Reactivity No further relevant information available.

· Chemical stability

· Thermal decomposition / conditions to be avoided: No decomposition if used according to specifications.

· Possibility of hazardous reactions No dangerous reactions known

· Conditions to avoid No further relevant information available.

· Incompatible materials: No further relevant information available.

· Hazardous decomposition products: No dangerous decomposition products known

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11 Toxicological information

- **Information on toxicological effects**
- **Acute toxicity:**

- **LD/LC50 values for hazardous components per OSHA criteria:**

Proprietary Reagent MK5

Oral	LD50	7060 mg/kg (rat)
Inhalative	LC50/4 h	20000 mg/l (rat)

Proprietary Reagent MK6

Oral	LD50	4570 mg/kg (rat)
Dermal	LD50	13400 mg/kg (rab)
Inhalative	LC50/4 h	30 mg/l (rat)

Proprietary Reagent MK7

Oral	LD50	5628 mg/kg (rat)
Dermal	LD50	20000 mg/kg (rat)

- **Primary irritant effect:**
- **on the skin:** No irritant effect.
- **on the eye:** Irritant effect.
- **Sensitization:** No sensitizing effects known.
- **Additional toxicological information:**
The product shows the following dangers according to the calculation method of the General EU Classification Guidelines for Preparations as issued in the latest version:
Harmful

- **Carcinogenic categories**

- **IARC (International Agency for Research on Cancer)**

Proprietary Reagent MK5	1
Proprietary Reagent MK6	3

- **NTP (National Toxicology Program)**

None of the ingredients is listed.

- **OSHA-Ca (Occupational Safety & Health Administration)**

None of the ingredients is listed.

12 Ecological information

- **Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **Persistence and degradability** No further relevant information available.
- **Behavior in environmental systems:**
- **Bioaccumulative potential** No further relevant information available.
- **Mobility in soil** No further relevant information available.
- **Additional ecological information:**
- **General notes:**
Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water.
Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.

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- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **Other adverse effects** No further relevant information available.

13 Disposal considerations

- **Waste treatment methods**
- **Recommendation** Dispose of waste in accordance to applicable national, regional, or local regulations.
- **Uncleaned packagings:**
- **Recommendation:** Disposal must be made according to official regulations.
- **Recommended cleansing agent:** Water, if necessary with cleansing agents.

14 Transport information

- | | |
|--|--|
| · UN-Number | UN1993 |
| · DOT, ADR, IMDG, IATA | |
| · UN proper shipping name | Flammable liquids, n.o.s. (Ethanol, Methanol) |
| · DOT | 1993 FLAMMABLE LIQUID, N.O.S. (vapour pressure at 50 °C not more than 110 kPa) (ETHANOL (ETHYL ALCOHOL), METHANOL) |
| · ADR | FLAMMABLE LIQUID, N.O.S. (ETHANOL (ETHYL ALCOHOL), METHANOL) |
| · IMDG | Flammable liquid, n.o.s. (Ethanol, Methanol) |
| · IATA | |
| · Transport hazard class(es) | 3 |
| · Label | 3 Flammable liquids |
| · ADR, IMDG, IATA | 3 |
| · Class | |
| · Label | |
| · Packing group | II |
| · DOT, ADR, IMDG, IATA | |
| · Environmental hazards: | Not applicable. |
| · Special precautions for user | Warning: Flammable liquids |
| · Danger code (Kemler): | 33 |
| · EMS Number: | F-E, S-E |
| · Stowage Category | B |
| · Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code | Not applicable. |

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· **Transport/Additional information:**· **ADR**· **Excepted quantities (EQ)**

Code: E2

Maximum net quantity per inner packaging: 30 ml

Maximum net quantity per outer packaging: 500 ml

· **IMDG**· **Limited quantities (LQ)**· **Excepted quantities (EQ)**

1L

Code: E2

Maximum net quantity per inner packaging: 30 ml

Maximum net quantity per outer packaging: 500 ml

· **UN "Model Regulation":**

UN 1993 FLAMMABLE LIQUIDS, N.O.S. (ETHANOL, METHANOL), 3, II

* **15 Regulatory information**· **Safety, health and environmental regulations/legislation specific for the substance or mixture**· **SARA (Superfund Amendments and Reauthorization Act of 1986 - USA)**· **Section 302/304 (40CFR355.30 / 40CFR355.40):**

None of the ingredients is listed.

· **Section 313 (40CFR372.65):**

Proprietary Reagent MK6

Proprietary Reagent MK7

· **TSCA (Toxic Substances Control Act):**

Proprietary Reagent MK5

Proprietary Reagent MK6

Proprietary Reagent MK7

67-68-5 dimethyl sulfoxide

7732-18-5 water

· **California Proposition 65:**· **Developmental Toxicity**

Proprietary Reagent MK5

· **Carcinogenic categories**· **EPA (Environmental Protection Agency)**

None of the ingredients is listed.

· **TLV (Threshold Limit Value established by ACGIH)**

Proprietary Reagent MK5

A3

Proprietary Reagent MK6

A4

· **MAK (German Maximum Workplace Concentration)**

Proprietary Reagent MK5

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· **NIOSH-Ca (National Institute for Occupational Safety and Health)**

None of the ingredients is listed.

· **National regulations**

· **Technical instructions (air):**

Class	Share in %
I	2.5-5
NK	20-35

· **Water hazard class:** Water hazard class 1 (Self-assessment): slightly hazardous for water.

· **Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

16 Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

· **Department issuing SDS:** Environmental Health and Safety.

· **Contact:**

Life Science Group, Environmental Health and Safety, 2000 Alfred Nobel Drive, Hercules, California, 94547: 1(510) 741-1000

Diagnostic Group, Environmental Health and Safety, 4000 Alfred Nobel Drive, Hercules, California, 94547: 1(510) 724-7000

· **Date of preparation / last revision** 03/16/2016 / -

· **Abbreviations and acronyms:**

ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

DOT: US Department of Transportation

IATA: International Air Transport Association

ACGIH: American Conference of Governmental Industrial Hygienists

EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society)

NFPA: National Fire Protection Association (USA)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

Flam. Liq. 2: Flammable liquids, Hazard Category 2

Acute Tox. 2: Acute toxicity, Hazard Category 2

Eye Irrit. 2: Serious eye damage/eye irritation, Hazard Category 2

Carc. 1A: Carcinogenicity, Hazard Category 1A

STOT SE 1: Specific target organ toxicity - Single exposure, Hazard Category 1

STOT SE 2: Specific target organ toxicity - Single exposure, Hazard Category 2

STOT SE 3: Specific target organ toxicity - Single exposure, Hazard Category 3

· *** Data compared to the previous version altered.**