


|   |  |                                       |
|---|--|---------------------------------------|
|  | <b>EU – Safety Data Sheet</b>              | Acc. to Directive<br>1907/2006/EU     |
|   | <b>Generic E. coli   360 HCP ELISA Kit</b> | Version: 04<br>Issued at: 25 May 2021 |

## 1 Identification of the substance/mixture and of the company

- 1.1 Trade Name (As Labeled): **E. coli | 360 HCP ELISA**
- 1.2 Product Use: Regulations require HCPs to be reduced to the lowest levels possible. This generic ELISA kit is useful in both process development and process validation.
- 1.3 Manufacturer's Name: BioGenes GmbH  
Address: Köpenicker Str. 325, 12555 Berlin, Germany  
Business Phone: +49 30 65762378 (Product information)  
E-Mail: service@biogenes.de
- 1.4 Emergency telephone number: +49-30-19 24 0

## 2 HAZARD IDENTIFICATION

### 2.1 Classification of the substance or mixture Classification according to Regulation (EC) No. 1272/2008 [CLP]

This mixture is classified as not hazardous according to regulation (EC) 1272/2008 [CLP].

### 2.2 Label elements Labelling according to Regulation (EC) No 1272/2008 [CLP]

According to EC directives or the corresponding national regulations the product does not have to be labelled.

### 2.3 Other hazards

No ingredients are PBT/vPvB, according to the criteria in REACH Annex XIII.


## 3 COMPOSITION AND INFORMATION ON INGREDIENTS

This kit contains 8 components making up the E. coli | 360 HCP ELISA Kit. This product is used in laboratories to determine the presence of HCP contamination in products manufactured by expression in E. coli. The kit contains an antibody-coated Microtest Plate and the following mixtures: Enzyme Conjugate, Detector Antibody, E.coli HCP Kit Standard, Washing and Assay Buffer, Stop Solution and TMB Substrate.

### 3.1 Mixture

96-well, pre-coated with affinity-purified anti-E.coli-HCP-IgG (polyclonal) dried and sealed in foil bag with desiccant ready-to-use Microtest Plate.

| HAZARDOUS INGREDIENTS:<br>Antibody-coated Microtiter Plate | CAS No./<br>EC No./<br>Registration No. | Amount  | Hazard Classification;<br>Hazard Statements |
|--|---|---------|---|
| Affinity Purified Rabbit Antibody to E.coli HCP            | Not Listed                              | <100 µg | Not Classified<br>None                      |

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Kit standard of E. coli-HCP in stabilized solution.


| <b>HAZARDOUS INGREDIENTS:<br/>E.coli-HCP Kit Standard, 100 µl</b>  | <b>CAS No./<br/>EC No./<br/>Registration No.</b>        | <b>Amount</b> | <b>Hazard Classification;<br/>Hazard Statements<br/>According to Regulation (EC)<br/>No 1278/2008 (CLP)</b>  |
|--|---|---------------|--|
| BSA (Albumin Fraktion V, bovine, proteasefree, ≥ 98 %)   | 9048-46-8/<br>232-936-2/<br>Not applicable              | 1 %           | Not Classified,<br>None  |
| Sodium Chloride  | 7647-14-5/<br>231-598-3/<br>Not applicable              | 1-2 %         | Not Classified<br>None   |
| reaction mass of CMIT/MIT:<br>5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2- methyl-2H -isothiazol-3-one [EC no. 220-239-6] (CMIT/MIT = 3:1) | 55965-84-9/<br>Not applicable/<br>01-2120764691-48-XXXX | < 0.0014 %    | Acute Tox. 2, H330; Acute Tox. 2; H310, Acute Tox. 3, H301; Skin Corr. 1C, H314; Eye Dam 1, H318; Skin Sens. 1A, H317; Aquatic Acute 1, H400; Aquatic Chronic 1, H410; EUH071<br><b>SCL and/or M-factor:</b><br>Skin Corr. 1C; H314: C ≥ 0.6%; Skin Irrit. 2; H315: 0.06% ≤ C < 0.6%; Eye Dam 1, H318; C ≥ 0.6%; Eye Irrit. 2; H319: 0.06% ≤ C < 0.6%; Skin Sens. 1A; H317: C ≥ 0.0015% M-factor=100 |

