	EU – Material Safety Data Sheet	Acc. to Directive 1907/2006/EU
	Generic E.coli HCP ELISA kit	Version: 01 Issued at: 29/09/15

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 (competent person):	service@biogenes.de
1.4 Emergency telephone number:	+49-30-19 24 0

2 HAZARD IDENTIFICATION

2.1 EMERGENCY OVERVIEW

Product Description: This kit contains 8 components making up the E.coli 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 a Coated Plate and the following mixtures: Conjugate, Buffer, Detector Antibody, Standards, Stop Solution, TMB Substrate, and Wash Concentrate.

Health Hazards: Possible skin and eye irritant.

Flammability Hazards: Non-flammable solution.

Reactivity Hazards: None known.

Environmental Hazards: Not expected to have significant environmental effects.

Emergency Considerations: Emergency responders must wear the proper personal protective equipment (and have appropriate fire-suppression equipment) suitable for the situation to which they are responding.

2.2 EU LABELING AND CLASSIFICATION:

EU DANGEROUS PREPARATIONS DIRECTIVE (DPD) LABELING AND CLASSIFICATION:

This product does not meet the definition of any hazard class, as defined by the European Union Council Directives 67/548/EEC and 1999/445/EC and subsequent Directives.

EU CLASSIFICATION:

Classification: [Xi] Irritant, [Xn] Harmful

Hazard Phrases:

H302 Harmful if swallowed.

H314 Causes severe skin burns and eye damage.

H317 May cause an allergic skin reaction.

H319 cause serious eye irritation

H332 Harmful if inhaled.

H335 May cause respiratory irritation

H410 Very toxic to aquatic life with long lasting effects

Precaution Phrases:


P273 Avoid release to the environment.

P280 Wear protective gloves/ protective clothing/ eye protection/ face protection

P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P310 Immediately call a POISON CENTER or doctor/ physician.

P501 Dispose of contents/ container to an approved waste disposal plant

	EU – Material Safety Data Sheet	Acc. to Directive 1907/2006/EU
	Generic E.coli HCP ELISA kit	Version: 01 Issued at: 29/09/15

Hazard Symbol according to EC No. 1272/2008



HEALTH HAZARDS OR RISKS FROM EXPOSURE:

Acute Prolonged contact with the components in this kit may irritate the skin. Contact with eyes may cause irritation or redness. This product is to be used in a laboratory environment. Individuals using this product should be wearing the proper personal protective equipment to prevent skin and eye contact.

Chronic None known


3 COMPOSITION AND INFORMATION ON INGREDIENTS

3.1 SUBSTANCE


This substance is a mixture.

3.2 MIXTURE

HAZARDOUS INGREDIENTS: PLATE: ANTI-E.COLI COATED MICROTITER PLATE	CAS#	EINECS#	ICSC#	Amount	Hazard Classification; Hazard Phrases
Affinity Purified Goat Antibody to E.COLI HCP	Not Listed	Not Listed	Not Established	<100 µg	Not Classified None
HAZARDOUS INGREDIENTS: STANDARDS: E.COLI HCP STANDARDS, 0.1 mL	CAS#	EINECS #	ICSC#	Amount	Hazard Classification; Hazard Phrases
Distilled Water	7732-18-5	231-791-2	Not Listed	>97%	Not Classified None
Tris Hydrochloride	1185-53-1	214-684-5	Not Listed	<1.0%	Not Classified None
Sodium Chloride	7647-14-5	231-598-3	Not Listed	<1.0%	Not Classified None
Bovine Serum Albumine	Not Listed	Not Listed	Not Listed	<1.0%	Not Classified None
Triton X-100	9002-93-1	Not Listed	Not Listed	<1.0%	Irritant, Harmful Hazard Phrases: H302, H319 Precaution Phrases: P273, P280, P305 + P351 + P338,
ProCline 300 Preservative	55965-84-9	Not Listed	613-167-00-5	<0.1%	Irritant Hazard Phrases: H302, H314, H317, H332; H410 Precaution Phrases: P273, P280, P305 + P351 + P338, P310, P501


	EU – Material Safety Data Sheet	Acc. to Directive 1907/2006/EU
	Generic E.coli HCP ELISA kit	Version: 01 Issued at: 29/09/15

