

**Safety Data Sheet**

according to Regulation (EC) No 1907/2006

**HISTO SPOT® AB Reagent Kit Conjugate**

Revision date: 03.06.2022

Product code: BAG-013

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**SECTION 1: Identification of the substance/mixture and of the company/undertaking****1.1. Product identifier**

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**1.2. Relevant identified uses of the substance or mixture and uses advised against****Use of the substance/mixture**Laboratory chemicals  
In-vitro diagnostics**Uses advised against**Only use for the intended purpose.  
The product is intended for professional use.**1.3. Details of the supplier of the safety data sheet**

Company name:	BAG Diagnostics GmbH	
Street:	Amtsgerichtsstr. 1-5	
Place:	D-35423 Lich	
Telephone:	+49 (0) 6404 / 925 -100	Telefax: +49 (0) 6404 / 925 -460
e-mail:	info@bag-diagnostics.com	
Internet:	www.bag-diagnostics.com	
Responsible Department:	Information on the MSDS: eu-sds@asseso.eu Contact person for the product: Customer Service, + 49-6404-925-125, info@bag-diagnostics.com	

**1.4. Emergency telephone number:**

national emergency number: +353 1 8092566

**SECTION 2: Hazards identification****2.1. Classification of the substance or mixture****Regulation (EC) No 1272/2008**

Skin Sens. 1; H317

Full text of hazard statements: see SECTION 16.

**2.2. Label elements****Regulation (EC) No 1272/2008****Hazard components for labelling**Gentamicin  
reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1)**Signal word:** Warning**Pictograms:****Hazard statements**

H317 May cause an allergic skin reaction.

**Precautionary statements**

P280	Wear protective gloves/protective clothing/eye protection/face protection.
P302+P352	IF ON SKIN: Wash with plenty of water.
P333+P313	If skin irritation or rash occurs: Get medical advice/attention.
P501	Do not discard content with household waste and forward for disposal according to regional/national guidelines.

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**2.3. Other hazards**

The components in this mixture do not meet the criteria for classification as PBT or vPvB.

**SECTION 3: Composition/information on ingredients**
**3.2. Mixtures**
**Hazardous components**

CAS No	Chemical name			Quantity
	EC No	Index No	REACH No	
	Classification (Regulation (EC) No 1272/2008)			
1403-66-3	Gentamicin			<3 %
	215-765-8			
	Skin Sens. 1; H317			
55965-84-9	reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1)			<0,0015 %
	911-418-6	613-167-00-5		
	Acute Tox. 2, Acute Tox. 2, Acute Tox. 3, Skin Corr. 1C, Eye Dam. 1, Skin Sens. 1A, Aquatic Acute 1, Aquatic Chronic 1; H330 H310 H301 H314 H318 H317 H400 H410 EUH071			

Full text of H and EUH statements: see section 16.

**Specific Conc. Limits, M-factors and ATE**

CAS No	EC No	Chemical name	Quantity
		Specific Conc. Limits, M-factors and ATE	
55965-84-9	911-418-6	reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1)	<0,0015 %
	inhalation: ATE = 0,5 mg/l (vapours); inhalation: ATE = 0,05 mg/l (dusts or mists); dermal: ATE = 50 mg/kg; oral: ATE = 100 mg/kg Skin Corr. 1C; H314: >= 0,6 - 100 Skin Irrit. 2; H315: >= 0,06 - < 0,6 Eye Dam. 1; H318: >= 0,6 - 100 Eye Irrit. 2; H319: >= 0,06 - < 0,6 Skin Sens. 1A; H317: >= 0,0015 - 100 Aquatic Acute 1; H400: M=100 Aquatic Chronic 1; H410: M=100		

**SECTION 4: First aid measures**
**4.1. Description of first aid measures**
**General information**

In case of troubles or persistent symptoms, consult an doctor/physician.

First aider: Pay attention to self-protection!

**After inhalation**

If irritations or allergic reactions should occur as a consequence of handling the product (particularly if large quantities have been inhaled): Move victim to fresh air. Put victim at rest and keep warm. In case of allergic symptoms, especially in the breathing area, seek medical advice immediately.

**After contact with skin**

After contact with skin, wash immediately with plenty of water and soap. Change contaminated clothing. In case of skin irritation, consult a physician.

**After contact with eyes**

Remove contact lenses. In case of contact with eyes, rinse immediately with plenty of flowing water for 10 to 15 minutes holding eyelids apart. In case of troubles or persistent symptoms, consult an ophthalmologist.

**After ingestion**

Rinse mouth, spit liquid again. Let water be drunken in little sips (dilution effect). Seek medical attention if problems persist.

