

Safety Data Sheet

acc. to OSHA HCS



Printing date 03/15/2016

Reviewed on 03/15/2016

1 Identification

- **Product identifier**
- **Trade name:** Amplichek STI, Positive
- **Catalog or product number:** 12000992, 12000994
- **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**
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- GHS02 GHS08
- **Signal word** Danger
 - **Hazard-determining components of labeling:**
methanol
ethanol
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.
P233 Keep container tightly closed.
P303+P361+P353 If on skin (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower.

(Contd. on page 2)

-QUS

Safety Data Sheet
acc. to OSHA HCS

Printing date 03/15/2016

Reviewed on 03/15/2016

Trade name: Amplichek STI, Positive

(Contd. of page 1)

- **Emergency overview:**
- **Routes of exposure:**
Ingestion
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%
	Bovine Serum	2.5-5%
CAS: 67-68-5 EINECS: 200-664-3	dimethyl sulfoxide	0.1-1.0%
CAS: 50-00-0 EINECS: 200-001-8	formaldehyde Acute Tox. 3, H301; Acute Tox. 3, H311; Acute Tox. 3, H331 Muta. 2, H341; Carc. 1B, H350 Skin Corr. 1B, H314 Skin Sens. 1, H317	.001-.01%
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.

QUS
(Contd. on page 3)

Safety Data Sheet

acc. to OSHA HCS

Printing date 03/15/2016

Reviewed on 03/15/2016

Trade name: Amplichek STI, Positive

(Contd. of page 2)

4 First-aid measures

- **Description of first aid measures**
- **General information**
Symptoms of poisoning may even occur after several hours; therefore medical observation for at least 48 hours after the accident.
- **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**
Rinse mouth with water. Seek medical attention and appropriate follow-up.
Immediately call a doctor.
- **Information for doctor**
- **Most important symptoms and effects, both acute and delayed** No further relevant information available.
- **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**
Wear protective equipment (See section 8). Keep unprotected persons away.
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 precautions are necessary if used correctly.

(Contd. on page 4)

- QUS -

Safety Data Sheet
acc. to OSHA HCS

Printing date 03/15/2016

Reviewed on 03/15/2016

Trade name: Amplichek STI, Positive

(Contd. of page 3)

- **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:** According to product specification
- **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.
- **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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57-50-1 sucrose, pure

PEL (United States)	Long-term value: 15* 5** mg/m ³ *total dust **respirable fraction
REL (United States)	Long-term value: 10* 5** mg/m ³ *total dust **respirable fraction
TLV (United States)	Long-term value: 10 mg/m ³

26628-22-8 sodium azide

REL (United States)	Ceiling limit value: 0.3** mg/m ³ , 0.1* ppm *as HN ₃ ; **as NaN ₃ ; Skin
TLV (United States)	Ceiling limit value: 0.29** mg/m ³ , 0.11* ppm *as HN ₃ vapor **as NaN ₃

(Contd. on page 5)

Safety Data Sheet
acc. to OSHA HCS

Printing date 03/15/2016

Reviewed on 03/15/2016

Trade name: Amplichek STI, Positive

(Contd. of page 4)

50-00-0 formaldehyde

PEL (United States)	Short-term value: 2 ppm Long-term value: 0.75 ppm see 29 CFR 1910.1048(c)
REL (United States)	Long-term value: 0.016 ppm Ceiling limit value: 0.1* ppm *15-min; See Pocket Guide App. A
TLV (United States)	Ceiling limit value: 0.37 mg/m ³ , 0.3 ppm DSEN; RSEN

· 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.

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

(Contd. on page 6)

Safety Data Sheet
acc. to OSHA HCS

Printing date 03/15/2016

Reviewed on 03/15/2016

Trade name: Amplichek STI, Positive

(Contd. of page 5)

Boiling point/Boiling range: 81-109 °C	
· Flash point:	≤30 °C
· Flammability (solid, gaseous) Not applicable.	
· 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 %
Solids content:	0.1 %
· 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**
This product contains sodium azide. Sodium azide can react with copper, brass, lead, and solder in piping systems to form explosive compounds of lead azide and copper azide.
- **Conditions to avoid** No further relevant information available.
- **Incompatible materials:** No further relevant information available.
- **Hazardous decomposition products:** No dangerous decomposition products known

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)

(Contd. on page 7)

Safety Data Sheet
acc. to OSHA HCS

Printing date 03/15/2016

Reviewed on 03/15/2016

Trade name: Amplichek STI, Positive

(Contd. of page 6)

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
50-00-0	formaldehyde	1

· **NTP (National Toxicology Program)**

50-00-0	formaldehyde	K
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· **OSHA-Ca (Occupational Safety & Health Administration)**

50-00-0	formaldehyde	
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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.