HAZARDOUS INGREDIENTS: DETECTOR-ANTIBODY: anti-E.COLI-HCP-Biotin, 0.3 mL	CAS#	EINECS #	ICSC#	Amount	Hazard Classification; Hazard Phrases
Distilled Water	7732-18-5	231-791-2	Not Listed	>95%	Not Classified None
Tris Hydrochloride	1185-53-1	214-684-5	Not Listed	<5.0%	Not Classified None
Sodium Chloride	7647-14-5	231-598-3	Not Listed	<1.0%	Not Classified None
Biotin	58-85-5	200-399-3	Not Listed	<0.1%	Not Classified None
ProClin® 300 Preservative	55965-84-9	Not Listed	613-167-00-5	<0.1%	Irritant Hazard Phrases: H302, H314, H317, H332; H410 Precaution Phrases: P273, P280, P305 + P351 + P338, P310, P501
HAZARDOUS INGREDIENTS: ENZYME CONJUGATE, STREPTAVIDIN- PEROXIDASE conjugate, 0.3 mL	CAS#	EINECS #	ICSC#	Amount	Hazard Classification; Hazard Phrases
Distilled Water	7732-18-5	231-791-2	Not Listed	>95%	Not Classified None
Tris Hydrochloride	1185-53-1	214-684-5	Not Listed	<5.0%	Not Classified None
Streptavidin-Peroxidase	Not Listed	Not Listed	Not Listed	<1.0%	Not Classified None
Sodium Chloride	7647-14-5	231-598-3	Not Listed	<1.0%	Not Classified None
ProClin® 300 Preservative	55965-84-9	Not Listed	613-167-00-5	<0.1%	Irritant Hazard Phrases: H302, H314, H317, H332; H410 Precaution Phrases: P273, P280, P305 + P351 + P338, P310, P501
HAZARDOUS INGREDIENTS: WASH BUFFER (10x CONCENTRATE), 100 mL	CAS#	EINECS#	ICSC#	Amount	Hazard Classification; Hazard Phrases
Distilled Water	7732-18-5	231-791-2	Not Listed	>85%	Not Classified None
Tris Hydrochloride	1185-53-1	214-684-5	Not Listed	6-8%	Not Classified None
Sodium Chloride	7647-14-5	231-598-3	Not Listed	7-9%	Not Classified Hazard Phrases: None
Triton X-100	9002-93-1	Not Listed	Not Listed	<1.0%	Irritant, Harmful Hazard Phrases: H302, H319 Precaution Phrases: P273, P280, P305 + P351 + P338,
Phenol Red	143-74-8	205-609-7	Not Listed	<0.1%	Irritant Hazard Phrases: H315 H319, H335 Precaution Phrases: P305 + P351 + P338

	EU – Material Safety Data Sheet		Acc. to Directive 1907/2006/EU		
	Generic E.coli HCP ELISA kit		Version: 01 Issued at: 29/09/15		

ProClin® 300 Preservative	55965-84-9	Not Listed	613-167-00-5	<0.1%	Irritant Hazard Phrases: H302, H314, H317, H332; H410 Precaution Phrases: P273, P280, P305 + P351 + P338, P310, P501
HAZARDOUS INGREDIENTS: TMB One SUBSTRATE SOLUTION, 20 mL	CAS#	EINECS #	ICSC#	Amount	Hazard Classification; Hazard Phrases
Distilled Water	7732-18-5	231-791-2	Not Listed	>95%	Not Classified None
TMB	54827-17-7	259-364-6	Not Listed	<0,02%	The concentration is low, and does not affect the classification of the mixture
HAZARDOUS INGREDIENTS: ASSAY BUFFER, 100 mL	CAS#	EINECS #	ICSC#	Amount	Hazard Classification; Hazard Phrases
Distilled Water	7732-18-5	231-791-2	Not Listed	>85%	Not Classified None
Sodium Chloride	7647-14-5	231-598-3	Not Listed	7-9%	Not Classified None
Tris Hydrochloride	1185-53-1	214-684-5	Not Listed	6-8%	Not Classified None
Bovine Serum Albumine	9048-46-8	232-936-2	Not Listed	<1.0%	Not Classified None
Triton X-100	9002-93-1	Not Listed	Not Listed	<1.0%	Irritant, Harmful Hazard Phrases: H319, H302 Precaution Phrases: P273, P280, P305 + P351 + P338
ProClin® 300 Preservative	55965-84-9	Not Listed	613-167-00-5	<0.1%	Irritant Hazard Phrases: H302, H314, H317, H332; H410 Precaution Phrases: P273, P280, P305 + P351 + P338, P310, P501
HAZARDOUS INGREDIENTS: STOP SOLUTION, 20 mL	CAS#	EINECS #	ICSC#	Amount	Hazard Classification; Hazard Phrases
Distilled Water	7732-18-5	231-791-2	Not Listed	>95%	Not Classified None
Sulfuric Acid	7664-93-9	Not Listed	Not Listed	<5.0%	Highly corrosive Hazard Phrases: H314 Precaution Phrases: P280-P305, P351, P338
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 Hazard Phrases: None		
ProClin is a registered trademark of Rohm and Hass Company.					

