

MATERIAL SAFETY DATA SHEET

according to Regulation (EC) No 1907/2006 (REACH),
amended by (EU) 2015/830

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Section 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE

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Product Name: BPI (non recombinant)
Catalog Number: 19200/19201/19205
Relevant identified uses: For research use or IVD manufacturing only.
Emergency telephone number: Poison Control Center Freiburg, Germany
Tel. +49 761 19240 (24 hours)

Section 2: HAZARDS IDENTIFICATION

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Classification: This substance does not need to be classified according to regulation (EC) No. 1272/2008.

Label: This product does not need to be labeled in accordance with EC directives or respective national laws.

Other hazards: This product contains protein of human origin. Each donor has been tested and found to be non-reactive to HBs antigen and HIV-p24 antigen as well as negative for anti-HBc, anti-HIV1/2 and, anti-HCV and anti-*Treponema pallidum*. Additionally, samples were tested negative for HIV-1-RNA, HCV-RNA, HBV-DNA, HAV-RNA, Parvovirus-B19-DNA. However, no known test can offer complete assurance that the viruses/infectious agents that cause a disease are not present. Proper precautions and biological containment should be taken when handling materials of human origin, due to their potential biohazardous nature.

Section 3: COMPOSITION/INFORMATION ON INGREDIENTS

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General information: Aqueous solution of non recombinant human Bactericidal/permeability-increasing protein (BPI).

REACH registration number: No registration number is given yet for this mixture since the annual import quantity is less than one tonnage per annum or the transition period for its registration according to Article 23 of REACH has not yet expired.

Ingredients: This product is a mixture of substances. According to regulation (EC) No. 1272/2008, mixtures with hazardous and carcinogenic ingredients with a concentration of less than 1% and 0.1%, respectively, are not considered "relevant ingredients". Hazardous and carcinogenic ingredients that exceed these criteria are listed below.

Section 3: COMPOSITION/INFORMATION ON INGREDIENTS (continued) *

Ingredient	CAS No.	EC No.	Concentration
N/A	N/A	N/A	N/A

Section 4: FIRST AID MEASURES *

General information:	Consult a physician and show this safety data sheet.
Inhalation:	Remove to fresh air and monitor breathing. Consult a physician.
Skin contact:	Wash skin immediately with soap and copious amounts of water. Remove contaminated clothing and shoes and wash before wearing. Consult a physician.
Eye contact:	Flush eyes immediately with copious amounts of water for at least 15 minutes. Assure adequate flushing by separating eyelids with fingers. Consult a physician.
Ingestion:	If the person is conscious, wash out mouth with water. Consult a physician.
First aider:	Wear suitable protective clothing, such as chemical resistant gloves and chemical safety goggles. Use a NIOSH/MSHA approved respirator. Handle in laboratory with adequate ventilation.
Most important symptoms and effects:	May be harmful by inhalation, ingestion or skin absorption. May cause irritation. Prolonged or repeated contact may cause adverse effects in certain sensitive individuals. Toxicological properties have not been thoroughly investigated.

Section 5: FIREFIGHTING MEASURES

Extinguishing media:	Use extinguishing media appropriate to surrounding fire conditions (dry chemical powder, carbon dioxide or water spray recommended).
Hazardous Combustion or Decomposition Products:	Nature of decomposition products not known.
Advice for firefighters:	Wear self-contained breathing apparatus and full protective clothing to prevent contact with skin and eyes.

Section 6: ACCIDENTAL RELEASE MEASURES

For non-emergency personnel:	Evacuate area. Wear suitable protective clothing, such as chemical resistant gloves and chemical safety goggles. Use a NIOSH/MSHA approved respirator. Handle in laboratory with adequate ventilation.
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Section 6: ACCIDENTAL RELEASE MEASURES (continued)

For emergency responders:	Wear suitable protective clothing, such as chemical resistant gloves and chemical safety goggles. Use a NIOSH/MSHA approved respirator. Handle in laboratory with adequate ventilation.
Environmental precautions:	Do not let product enter drains.
Containment:	Place in a suitable, closed bag/container. Avoid raising dust. Hold for appropriate waste disposal.
Cleaning up:	Sweep up, avoid raising dust. Ventilate area and wash spill site after material pickup is complete.