Affinity-purified, biotin-conjugated anti-E.coli HCP-IgG (polyclonal) as 100x concentrate.

| <b>HAZARDOUS INGREDIENTS:<br/>Detector antibody anti-E.coli HCP-Biotin, 300 µl</b>   | <b>CAS No./<br/>EC No./<br/>Registration No.</b>        | <b>Amount</b> | <b>Hazard Classification;<br/>Hazard Statements<br/>According to Regulation (EC) No 1278/2008 (CLP)</b>  |
|--|---|---------------|--|
| Tris Hydrochloride   | 1185-53-1/<br>214-684-5                                 | 6-9 %         | Not Classified<br>None   |
| Ethanediol   | 107-21-1/<br>203-473-3                                  | <10%          | Hazardous, Irritant<br>Hazard Phrases: H302, H373<br>Precaution Phrases:<br>301+312+330  |
| reaction mass of CMIT/MIT:<br>5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2- methyl-2H -isothiazol-3-one [EC no. 220-239-6] (CMIT/MIT = 3:1) | 55965-84-9/<br>Not applicable/<br>01-2120764691-48-XXXX | < 0.0014 %    | Acute Tox. 2, H330; Acute Tox. 2; H310, Acute Tox. 3, H301; Skin Corr. 1C, H314; Eye Dam 1, H318; Skin Sens. 1A, H317; Aquatic Acute 1, H400; Aquatic Chronic 1, H410; EUH071<br><b>SCL and/or M-factor:</b><br>Skin Corr. 1C; H314: C ≥ 0.6%; Skin Irrit. 2; H315: 0.06% ≤ C < 0.6%; Eye Dam 1, H318; C ≥ 0.6%; Eye Irrit. 2; H319: 0.06% ≤ C < 0.6%; Skin Sens. 1A; H317: C ≥ 0.0015% M-factor=100 |

Streptavidin-conjugated Peroxidase in stabilized solution.

| <b>HAZARDOUS INGREDIENTS:<br/>Enzyme Conjugate Streptavidin-<br/>Peroxidase Conjugate, 300 µl</b>  | <b>CAS No./<br/>EC No./<br/>Registration No.</b>        | <b>Amount</b> | <b>Hazard Classification;<br/>Hazard Statements<br/>According to Regulation (EC) No 1278/2008 (CLP)</b>  |
|--|---|---------------|--|
| reaction mass of CMIT/MIT:<br>5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2- methyl-2H -isothiazol-3-one [EC no. 220-239-6] (CMIT/MIT = 3:1) | 55965-84-9/<br>Not applicable/<br>01-2120764691-48-XXXX | < 0.0014 %    | Acute Tox. 2, H330; Acute Tox. 2; H310, Acute Tox. 3, H301; Skin Corr. 1C, H314; Eye Dam 1, H318; Skin Sens. 1A, H317; Aquatic Acute 1, H400; Aquatic Chronic 1, H410; EUH071<br><b>SCL and/or M-factor:</b><br>Skin Corr. 1C; H314: C ≥ 0.6%; Skin Irrit. 2; H315: 0.06% ≤ C < 0.6%; Eye Dam 1, H318; C ≥ 0.6%; Eye Irrit. 2; H319: 0.06% ≤ C < 0.6%; Skin Sens. 1A; H317: C ≥ 0.0015% M-factor=100 |

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TRIS-based buffer with Tween and 350 mM NaCl 10x stock solution.

| HAZARDOUS INGREDIENTS:<br>Washing Buffer (10x concentrate;<br>100 mL)   | CAS No./<br>EC No./<br>Registration<br>No.                      | Amount     | Hazard Classification;<br>Hazard Statements<br>According to Regulation (EC) No<br>1278/2008 (CLP)   |
|---|---|------------|---|
| TRIS  | 77-86-1/ 201-064-4/ 01-2119957659-16- XXXX                      | < 2 %      | Skin irrit. 2, H315, Eye irrit. 2, H319   |
| reaction mass of CMIT/MIT:<br>5-chloro-2-methyl-4-isothiazolin-3-one [EC<br>no. 247-500-7] and 2- methyl-2H -isothiazol-<br>3-one [EC no. 220-239-6] (CMIT/MIT = 3:1) | 55965-84-9/<br>Not applicable/<br>01-<br>2120764691-<br>48-XXXX | < 0.0014 % | Acute Tox. 2, H330; Acute Tox. 2;<br>H310, Acute Tox. 3, H301; Skin Corr.<br>1C, H314; Eye Dam 1, H318; Skin<br>Sens. 1A, H317; Aquatic Acute 1,<br>H400; Aquatic Chronic 1, H410;<br>EUH071<br><b>SCL and/or M-factor:</b><br>Skin Corr. 1C; H314: C ≥ 0.6%; Skin<br>Irrit. 2; H315: 0.06% ≤ C < 0.6%; Eye<br>Dam 1, H318; C ≥ 0.6%; Eye Irrit. 2;<br>H319: 0.06% ≤ C < 0.6%; Skin Sens.<br>1A; H317: C ≥ 0.0015% M-factor=100 |

