

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

1.1. Product identifier

Trade name or designation of the mixture	ImmunoCard STAT!® Giardia Positive Control
Registration number	-
Synonyms	None.
Kit number	75820
Issue date	22-May-2012
Version number	01
Revision date	-
Supersedes date	-

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

Identified uses	Component of ImmunoCard STAT!® Crypto/Giardia Rapid Assay Control Set. For use with the ImmunoCard STAT! Crypto/Giardia Rapid Assay Kit as unassayed control material to monitor test performance. For In Vitro Diagnostic use only.
Uses advised against	Use in accordance with supplier's recommendations.

1.3. Details of the supplier of the safety data sheet

Corporate Headquarters	Sekisui Diagnostics, LLC 31 New York Avenue, Framingham, MA 01701 USA www.sekisuidiagnostics.com Phone: 800-332-1042
Distributor	Sekisui Diagnostics (UK) Limited 50 Gibson Drive, Kings Hill, West Malling Kent ME19 4AF UK www.sekisuidiagnostics.com Phone: 44 (0) 1732 220022 info@sekisuidiagnostics.com
Contact person	Americas 1-760-476-3962
1.4. Emergency telephone number	Europe, Middle East & Africa +1-760-476-3961 Asia Pacific +1-760-476-3960
Access code	333512

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

The mixture has been assessed and/or tested for its physical, health and environmental hazards and the following classification applies.

Classification according to Directive 67/548/EEC or 1999/45/EC as amended

This preparation is not classified as dangerous according to Directive 1999/45/EC and its amendments.

Classification according to Regulation (EC) No 1272/2008 as amended

This mixture does not meet the criteria for classification according to Regulation (EC) 1272/2008 as amended.

Hazard summary

Physical hazards	Not classified for physical hazards.
Health hazards	Not classified for health hazards.
Environmental hazards	Not classified for hazards to the environment.
Specific hazards	This preparation contains formalin, which is composed of formaldehyde and water. Formaldehyde causes cancer and skin sensitization (allergy). Avoid contact with eyes and skin. Do not ingest or inhale.
Main symptoms	Direct contact with skin and eyes may cause irritation.

2.2. Label elements

Label according to Regulation (EC) No. 1272/2008 as amended

Hazard pictograms	None.
Signal word	None.
Hazard statements	The mixture does not meet the criteria for classification.

Precautionary statements

Prevention	None.
Response	None.
Storage	None.
Disposal	None.

Supplemental label information Contains formaldehyde. May produce an allergic reaction.

2.3. Other hazards Not a PBT or vPvB substance or mixture.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

General information

Chemical name	%	CAS-No. / EC No.	REACH Registration No.	INDEX No.	Notes
---------------	---	------------------	------------------------	-----------	-------

Formaldehyde	0.1	50-00-0 200-001-8	-	605-001-00-5	
--------------	-----	----------------------	---	--------------	--

Classification:	DSD: Carc. Cat. 3;R40, T;R23/24/25, C;R34, R43
	CLP: Acute Tox. 3;H301, Acute Tox. 3;H311, Skin Corr. 1B;H314, Skin Sens. 1;H317, Acute Tox. 3;H331, STOT SE 3;H335, Carc. 2;H351

#: This substance has been assigned Community workplace exposure limit(s).

DSD: Directive 67/548/EEC.

CLP: Regulation No. 1272/2008.

Composition comments The full text for all R- and H-phrases is displayed in section 16. All concentrations are in percent by weight unless ingredient is a gas. Gas concentrations are in percent by volume.

SECTION 4: First aid measures

General information Not available.

4.1. Description of first aid measures

Inhalation	Move to fresh air. Call a physician if symptoms develop or persist.
Skin contact	For skin contact flush with large amounts of water while removing contaminated clothing. Get medical attention if irritation develops and persists.
Eye contact	In case of contact, immediately flush eyes with fresh water for at least 15 minutes while holding the eyelids open. Remove contact lenses if worn. Get medical attention if irritation persists.
Ingestion	If material is ingested, immediately contact a physician or poison control centre.

4.2. Most important symptoms and effects, both acute and delayed Direct contact with skin and eyes may cause irritation.

4.3. Indication of any immediate medical attention and special treatment needed Provide general supportive measures and treat symptomatically.

SECTION 5: Firefighting measures

General fire hazards The product is not flammable.