Section 7: HANDLING AND STORAGE

Handling:	Avoid all unnecessary exposure. Keep container closed and open only as necessary. Wear protective equipment and follow general precautionary procedures applying to working in a laboratory/industrial environment (e.g. wash hands after handling). Follow general rules/regulations of laboratory waste disposal.
Storage:	Store at or below -70°C.

Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

Engineering controls:	Handle in laboratory with adequate ventilation.
Personal protection equipment	
Eye and face protection:	Wear chemical safety goggles according to appropriate standards such as EN 166 (EU) NIOSH or (US).
Skin protection:	Wear chemical resistant gloves, which meet the specifications of directive 89/686/EEC. Wear suitable protective clothing according to the planned work and specific work-place.
Respiratory protection:	Use a CEN (EU) or NIOSH/MSHA (US) approved respirator.
Environmental exposure controls:	Do not let product enter drains.

Section 9: PHYSICAL AND CHEMICAL PROPERTIES

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General information:	The physical, chemical and toxicological characteristics of the mixture have not been thoroughly investigated.
Appearance:	Clear solution
Physical State:	Liquid

Section 10: STABILITY AND REACTIVITY

Chemical stability:	Stable under recommended storage conditions.
Hazardous decomposition products:	Nature of decomposition products not known.
Hazardous polymerization:	Mixture will not form hazardous polymers.

Section 11: TOXICOLOGICAL INFORMATION

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General information:	<p>The physical, chemical and toxicological characteristics of the mixture have not been thoroughly investigated.</p> <p>Only those hazardous and carcinogenic ingredients of the mixture are listed, which are present in a concentration of at least 1% and 0.1%, respectively.</p> <p>Test data are only available for individual ingredients if not indicated otherwise.</p>
Mixture	
Chronic exposure:	Prolonged or repeated exposure to the mixture may cause adverse effects in certain sensitive individuals.
Carcinogenicity:	No component or substance of this product at levels greater or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

Section 12: ECOLOGICAL INFORMATION

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General information:	The ecological hazard characteristics of the mixture have not been thoroughly investigated.
Aquatic toxicity:	No information available

Section 13: DISPOSAL CONSIDERATIONS

Product/packaging disposal:	Due to the biological nature of this product and as good laboratory practice, we recommend that its disposal includes a biological inactivation step (e.g. by autoclaving, incineration, etc.), even though the biohazard properties of the product do not make such a step mandatory.
Sewage disposal-relevant information:	Waste should not be disposed of by release to sewer.
Other disposal recommendations:	Country, federal, state and local regulations concerning disposal vary and change frequently. It remains the responsibility of the waste treatment operator to comply with these regulations. For this reason, we recommend that you contact your authorities for

Section 13: DISPOSAL CONSIDERATIONS (continued)

information on the disposal of this product and observe any applicable regulations. Alternatively, arrange for disposal by a licensed disposal company.

Section 14: TRANSPORT INFORMATION

This product is not hazardous and no precautionary steps according to ADR/RID, IMDG, and IATA are necessary.

Section 15: REGULATORY INFORMATION *

General information: This safety datasheet was generated according to Regulations (EC) No 1907/2006 and 1272/2008, and amendment (EU) 2015/830 and without taking into account any special national regulations for handling hazardous substances and chemicals. Each user must implement the national special regulations independently.

Safety, health and environmental regulations/legislation specific for the substance or mixture: Not known.

Chemical safety assessment: Not carried out.

Section 16: Other information *

Caution: Product has not been fully tested. Based on general health and good laboratory practice considerations, the observation of the following hazard and precautionary statements is recommended:

Hazard Statements:
Not applicable

Precautionary Statements:
Not applicable

Disclaimer: Material should only be handled by qualified, experienced professionals. 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. This product is intended for research use or manufacturing only. DIARECT AG shall not be held liable for any damage resulting from the handling or from contact with the above product.

* Data changed compared to previous version.