TRIS-based buffer with Tween and 350 mM NaCl 10x stock solution.

| HAZARDOUS INGREDIENTS:<br>Assay Buffer (10x concentrate; 100 mL)  | CAS No./<br>EC No./<br>Registration<br>No.                      | Amount     | Hazard Classification;<br>Hazard Statements<br>According to Regulation (EC) No<br>1278/2008 (CLP)   |
|---|---|------------|---|
| TRIS  | 77-86-1/ 201-064-4/ 01-2119957659-16- XXXX                      | < 2 %      | Skin irrit. 2, H315, Eye irrit. 2, H319   |
| reaction mass of CMIT/MIT:<br>5-chloro-2-methyl-4-isothiazolin-3-one [EC<br>no. 247-500-7] and 2- methyl-2H -isothiazol-<br>3-one [EC no. 220-239-6] (CMIT/MIT = 3:1) | 55965-84-9/<br>Not applicable/<br>01-<br>2120764691-<br>48-XXXX | < 0.0014 % | Acute Tox. 2, H330; Acute Tox. 2;<br>H310, Acute Tox. 3, H301; Skin Corr.<br>1C, H314; Eye Dam 1, H318; Skin<br>Sens. 1A, H317; Aquatic Acute 1,<br>H400; Aquatic Chronic 1, H410;<br>EUH071<br><b>SCL and/or M-factor:</b><br>Skin Corr. 1C; H314: C ≥ 0.6%; Skin<br>Irrit. 2; H315: 0.06% ≤ C < 0.6%; Eye<br>Dam 1, H318; C ≥ 0.6%; Eye Irrit. 2;<br>H319: 0.06% ≤ C < 0.6%; Skin Sens.<br>1A; H317: C ≥ 0.0015% M-factor=100 |


TMB One substrate solution, ready-to-use solution

| HAZARDOUS INGREDIENTS: TMB One<br>SUBSTRATE SOLUTION, 20 mL | CAS No./<br>EC No./<br>Registration<br>No.   | Amount | Hazard Classification;<br>Hazard Statements<br>According to Regulation (EC) No<br>1278/2008 (CLP) |
|---|--|--------|---|
| TMB<br>3,3',5,5'-Tetramethylbenzidine                       | 548227-17-7/<br>259-364-6/ Not<br>applicable | <0,02% | The concentration is low, and does<br>not affect the classification of the<br>mixture             |

Stop solution with 0.5 M sulfuric acid

| HAZARDOUS INGREDIENTS: STOP<br>SOLUTION, 20 mL | CAS No./<br>EC No./<br>Registration<br>No. | Amount | Hazard Classification;<br>Hazard Statements<br>According to Regulation (EC) No<br>1278/2008 (CLP)                  |
|--|--|--------|--|
| Sulfuric Acid                                  | 7664-93-9/<br>231-639-5<br>Not applicable  | < 5%   | Severe skin burns and eye damage<br>(Skin Corr. 1A) - H314;<br>May be corrosive to metals<br>(Met. Corr. 1) - H290 |

|   |   |
|---|---|
| Each of the other components is present in less than 1 percent concentration (0.1% concentration for potential carcinogens, reproductive toxins, respiratory tract sensitizers, and mutagens) | Hazard Classification: Not Classified<br>Hazard Phrases: None |
|---|---|

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## 4 FIRST-AID MEASURES

### 4.1 Description of first aid measures

#### General information:

Contaminated individuals of chemical exposure must be taken for medical attention if any adverse effect occurs. Rescuers should be taken for medical attention, if necessary. Take copy of label and EU-SDS to health professional with contaminated individual.