5.1. Extinguishing media

Suitable extinguishing media	Extinguish with water spray, carbon dioxide, dry chemical or material appropriate for the surrounding fire.
Unsuitable extinguishing media	None known.

5.2. Special hazards arising from the substance or mixture Irritating and/or toxic gases may be emitted upon the products decomposition.

5.3. Advice for firefighters

Special protective equipment for firefighters	Self-contained breathing apparatus and full protective clothing must be worn in case of fire.
Special fire fighting procedures	Use standard firefighting procedures and consider the hazards of other involved materials.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

For non-emergency personnel	Keep unnecessary personnel away. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing.
------------------------------------	--

For emergency responders	Use personal protection as recommended in section 8 of the SDS.
6.2. Environmental precautions	Do not allow to enter drains, sewers or watercourses.
6.3. Methods and material for containment and cleaning up	Absorb spill with vermiculite or other inert material. Dispose of waste in accordance with all applicable federal, state, local and provincial environmental regulations, per Section 13.
6.4. Reference to other sections	For personal protection, see section 8. For waste disposal, see section 13.
SECTION 7: Handling and storage	
7.1. Precautions for safe handling	Avoid contact with skin and eyes. Wash thoroughly after handling. In case of insufficient ventilation, wear suitable respiratory equipment. Handle and open container with care.
7.2. Conditions for safe storage, including any incompatibilities	Store at 2-8°C (35-46°F). Store in a closed container away from incompatible materials.
7.3. Specific end use(s)	Component of ImmunoCard STAT!® Crypto/Giardia Rapid Assay Control Set. For use with the ImmunoCard STAT! Crypto/Giardia Rapid Assay Kit as unassayed control material to monitor test performance. For In Vitro Diagnostic use only.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Occupational exposure limits

UK. EH40 Workplace Exposure Limits (WELs)

Components	Type	Value
Formaldehyde (CAS 50-00-0)	STEL	2.5 mg/m3
		2 ppm
	TWA	2.5 mg/m3
		2 ppm

Biological limit values No biological exposure limits noted for the ingredient(s).

Recommended monitoring procedures Follow standard monitoring procedures.

Derived no-effect level (DNEL)

Components	Type	Route	Value	Form
Formaldehyde (CAS 50-00-0)	Workers	Dermal	240 mg/kg/day	Long term Systemic effects
		Inhalation	9 mg/m3	Long term Systemic effects
		Inhalation	1 mg/m3	Acute Local effects
		Inhalation	0.5 mg/m3	Long term Local effects

Predicted no effect concentrations (PNECs)

Components	Type	Route	Value	Form
Formaldehyde (CAS 50-00-0)	Aqua (freshwater)	Not applicable	0.47 mg/l	
	Aqua (intermittent releases)	Not applicable	4.7 mg/l	
	Aqua (marine water)	Not applicable	0.47 mg/l	
	Sediment (freshwater)	Not applicable	2.44 mg/kg	
	Sediment (marine water)	Not applicable	2.44 mg/kg	
	Sewage Treatment Plant	Not applicable	0.19 mg/l	
	Soil	Not applicable	0.21 mg/kg	

8.2. Exposure controls

Appropriate engineering controls Provide adequate ventilation. Observe Occupational Exposure Limits and minimise the risk of inhalation of vapours. Provide easy access to water supply and eye wash facilities.

Individual protection measures, such as personal protective equipment

General information	Personal protective equipment should be chosen according to the CEN standards and in discussion with the supplier of the personal protective equipment.
Eye/face protection	Wear approved safety glasses or goggles.
Skin protection	
- Hand protection	Wear appropriate chemical resistant gloves.

- Other	Wear lab coat or other protective garments. Remove contaminated clothing promptly.
Respiratory protection	In case of inadequate ventilation or risk of inhalation of vapours, use suitable respiratory equipment with gas filter (type A2).
Thermal hazards	Wear appropriate thermal protective clothing, when necessary.
Hygiene measures	Handle in accordance with good industrial hygiene and safety practices.
Environmental exposure controls	Inform appropriate managerial or supervisory personnel of all environmental releases.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance	Clear to amber liquid.
Physical state	Liquid.
Form	Liquid.
Colour	Clear to amber.
Odour	May have pungent odor.
Odour threshold	Not available.
pH	5.5
Melting point/freezing point	Not applicable
Initial boiling point and boiling range	Not available.
Flash point	Not applicable.
Evaporation rate	Not applicable.
Flammability (solid, gas)	Not applicable.
Upper/lower flammability or explosive limits	
Flammability limit - lower (%)	Not available.
Flammability limit - upper (%)	Not available.
Vapour pressure	Not applicable.
Vapour density	Not applicable.
Relative density	Not available.
Solubility(ies)	Soluble
Partition coefficient (n-octanol/water)	Not available.
Auto-ignition temperature	Not applicable
Decomposition temperature	Not available.
Viscosity	Not applicable.
Explosive properties	Not available.
Oxidizing properties	Not available.
9.2. Other information	No relevant additional information available.