Note: ALL WHMIS required information is included in appropriate sections based on the ANSI Z400.1-2004 format. This product has been classified in accordance with the hazard criteria of the CPR and the MSDS contains all the information required by the CPR and EU Directives. See Section 2 for full text of Ingredient Hazard and Precaution Phrases

	EU – Material Safety Data Sheet	Acc. to Directive 1907/2006/EU
	Generic E.coli HCP ELISA kit	Version: 01 Issued at: 29/09/15

4 FIRST-AID MEASURES

4.1 DISCRIPTION OF FIRST-AID MEASURES

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 MSDS to health professional with contaminated individual.

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.

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.

EYE CONTACT: If chemical contacts the eyes, open victim's eyes while under gentle running water. Use sufficient force to open eyelids. Have victim "roll" eyes. Minimum flushing is for 15 minutes. Remove contact lenses, if worn. Seek medical attention if irritation persists.

INGESTION: If chemical is swallowed, call physician or poison control center for most current information. If professional advice is not available, do not induce vomiting. Never induce vomiting or give diluents (milk or water) to someone who is unconscious, have convulsions, or who cannot swallow. Victims of chemical exposure must be taken for medical attention. Rescuers should be taken for medical attention, if necessary. Take a copy of the label and MSDS with the victim to the health professional.

4.2 MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE

None known

4.3 RECOMMENDATIONS TO PHYSICIANS

Treat symptoms and eliminate overexposure.

5 FIRE-FIGHTING MEASURES

5.1 FIRE EXTINGUISHING MATERIALS

Use extinguishing media appropriate for surrounding fire.

5.2 UNUSUAL FIRE AND EXPLOSION HAZARDS

The product is a water-based mixture with no known fire or explosion hazards.

5.3 SPECIAL FIRE-FIGHTING PROCEDURES

Incipient fire responders should wear eye protection. Structural firefighters must wear Self-Contained Breathing Apparatus and full protective equipment. Isolate materials not yet involved in the fire and protect personnel. Move containers from fire area if this can be done without risk; otherwise, cool with carefully applied water spray. If possible, prevent runoff water from entering storm drains, bodies of water, or other environmentally sensitive areas.

5.4 ADDITIONAL INFORMATIONS


FLASH POINT: Non-flammable

AUTOIGNITION TEMPERATURE: Not applicable

FLAMMABLE LIMITS (in air by volume, %): Lower N/A Upper N/A

EXPLOSION SENSITIVITY TO MECHANICAL IMPACT: Not sensitive

EXPLOSION SENSITIVITY TO STATIC DISCHARGE: Not sensitive

	EU – Material Safety Data Sheet	Acc. to Directive 1907/2006/EU
	Generic E.coli HCP ELISA kit	Version: 01 Issued at: 29/09/15

6 ACCIDENTAL RELEASE MEASURES

6.1 PERSONAL PRECAUTIONS, PROTECTIVE EQUIPMENT AND EMERGENCY PROCEDURE

SPILL AND LEAK RESPONSE: Proper protective equipment should be used. Personnel should be trained for spill response operations.

Spills: Trained personnel following pre-planned procedures should handle non-incident releases.

6.2 ENVIRONMENTAL PRECAUTION

Avoid release to the environment

6.3 METHODS AND MATERIAL FOR CONTAINMENT AND CLEANING UP

Absorb spilled material using polypads or other suitable absorbent material. Place all spill residue in an appropriate container and seal. Decontaminate the area thoroughly. Do not mix with wastes from other materials. Dispose of in accordance with applicable Federal, State, and local procedures (see Section 13, Disposal Considerations.)

7 HANDLING AND STORAGE

7.1 WORK PRACTICES AND HYGIENE PRACTICES: As with all chemicals, avoid getting this product ON YOU or IN YOU. Wash thoroughly after handling this product. Do not eat, drink, smoke, or apply cosmetics while handling this product. Avoid breathing mists or sprays generated by this product. Use in a well-ventilated location. Remove contaminated clothing immediately.

7.2 STORAGE AND HANDLING PRACTICES: Store product in properly labeled, closed containers at temperatures between 2-8°C. Protect from physical damage. Keep containers closed when not in use.

8 EXPOSURE CONTROLS – PERSONAL PROTECTION

VENTILATION AND ENGINEERING CONTROLS: Use with adequate ventilation to ensure exposure levels are maintained below the established limits.

Currently, International exposure limits are not established for all the components of this product. Please check with competent authority in each country for the most recent limits in place.