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

Irritations/allergic reactions upon contact with skin.

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

Treat symptomatically.

**SECTION 5: Firefighting measures****5.1. Extinguishing media****Suitable extinguishing media**Co-ordinate fire-fighting measures to the fire surroundings.  
Water fog. alcohol resistant foam. Carbon dioxide (CO<sub>2</sub>).**Unsuitable extinguishing media**

High power water jet.

**5.2. Special hazards arising from the substance or mixture**In case of fire may be liberated: Carbon monoxide. Carbon dioxide. Hydrogen chloride (HCl).  
Irritating/poisonous gasses and vapours.**5.3. Advice for firefighters**Co-ordinate fire-fighting measures to the fire surroundings.  
Avoid contact with skin and eyes. Do not inhale vapors.  
Wear a self-contained breathing apparatus and chemical protective clothing.**Additional information**Suppress gases/vapours/mists with water spray jet.  
Contaminated fire-fighting water must be collected separately. Do not allow to enter into surface water or drains.  
Use water spray jet to protect personnel and to cool endangered containers.**SECTION 6: Accidental release measures****6.1. Personal precautions, protective equipment and emergency procedures****General advice**Provide adequate ventilation. Avoid contact with skin, eyes and clothes. Wear personal protection equipment.  
Special danger of slipping by leaking/spilling product.**6.2. Environmental precautions**

Do not allow to enter into surface water or drains. Do not allow to enter into soil/subsoil. In case of gas escape or of entry into waterways, soil or drains, inform the responsible authorities.

**6.3. Methods and material for containment and cleaning up****For containment**Absorb with liquid-binding material (sand, diatomaceous earth, acid- or universal binding agents).  
Treat the recovered material as prescribed in the section on waste disposal.**For cleaning up**

Clean contaminated articles and floor according to the environmental legislation.

**6.4. Reference to other sections**Safe handling: see section 7  
Personal precautions: refer to section 8  
Disposal: see section 13**SECTION 7: Handling and storage****7.1. Precautions for safe handling****Advice on safe handling**When in use in confined, warm rooms: Ensure adequate ventilation.  
At the place of work (in production and when refilling): Wear personal protection equipment.  
Do not empty into drains; dispose of this material and its container in a safe way.

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**Advice on protection against fire and explosion**

Usual measures for fire prevention.

**Advice on general occupational hygiene**

Remove contaminated, saturated clothing immediately. Wash hands and face before breaks and after work and take a shower if necessary. When using do not eat, drink, smoke, sniff.

**Further information on handling**

When using do not eat, drink or smoke.

**7.2. Conditions for safe storage, including any incompatibilities****Requirements for storage rooms and vessels**

Keep container tightly closed in a cool, well-ventilated place.

**Hints on joint storage**

Keep away from food, drink and animal feedingstuffs.

**Further information on storage conditions**

Recommended storage temperature: 4°C

**7.3. Specific end use(s)**Laboratory chemicals  
In-vitro diagnostics**SECTION 8: Exposure controls/personal protection****8.1. Control parameters****Additional advice on limit values**

Until today no further national limits have been defined.

**8.2. Exposure controls****Appropriate engineering controls**

If handled uncovered, arrangements with local exhaust ventilation have to be used. Do not breathe gas/fumes/vapour/spray. Provide protection equipment (eye wash bottles, etc.).

**Individual protection measures, such as personal protective equipment****Eye/face protection**

Eye glasses with side protection

**Hand protection**

Wear suitable gloves.

Chemical resistant safety shoes.

Recommended material: Butyl rubber. NBR (Nitrile rubber).

Thickness of glove material: 0,11 mm / Breakthrough time &gt;60 min

When handling with chemical substances, protective gloves must be worn with the CE-label including the four control digits. The quality of the protective gloves resistant to chemicals must be chosen as a function of the specific working place concentration and quantity of hazardous substances.

For special purposes, it is recommended to check the resistance to chemicals of the protective gloves mentioned above together with the supplier of these gloves.

**Skin protection**

Use of protective clothing.

**Respiratory protection**

exceeding exposure limit values: gas filtering equipment (EN 141).

**SECTION 9: Physical and chemical properties****9.1. Information on basic physical and chemical properties**

Physical state: liquid

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Colour:	colourless to yellowish	
Odour:	characteristic	
Melting point/freezing point:		not determined
Boiling point or initial boiling point and boiling range:		not determined
Flammability		
Solid/liquid:		No data available.
Gas:		No data available.
Lower explosion limits:		No data available.
Upper explosion limits:		No data available.
Flash point:		not determined
Auto-ignition temperature:		No data available.
Decomposition temperature:		No data available.
pH-Value:		No data available.
Viscosity / kinematic:		No data available.
Water solubility:		No data available.
Solubility in other solvents		
No data available.		
Partition coefficient n-octanol/water:		No data available.
Vapour pressure:		No data available.
Density:		not determined
Relative vapour density:		No data available.