SECTION 10: Stability and reactivity

10.1. Reactivity	The product is stable and non reactive under normal conditions of use, storage and transport.
10.2. Chemical stability	The product is stable.
10.3. Possibility of hazardous reactions	Formaldehyde readily polymerizes.
10.4. Conditions to avoid	No data available.
10.5. Incompatible materials	Formaldehyde is incompatible with oxidizers, alkalis, acids, phenols, and urea. Explosive reactions occur with peroxide, nitrogen oxide, and performic acid.
10.6. Hazardous decomposition products	Thermal decomposition can lead to release of irritating gases and vapors.

SECTION 11: Toxicological information

General information	Occupational exposure to the substance or mixture may cause adverse effects.
Information on likely routes of exposure	
Ingestion	May cause discomfort if swallowed.
Inhalation	Formaldehyde vapor is irritating to the nasal passages and throat and causes cancer in nasal tissues.

Skin contact	Repeated exposure may cause skin dryness or cracking.
Eye contact	May cause eye irritation.
Symptoms	Direct contact with skin and eyes may cause irritation.

11.1. Information on toxicological effects

Acute toxicity	May cause discomfort if swallowed.
-----------------------	------------------------------------

Components	Species	Test results
Formaldehyde (CAS 50-00-0)		
Acute		
<i>Inhalation</i>		
LC50	Rat	0.48 mg/l, 4 Hours
Skin corrosion/irritation	May cause skin irritation.	
Serious eye damage/irritation	May cause eye irritation.	
Respiratory sensitisation	Not classified.	
Skin sensitisation	The product contains a small amount of sensitising substance which may provoke an allergic reaction among sensitive individuals.	
Germ cell mutagenicity	Not classified.	
Carcinogenicity	Not classified.	

IARC Monographs. Overall Evaluation of Carcinogenicity

Formaldehyde (CAS 50-00-0)	1 Carcinogenic to humans.
----------------------------	---------------------------

Reproductive toxicity	Not classified.
Specific target organ toxicity - single exposure	Not classified.
Specific target organ toxicity - repeated exposure	Not classified.
Aspiration hazard	Not classified.
Mixture versus substance information	Not available.
Other information	According to IARC, formaldehyde is carcinogenic to humans (Group 1), on the basis of sufficient evidence in humans and sufficient evidence in experimental animals. Results of the largest and most informative cohort study of industrial workers exposed to formaldehyde in the USA, supported by the largely positive findings from other studies, provided sufficient epidemiological evidence that formaldehyde causes nasopharyngeal cancer in humans.

SECTION 12: Ecological information

12.1. Toxicity	The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.
-----------------------	--

Components	Species	Test results
Formaldehyde (CAS 50-00-0)		
Aquatic		
Crustacea	EC50	Water flea (<i>Daphnia pulex</i>)
		4.3 - 7.8 mg/l, 48 hours
Fish	LC50	American eel (<i>Anguilla rostrata</i>)
		0 - 197.79 mg/l, 96 hours
12.2. Persistence and degradability	No data is available on the degradability of this product.	
12.3. Bioaccumulative potential	Not available.	
Partition coefficient n-octanol/water (log Kow)		
Formaldehyde		0.35
Bioconcentration factor (BCF)	Not available.	
12.4. Mobility in soil	Not available.	
Mobility in general	The product is soluble in water.	
12.5. Results of PBT and vPvB assessment	Not a PBT or vPvB substance or mixture.	
12.6. Other adverse effects	The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.	

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Residual waste	Dispose in accordance with all applicable regulations.
Contaminated packaging	Empty containers should be taken to an approved waste handling site for recycling or disposal.
EU waste code	The Waste code should be assigned in discussion between the user, the producer and the waste disposal company.
Disposal methods/information	Contaminated instruments and surfaces should be disinfected in accordance with your employer's chemical-specific and universal/standard precautions.