The following information on appropriate Personal Protective Equipment is provided to assist employers in complying with OSHA regulations found in 29 CFR Subpart I (beginning at 1910.132) or equivalent standard of Canada, or standards of EU member states (including EN 149 for respiratory PPE, and EN 166 for face/eye protection,) and those of Japan. Please reference applicable regulations and standards for relevant details.

RESPIRATORY PROTECTION: If exposure limits are exceeded, use only respiratory protection authorized in the U.S. Federal OSHA Respiratory Protection Standard (29 CFR 1910.134,) equivalent U.S. State standards, Canadian CSA Standard Z94.4-93, the European Standard EN149, or EU member states.

EYE PROTECTION: Splash goggles or safety glasses with side shields recommended. If necessary, refer to U.S. OSHA 29 CFR 1910.133, Canadian Standards, and the European Standard EN166, Australian Standards, or relevant Japanese Standards.

HAND PROTECTION: Compatible protective gloves recommended. Wash hands after removing gloves. If necessary, refer to U.S. OSHA 29 CFR 1910.138, the European Standard DIN EN 374, the appropriate Standards of Canada, Australian Standards, or relevant Japanese Standards.

BODY PROTECTION: Use body protection appropriate for task. Coveralls, rubber aprons, or chemical protective clothing made from natural rubber are generally acceptable, depending upon the task. If necessary, refer to appropriate Standards of Canada, or appropriate Standards of the EU, Australian Standards, or relevant Japanese Standards. If a hazard of injury to the feet exists due to falling objects, rolling objects, where objects may pierce the soles of the feet or where employee's feet may be exposed to electrical hazards, use foot protection, as described in U.S. OSHA 29 CFR 1910.136.

	EU – Material Safety Data Sheet	Acc. to Directive 1907/2006/EU
	Generic E.coli HCP ELISA kit	Version: 01 Issued at: 29/09/15

9 PHYSICAL and CHEMICAL PROPERTIES

VAPOR DENSITY: N/A **EVAPORATION RATE (n-BuAc=1):** N/A

SPECIFIC GRAVITY @ 20°C: No Data (water=1) **SOLUBILITY IN WATER:** Soluble

VAPOR PRESSURE: No Data @20°C **pH:** Not Established

APPEARANCE, ODOR and COLOR: This product contains both clear and colored liquids with a varying mild odor.

10 STABILITY AND REACTIVITY

10.1 STABILITY: Stable under ordinary conditions of use and storage.

10.2 DECOMPOSITION PRODUCTS: When stored as labeled, no known hazardous decomposition products are formed during the shelf life of this product.

10.3 MATERIALS WITH WHICH SUBSTANCE IS INCOMPATIBLE: No information available

10.4 HAZARDOUS DEPOLYMERIZATION: Will not occur

10.5 CONDITIONS TO AVOID: Temperatures above or below the recommended range of 2-8°C

11 TOXICOLOGICAL INFORMATION

TOXICITY DATA: No data available

SUSPECTED CANCER AGENT: The components of this product are not listed by agencies tracking the carcinogenic potential of chemical compounds as follows:

Carcinogenity

NTP Regulated – No

IARC Regulated – No

OSHA Regulated – No

IRRITANCY OF PRODUCT: None known

SENSITIZATION TO THE PRODUCT: This product is not known to cause human skin or respiratory sensitization.

REPRODUCTIVE TOXICITY INFORMATION: Listed below is information concerning the effects of this product and its components on the human reproductive system.

Mutagenicity – The components of this product are not reported to produce mutagenic effects in humans.

Embryotoxicity – The components of this product are not reported to produce embryotoxic effects in humans.

Teratogenicity – The components of this product are not reported to produce teratogenic effects in humans.

Reproductive Toxicity – The components of this kit are not reported to produce reproductive effects in humans.

12 ECOLOGICAL INFORMATION


ALL WORK PRACTICES MUST BE AIMED AT ELIMINATING ENVIRONMENTAL CONTAMINATION

ENVIRONMENTAL FATE: No data available

ENVIRONMENTAL TOXICITY: No data available

13 DISPOSAL CONSIDERATIONS

PREPARING WASTES FOR DISPOSAL: Waste disposal must be in accordance with appropriate U.S. Federal, State, and local regulations, those of Canada, Australia, EU Members States and Japan.