#### **9.2. Other information**

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

Explosive properties

No data available.

Self-ignition temperature

Solid:

No data available.

Oxidizing properties

No data available.

##### **Other safety characteristics**

Evaporation rate:

No data available.

Viscosity / dynamic:

No data available.

##### **Further Information**

No data available.

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

#### **10.1. Reactivity**

No dangerous reactivity under regular conditions.

#### **10.2. Chemical stability**

The product is stable under regular conditions.

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

No data available

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

Thermal load.

#### **10.5. Incompatible materials**

Oxidizing agents, strong.

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

In case of fire may be liberated: Carbon monoxide. Carbon dioxide. Irritating/poisonous gasses and vapours.

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**SECTION 11: Toxicological information**
**11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008**
**Acute toxicity**

Based on available data, the classification criteria are not met.

CAS No	Chemical name				
	Exposure route	Dose	Species	Source	Method
55965-84-9	reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1)				
	oral	ATE 100 mg/kg			
	dermal	ATE 50 mg/kg			
	inhalation vapour	ATE 0,5 mg/l			
	inhalation dust/mist	ATE 0,05 mg/l			

**Irritation and corrosivity**

Based on available data, the classification criteria are not met.

**Sensitising effects**

May cause an allergic skin reaction. (Gentamicin; reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1))

**Carcinogenic/mutagenic/toxic effects for reproduction**

Based on available data, the classification criteria are not met.

**STOT-single exposure**

Based on available data, the classification criteria are not met.

**STOT-repeated exposure**

Based on available data, the classification criteria are not met.

**Aspiration hazard**

Based on available data, the classification criteria are not met.

**11.2. Information on other hazards**
**Endocrine disrupting properties**

none known

**SECTION 12: Ecological information**
**12.1. Toxicity**

No data available.

**12.2. Persistence and degradability**

No data available.

**12.3. Bioaccumulative potential**

No data available.

**12.4. Mobility in soil**

No data available.

**12.5. Results of PBT and vPvB assessment**

The substances in the mixture do not meet the PBT/vPvB criteria according to REACH, annex XIII.

**12.6. Endocrine disrupting properties**

This product does not contain a substance that has endocrine disrupting properties with respect to non-target organisms as no components meets the criteria.

**12.7. Other adverse effects**

No data available

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**SECTION 13: Disposal considerations****13.1. Waste treatment methods****Disposal recommendations**

Disposal according to official regulations.

Consult the local waste disposal expert about waste disposal. According to EAKV, allocation of waste identity numbers/waste descriptions must be carried out in a specific way for every industry and process.

**Contaminated packaging**

Recommended cleaning agent: Water.

Dispose of waste according to applicable legislation.

**SECTION 14: Transport information****Land transport (ADR/RID)**

<b>14.1. UN number or ID number:</b>	No dangerous good in sense of this transport regulation.
<b>14.2. UN proper shipping name:</b>	No dangerous good in sense of this transport regulation.
<b>14.3. Transport hazard class(es):</b>	No dangerous good in sense of this transport regulation.
<b>14.4. Packing group:</b>	No dangerous good in sense of this transport regulation.

**Inland waterways transport (ADN)**

<b>14.1. UN number or ID number:</b>	No dangerous good in sense of this transport regulation.
<b>14.2. UN proper shipping name:</b>	No dangerous good in sense of this transport regulation.
<b>14.3. Transport hazard class(es):</b>	No dangerous good in sense of this transport regulation.
<b>14.4. Packing group:</b>	No dangerous good in sense of this transport regulation.

**Marine transport (IMDG)**

<b>14.1. UN number or ID number:</b>	No dangerous good in sense of this transport regulation.
<b>14.2. UN proper shipping name:</b>	No dangerous good in sense of this transport regulation.
<b>14.3. Transport hazard class(es):</b>	No dangerous good in sense of this transport regulation.
<b>14.4. Packing group:</b>	No dangerous good in sense of this transport regulation.

**Air transport (ICAO-TI/IATA-DGR)**

<b>14.1. UN number or ID number:</b>	No dangerous good in sense of this transport regulation.
<b>14.2. UN proper shipping name:</b>	No dangerous good in sense of this transport regulation.
<b>14.3. Transport hazard class(es):</b>	No dangerous good in sense of this transport regulation.
<b>14.4. Packing group:</b>	No dangerous good in sense of this transport regulation.