SECTION 14: Transport information

ADR

The product is not covered by international regulation on the transport of dangerous goods.

RID

The product is not covered by international regulation on the transport of dangerous goods.

ADN

The product is not covered by international regulation on the transport of dangerous goods.

IATA

The product is not covered by international regulation on the transport of dangerous goods.

IMDG

The product is not covered by international regulation on the transport of dangerous goods.

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

EU regulations

Regulation (EC) No. 1005/2009 on substances that deplete the ozone layer, Annex I

Not listed.

Regulation (EC) No. 1005/2009 on substances that deplete the ozone layer, Annex II

Not listed.

Regulation (EC) No. 850/2004 On persistent organic pollutants, Annex I as amended

Not listed.

Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex I, part 1 as amended

Not listed.

Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex I, part 2 as amended

Not listed.

Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex I, part 3 as amended

Not listed.

Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex V as amended

Not listed.

Regulation (EC) No. 166/2006 Annex II Pollutant Release and Transfer Registry

Not listed.

Regulation (EC) No. 1907/2006, REACH Article 59(1) Candidate List as currently published by ECHA

Not listed.

Authorisations

Regulation (EC) No. 143/2011 Annex XIV Substances Subject to Authorisation

Not listed.

Restrictions on use

Regulation (EC) No. 1907/2006, REACH Annex XVII Substances subject to restriction on marketing and use as amended

Not listed.

Directive 2004/37/EC: on the protection of workers from the risks related to exposure to carcinogens and mutagens at work

Not regulated.

Directive 92/85/EEC: on the safety and health of pregnant workers and workers who have recently given birth or are breastfeeding

Formaldehyde (CAS 50-00-0)

Other EU regulations

Directive 96/82/EC (Seveso II) on the control of major-accident hazards involving dangerous substances

Not regulated.

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

Formaldehyde (CAS 50-00-0)

Directive 94/33/EC on the protection of young people at work

Formaldehyde (CAS 50-00-0)

Other regulations

This product does not meet the criteria for classification according to Regulation (EC) 1272/2008 (CLP Regulation) and Directive 1999/45/EC and their amendments respectively. This Safety Data Sheet complies with the requirements of Regulation (EC) No 1907/2006. In the European Union this product is regulated under the In Vitro Diagnostic Medical Devices Directive (98/79/EC).

National regulations

The product has not been classified as dangerous according to the legislation in force.

15.2. Chemical safety assessment

No Chemical Safety Assessment has been carried out.

SECTION 16: Other information

List of abbreviations

DNEL: Derived No-Effect Level.
PNEC: Predicted No-Effect Concentration.
LD50: Lethal Dose, 50%.

References

IARC Monographs. Overall Evaluation of Carcinogenicity
HSDB (2005)

Information on evaluation method leading to the classification of mixture

The classification for health and environmental hazards is derived by a combination of calculation methods and test data, if available.

Full text of any statements or R-phrases and H-statements under Sections 2 to 15

R23/24/25 Toxic by inhalation, in contact with skin and if swallowed.
R34 Causes burns.
R40 Limited evidence of a carcinogenic effect.
R43 May cause sensitisation by skin contact.
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.
H331 - Toxic if inhaled.
H335 - May cause respiratory irritation.
H351 - Suspected of causing cancer.

Training information

Follow training instructions when handling this material.

Disclaimer

The information above is provided in good faith. It is believed to be accurate and represents the best information currently available to us. HOWEVER, WE MAKE NO WARRANTY OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE OR OF ANY OTHER TYPE, EXPRESSED OR IMPLIED, WITH RESPECT TO PRODUCTS DESCRIBED OR DATA OR INFORMATION PROVIDED, AND WE ASSUME NO LIABILITY RESULTING FROM THE USE OF SUCH PRODUCTS, DATA OR INFORMATION. Users should make their own investigations to determine the suitability of the information for their particular purposes, and the user assumes all risk arising from their use of the material. The user is required to comply with all laws and regulations relating to the purchase, use, storage and disposal of the material, and must be familiar with and follow generally accepted safe handling procedures. In no event shall Sekisui Diagnostics be liable for any claims, losses, or damages of any individual or for lost profits or any special, indirect, incidental, consequential or exemplary damages, howsoever arising, even if Sekisui Diagnostics has been advised of the possibility of such damages.