	EU – Material Safety Data Sheet	Acc. to Directive 1907/2006/EU
	Generic E.coli HCP ELISA kit	Version: 01 Issued at: 29/09/15

14 TRANSPORTATION INFORMATION

US DOT, IATA, IMO, ADR:

DOT Classification Non-regulated material

DOT Labeling Requirements None

IATA Labeling Requirements None


U.S. DEPARTMENT OF TRANSPORTATION (DOT) SHIPPING REGULATIONS: This product is not classified as dangerous goods, per U.S. DOT regulations, under 49 CFR 172.101.

TRANSPORT CANADA, TRANSPORTATION OF DANGEROUS GOODS REGULATIONS: This product is not classified as Dangerous Goods, per regulations of Transport Canada.

INTERNATIONAL AIR TRANSPORT ASSOCIATION (IATA): This product is not classified as Dangerous Goods, by rules of IATA.

INTERNATIONAL MARITIME ORGANIZATION (IMO) DESIGNATION: This product is not classified as Dangerous Goods by the International Maritime Organization.

EUROPEAN AGREEMENT CONCERNING THE INTERNATIONAL CARRIAGE OF DANGEROUS GOODS BY ROAD (ADR): This product is not classified by the United Nations Economic Commission for Europe to be dangerous goods.

	EU – Material Safety Data Sheet	Acc. to Directive 1907/2006/EU
	Generic E.coli HCP ELISA kit	Version: 01 Issued at: 29/09/15

15 REGULATORY INFORMATION

UNITED STATES REGULATIONS:

SARA REPORTING CAS#111-42-2 Subject to SARA 313 reporting requirements.

REQUIREMENTS

MARINE POLLUTANT This product contains no component listed as a Marine Pollutant under 49 CFR 172.101, Appendix B.

TSCA All components in this product mixture are listed on the USA Toxic Substances Control Act (TSCA) inventory of chemicals or are exempt from listing.

SARA 311/312: Acute health: Yes; Chronic health: No; Fire: No; Reactivity: No

U.S. CERCLA REPORTABLE QUANTITY (RQ): CAS# 111-42-2 100 lbs.

U.S. TSCA INVENTORY STATUS – All of the components of this product are listed in the TSCA Inventory or exempt.

CALIFORNIA SAFE DRINKING WATER AND TOXIC ENFORCEMENT ACT (PROPOSITION 65):

This product does not contain any component above the 0.1% level which is listed as a California Proposition 65 chemical. Note the chemical identity of some or all components present is confidential business information (trade secret) and is being withheld as permitted by 29CFR1910.1200 (i).

CANADIAN REGULATIONS:

CANADIAN DSL/NDL INVENTORY STATUS: All of the components of this product are on the DSL Inventory or exempt.

CANADIAN ENVIRONMENTAL PROTECTION ACT (CEPA) PRIORITIES SUBSTANCES LISTS: No component of this product is on the CEPA First Priorities Substance Lists.

CANADIAN WHMIS CLASSIFICATION and SYMBOLS: Not regulated

EUROPEAN ECONOMIC COMMUNITY INFORMATION:

EU DANGEROUS PREPARATIONS DIRECTIVE (DPD) LABELING AND CLASSIFICATION: This product does not meet the definition of any hazard class, as defined by the European Union Council Directives 67/548/EEC and 1999/445/EC and subsequent Directives. For information on classification under CLP Regulation (EC) 1271/2008, please refer to section 16 (Other Information.)

Classification – [Xi] Irritant Risk Phrases –R36/38: Irritating to eyes and skin.

Safety Phrases – S26: In case of contact with eyes, rinse immediately with plenty of water and seek medical advice

AUSTRALIAN INFORMATION FOR PRODUCT:

AUSTRALIAN INVENTORY OF CHEMICAL SUBSTANCES (AICS) STATUS: All components of this product are listed on the AICS or exempt.

STANDARD FOR THE UNIFORM SCHEDULING OF DRUGS AND POISONS: Not applicable

JAPANESE INFORMATION FOR PRODUCT:

JAPANESE MINISTER OF INTERNATIONAL TRADE AND INDUSTRY (MITI) STATUS: The components of this product are not listed as Class I Specified Chemical Substances, Class II Specified Chemical Substances, or Designated Chemical Substances by the Japanese MITI.

INTERNATIONAL CHEMICAL INVENTORIES:

Listing of the components on individual country Chemical Inventories is as follows:

Asia-Pac – Listed or exempt

Australian Inventory of Chemical Substances (AICS) – Listed or exempt

Korean Existing Chemicals List (ECL) – Listed or exempt

Japanese Existing National Inventory of Chemical Substances (ENCS) – Listed or exempt

Philippines Inventory of Chemicals and Chemicals Substances (PICCS) – Listed or exempt

Swiss Giftliste List of Toxic Substances - Listed or exempt

U.S. TSCA - Listed or exempt