#### Following inhalation:

Not a normal route of entry, however if chemical is inhaled, or breathing is difficult, remove victim to fresh air. If necessary, use artificial respiration to support vital functions. Seek medical attention.

#### Following skin contact:

Wash contacted area with soap and water. Remove exposed or contaminated clothing, taking care not to contaminate eyes. Seek medical attention if irritation develops and persists.

#### Following eye contact:

After contact with the eyes, rinse with water with the eyelids open for a sufficient length of time, then consult an ophthalmologist immediately.

#### Following ingestion:

If accidentally swallowed rinse the mouth with plenty of water (only if the person is conscious) and obtain immediate medical attention.

### 4.2 Most important symptoms and effects, both acute and delayed symptoms and effects:

No further relevant information available.

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

No further relevant information available.

## 5 FIRE-FIGHTING MEASURES

### 5.1 Extinguishing media

Suitable extinguishing media: Carbon dioxide (CO<sub>2</sub>), foam, water, extinguishing powder.

### 5.2 Special hazards arising from the substance or mixture Hazardous combustion products:

None.

### 5.3 Advice for fire-fighters

Co-ordinate fire-fighting measures to the fire surroundings.

## 6 ACCIDENTAL RELEASE MEASURES

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


For non-emergency personnel: Use personal protective equipment, see Section 8. For emergency responders: Use personal protective equipment, see Section 8.

### 6.2 Environmental precautions

Do not allow to enter into surface water or drains. Do not allow to enter into soil/subsoil.

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

Clear contaminated areas thoroughly.

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## 7 HANDLING AND STORAGE

### 7.1 Precautions for safe handling

#### Protective measures:

Use in well-ventilated areas. Handle and open container with care. Always close containers tightly after the removal of product. Wear personal protective clothing (see Section 8).

#### Measures to prevent fire:

This product is not flammable. No special fire protection measures are necessary.

#### Advice on general occupational hygiene:

Avoid contact with skin, eyes and clothes. Provide eye shower and label its location conspicuously. Wash hands before breaks and after work. When using do not eat, drink, smoke, sniff. Remove contaminated, saturated clothing immediately. Wash contaminated clothing prior to re-use.

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

In well-ventilated premises. an at a temperature range of 2°-8°C.

## 8 EXPOSURE CONTROLS – PERSONAL PROTECTION

### 8.1 Control parameters

Does not contain substances above concentration limits fixing an occupational exposure limit.

### 8.2 Exposure controls

#### Personal Protection

**General protective and hygienic measures:** Keep away from foodstuffs, beverages and feed. Wash hands before breaks and at the end of work. Change contaminated clothing.


**Eye/face protection:** Safety glasses

**Skin protection:** Full contact: Glove material: Nitrile rubber Glove thickness: 0.11 mm Break through time: > 480 min Splash contact: Glove material: Nitrile rubber Glove thickness: 0.11 mm Break through time: > 480 min The protective gloves to be used must comply with the specifications of EC Directive 89/686/EEC and the related standard EN374. This recommendation applies only to the product stated in this safety data sheet and for the designated use. When dissolving in or mixing with other substances and under conditions deviating from those stated in EN374 please contact the supplier of CE-approved gloves.

## 9 PHYSICAL and CHEMICAL PROPERTIES

### 9.1 Information on basic physical and chemical properties

- (a) Appearance: (see description of components)
- (b) Odour: Odourless
- (c) Odour threshold: Does not apply, as substance is odourless
- (d) pH: (see description of components)
- (e) Melting point / freezing point: No data available
- (f) Initial boiling point and boiling range: No data available
- (g) Flash point: No data available
- (h) Evaporation rate: No data available
- (i) Flammability (solid, gas): Does not apply
- (j) Upper/lower flammability or explosive limits: Does not apply, mixture is not flammable
- (k) Vapour pressure: No data available
- (l) Vapour density: No data available
- (m) Relative density: No data available
- (n) Solubility(ies): Does not apply
- (o) Partition coefficient: n-octanol/water: No data available

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- (p) Auto-ignition temperature: No data available
- (q) Decomposition temperature: No data available
- (r) Viscosity: No data available
- (s) Explosive properties: Does not apply, mixture is not explosive
- (t) Oxidising properties: None

## 10 STABILITY AND REACTIVITY

### 10.1 Reactivity

No specific test data related to reactivity available for this product or its ingredients.