**14.5. Environmental hazards**

ENVIRONMENTALLY HAZARDOUS: No

**14.6. Special precautions for user**

No special precautions known.

**14.7. Maritime transport in bulk according to IMO instruments**

not applicable

**SECTION 15: Regulatory information****15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture****EU regulatory information**

Restrictions on use (REACH, annex XVII):

Entry 3, Entry 75

Information according to 2012/18/EU (SEVESO III): Not subject to 2012/18/EU (SEVESO III)

**Additional information**

Regulation (EC) No. 1005/2009 on substances that lead to the depletion of the ozone layer: not applicable

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Regulation (EC) No. 648/2004 [Detergents regulation]: not applicable

Regulation (EC) No 850/2004 on persistent organic pollutants: not applicable

Regulation (EC) No 649/2012 of the European Parliament and of the Council concerning the export and import of dangerous chemicals: This mix contains no chemicals that are subject to the export notification procedures (annex 1).

This mixture contains the following substances of very high concern (SVHC) which are included in the Candidate List according to Article 59 of REACH: none

This mixture contains the following substances of very high concern (SVHC) which are subject to authorisation according to Annex XIV of REACH: none

**National regulatory information**

Water hazard class (D): 1 - slightly hazardous to water

**Additional information**

Observe in addition any national regulations!

**15.2. Chemical safety assessment**

Chemical safety assessments for substances in this mixture were not carried out.

**SECTION 16: Other information****Changes**

This data sheet contains changes from the previous version in section(s): 1,2,5,8,9,10,15,16.

Version 1,00 - first creation

Version 2,00 - 06.05.2019 - General update

Version 3,00 - 03.06.2022 - Change and revision of the SDS because of new information / recipe

**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)

BImSchV (Fed.Imm.Prot.Act): Directive on the Implementation of the Federal Immission Protection Act

CAS: Chemical Abstracts Service

DIN: Norm of the Deutsche Institut für Normung (German Institute for Standardization)

EC: Effective Concentration

EG: European Community (Europäische Gemeinschaft)

EN: European Norm

IATA: International Air Transport Association

IBC Code: International Code for the Construction and Equipment of ships carrying Dangerous Chemicals in Bulk

ICAO: International Civil Aviation Organization

IMDG: International Maritime Code for Dangerous Goods

ISO: Norm of the International Standards Organization

CLP: Classification, Labeling, Packaging

IUCLID: International Uniform Chemical Information Database

LC: Lethal concentration

LD: Lethal dose

log Kow: Octanol/water partition coefficient

MARPOL: Maritime Pollution Convention = Convention for the Prevention of Maritime Pollution from Ships

OECD: Organisation for Economic Co-operation and Development

PBT: Persistent, bio-cumulative, toxic

RID: Regulation Concerning the International Transport of Dangerous Goods by Rail

TRGS: Technische Regeln für Gefahrstoffe

UN: United Nations

VOC: Volatile Organic Compounds

vPvB: very persistent and very bio-cumulative

WGK: German Water Hazard Class

GHS: Globally Harmonized System of Classification and Labelling of Chemicals

EINECS: European Inventory of Existing Commercial Chemical Substances



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ELINCS: European List of Notified Chemical Substances  
 DNEL: Derived No Effect Level  
 PNEC: Predicted No Effect Concentration  
 TLV: Threshold Limiting Value  
 STOT: Specific Target Organ Toxicity  
 AwSV: Ordinance on Installations for Handling Substances Hazardous to Water

**Classification for mixtures and used evaluation method according to Regulation (EC) No 1272/2008 [CLP]**

Classification	Classification procedure
Skin Sens. 1; H317	Calculation method

**Relevant H and EUH statements (number and full text)**

H301 Toxic if swallowed.  
 H310 Fatal 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.  
 EUH071 Corrosive to the respiratory tract.

**Further Information**

The information given in this safety data sheet is to describe the product's safety regulations. It is not for guaranteeing certain characteristics and is based on today's knowledge. The safety data sheet was generated upon information of pre-suppliers by:

assesio AG, Ottostraße 1, 63741, Aschaffenburg, Germany  
 Phone: +49 (0)6021 - 1 50 86-0, Fax: +49 (0)6021 - 1 50 86-77, E-Mail: eu-sds@assesio.eu, www.assesio.eu

*(The data for the hazardous ingredients were taken respectively from the last version of the sub-contractor's safety data sheet.)*