· **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.

Flush pipes with water frequently if discarding solutions containing sodium azide into metal piping systems.

(Contd. on page 8)

Safety Data Sheet

acc. to OSHA HCS

Printing date 03/15/2016

Reviewed on 03/15/2016

Trade name: Amplichek STI, Positive

(Contd. of page 7)

- **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	
· DOT, ADR, IMDG, IATA	UN1993
· UN proper shipping name	
· DOT	Flammable liquids, n.o.s. (Ethanol, Methanol)
· ADR	1993 FLAMMABLE LIQUID, N.O.S. (not viscous) (ETHANOL (ETHYL ALCOHOL), METHANOL)
· IMDG	FLAMMABLE LIQUID, N.O.S. (ETHANOL (ETHYL ALCOHOL), METHANOL)
· IATA	Flammable liquid, n.o.s. (Ethanol, Methanol)
· Transport hazard class(es)	
· Label	3
· ADR, IMDG, IATA	
· Class	3 Flammable liquids
· Label	3
· Packing group	
· DOT, ADR, IMDG, IATA	III
· Environmental hazards:	Not applicable.
· Special precautions for user	Warning: Flammable liquids
· Danger code (Kemler):	30
· 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.
· 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)	1L
· Excepted quantities (EQ)	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, III

QUS

(Contd. on page 9)

Safety Data Sheet
acc. to OSHA HCS

Printing date 03/15/2016

Reviewed on 03/15/2016

Trade name: Amplichek STI, Positive

(Contd. of page 8)

15 Regulatory information

- Safety, health and environmental regulations/legislation specific for the substance or mixture
- SARA (Superfund Amendants and Reauthorization Act of 1986 - USA)

· **Section 302/304 (40CFR355.30 / 40CFR355.40):**

26628-22-8	sodium azide
50-00-0	formaldehyde

· **Section 313 (40CFR372.65):**

	Proprietary Reagent MK6
	Proprietary Reagent MK7
26628-22-8	sodium azide
50-00-0	formaldehyde

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

	Proprietary Reagent MK5
	Proprietary Reagent MK6
	Proprietary Reagent MK7
67-68-5	dimethyl sulfoxide
57-50-1	sucrose, pure
9048-46-8	Bovine Serum Albumin
7558-79-4	disodium hydrogenorthophosphate
7647-14-5	sodium chloride
26628-22-8	sodium azide
26172-55-4	5-chloro-2-methyl-2H-isothiazol-3-one
2682-20-4	2-methyl-2H-isothiazol-3-one
50-00-0	formaldehyde
7447-40-7	potassium chloride
7778-77-0	potassium dihydrogenphosphate
56-86-0	glutamic acid

· **California Proposition 65:**

· **Chemicals known to cause cancer:**

50-00-0	formaldehyde
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· **Developmental Toxicity**

Proprietary Reagent MK5

· **Carcinogenic categories**

· **EPA (Environmental Protection Agency)**

50-00-0	formaldehyde	B1
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· **TLV (Threshold Limit Value established by ACGIH)**

	Proprietary Reagent MK5	A3
	Proprietary Reagent MK6	A4
57-50-1	sucrose, pure	A4
26628-22-8	sodium azide	A4

(Contd. on page 10)

Safety Data Sheet
acc. to OSHA HCS

Printing date 03/15/2016

Reviewed on 03/15/2016

Trade name: Amplichek STI, Positive

(Contd. of page 9)

50-00-0	formaldehyde	A2
· MAK (German Maximum Workplace Concentration)		
	Proprietary Reagent MK5	5
50-00-0	formaldehyde	4
· NIOSH-Ca (National Institute for Occupational Safety and Health)		
50-00-0	formaldehyde	

· 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** 03/15/2016 / -

· 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. 3: Acute toxicity, Hazard Category 3

Acute Tox. 2: Acute toxicity, Hazard Category 2

Skin Corr. 1B: Skin corrosion/irritation, Hazard Category 1B

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

Skin Sens. 1: Sensitisation - Skin, Hazard Category 1

Muta. 2: Germ cell mutagenicity, Hazard Category 2

Carc. 1A: Carcinogenicity, Hazard Category 1A

Carc. 1B: Carcinogenicity, Hazard Category 1B

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.**