### 10.2 Chemical stability

Stable under recommended storage conditions.

### 10.3 Possibility of hazardous reactions

No hazardous reaction when handled and stored according to provisions.

### 10.4 Conditions to avoid

No specific conditions to avoid.

### 10.5 Incompatible materials

No data available.

### 10.6 Hazardous decomposition products

Does not decompose when used for intended uses.

## 11 TOXICOLOGICAL INFORMATION

### 11.1 Information on toxicological effects

**Acute toxicity:**

No toxicological data available

**Skin corrosion/irritation:**

Conclusive but not sufficient for classification

**Serious eye damage/irritation:**

Conclusive but not sufficient for classification

**Respiratory or skin sensitisation:**

Conclusive but not sufficient for classification

**Germ cell mutagenicity:**

Conclusive but not sufficient for classification

**Carcinogenicity:**

Conclusive but not sufficient for classification

**Reproductive toxicity:**

Conclusive but not sufficient for classification

**Specific target organ toxicity (single exposure):**


Conclusive but not sufficient for classification

**Specific target organ toxicity (repeated exposure):**

Conclusive but not sufficient for classification

**Aspiration hazard:**

There are no data available for the ingredients.

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## 12 ECOLOGICAL INFORMATION

### 12.1 Toxicity

There are no data available for the ingredients.

### 12.2 Persistence and degradability

There are no data available for the ingredients.

### 12.3 Bioaccumulative potential

There are no data available for the ingredients.

### 12.4 Mobility in soil

There are no data available for the ingredients.

### 12.5 Results of PBT and vPvB assessment

This mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

### 12.6 Other adverse effects

There are no data available for the ingredients.

## 13 DISPOSAL CONSIDERATIONS

### 13.1 Waste treatment methods

Waste material must be disposed of in accordance with the Directive on waste 2008/98/EC as well as other national and local regulations.

**Product / Packaging disposal:** Handle uncleaned containers like the product itself.

## 14 TRANSPORTATION INFORMATION

### 14.1 UN number (ADR, RID, ADN, IMDG, IATA)

Not applicable.

### 14.2 UN proper shipping name (ADR, RID, ADN, IMDG, IATA)

Not applicable.

### 14.3 Transport hazard class(es) (ADR, RID, ADN, IMDG, IATA)

Not applicable.

### 14.4 Packing group (ADR, RID, ADN, IMDG, IATA)

Not applicable.

### 14.5 Environmental hazards


None.

### 14.6 Special precautions for user

Not applicable.

### 14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code

Not applicable.

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## 15 REGULATORY INFORMATION

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

#### Authorisations and/or restrictions on use:

No data available.

### 15.2 Chemical Safety Assessment

For this mixture a chemical safety assessment has not been carried out.

## 16 OTHER INFORMATION

All chemicals may pose unknown hazards and should be used with cautions. If this product is combined with other materials, deteriorates, or becomes contaminated, it may pose hazards not mentioned in this SDS. It shall be the user's responsibility to develop proper methods of handling and personal protection based on the actual conditions of use. The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide for experienced personnel. BioGenes GmbH assumes no responsibility for the completeness or accuracy of the information contained herein. Users should consider these data only as a supplement to other information gathered by them and must make independent determinations of suitability and completeness of information from all sources to assure proper use and disposal of these materials and the safety and health of employees and customers and protection of the environment.

#### Abbreviations and acronyms:

ADN: European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways

ADR: European Agreement concerning the International Carriage of Dangerous Goods by Road

CAS No: Chemical Abstracts Service number

CLP: Classification Labelling and Packaging Regulation

EC: European Commission

EC No: European Chemical number: EINECS, ELINCS or NLP

EEC: European Economic Community

EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

EU: European Union

IATA: International Air Transport Association

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

IMDG: International Maritime Dangerous Goods

LD50: Lethal dose, 50%

MARPOL: Marine Pollution

NLP: No-longer Polymers

RID: Regulations concerning the International Carriage of Dangerous Goods by Rail

SCL: Specific Concentration Limit

UN: United Nations

VwVwS: Verwaltungsvorschrift wassergefährdende Stoffe (Regulation for water hazardous substances, German regulation)

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

**End of EU SDS Sheet**