

1. Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Product Name	ImmunoCAP® Tryptase Calibrators Tryptase Calibrator 1 µg/l Tryptase Calibrator 5 µg/l Tryptase Calibrator 12.5 µg/l Tryptase Calibrator 50 µg/l Tryptase Calibrator 200 µg/l	Article Number	10-9302-XX
Product Name	ImmunoCAP® Tryptase Calibrator Strip	Article Number	10-9330-01

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

Use of the Preparation	<i>In vitro</i> diagnostic test
Uses advised against	All other uses

1.3 Details of the supplier of the safety data sheet

Manufacturer	Phadia AB
Address	Rapsgatan 7P, P.O. Box 6460, 751 37 Uppsala, SWEDEN
Telephone No.	+46 18 16 50 00
E-mail address	safetydatasheet.idd@phadia.com

1.4 Emergency telephone number

Emergency Tel. No.	+46 18 16 50 00
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2. Hazards identification

2.1 Classification of the substance or mixture

Classification according to Regulation (EC) 1272/2008	
Health hazards	To the best of our knowledge this preparation is not classified as hazardous according to EU, US or any other known national regulations.
Environmental hazards	None
Fire and explosion hazards	None.
Physical/chemical hazards	None.
Classification according to Directive 1999/45/EC	
None	



2.2 Label elements	
Hazard Pictogram	None
Signal Words	None
Hazard statement	None.
Precautionary statements	None.

2.3 Other hazards
The mixture does not meet the criteria for PBT or vPvB.
Reagents manufactured from human components have been tested for hepatitis B and C, for antibodies to HIV1 and HIV2, and found to be negative. May cause sensitization of susceptible persons by skin contact.

3. Composition/Information on Ingredients				
Mixture	CAS No.	EC No.	Conc.	Classification For further information, see section 16
Human Tryptase in buffer Conc. 1; 5; 12,5; 50; 200 µg/l	-		>99%	-
Sodium azide	26628-22-8	247-852-1	< 0.05%	T+,N; R28-32-50/53

4. First Aid Measures	
4.1 Description of first aid measures	
Skin contact	Gently wash with plenty of soap and water. .
Eye contact	In case of contact with eyes, rinse with plenty of water and seek medical advice.
Ingestion	Rinse mouth with water, then drink a cup of water or milk.
4.2 Most important symptoms and effects, both acute and delayed	
None	
4.3 Indication of any immediate medical attention and special treatment needed	
None	



5. Fire Fighting Measures

5.1 Extinguishing media	Extinguishing media should be chosen according to surrounding material.
5.2. Special hazards arising from the substance or mixture	This mixture does not pose a fire hazard.
5.3. Advice for firefighters	-

6. Accidental Release Measures

6.1. Personal precautions, protective equipment and emergency procedures	Wear suitable gloves and eye/face protection.
6.2. Environmental precautions	Flush into sewer with plenty of water.
6.3. Methods and material for containment and cleaning up	Wipe up with adsorbent material (e.g. cloth, fleece) discharge according to local regulation.
6.4. Reference to other sections	For information on hand protection see section 8, for information on waste handling see section 13.

7. Handling and Storage

7.1. Precautions for safe handling	Advice on general occupational hygiene: Do not eat, drink and smoke in work area Wash hands after use Remove contaminated clothing and protective equipment before entering eating areas.
7.2. Conditions for safe storage, including any incompatibilities	The expiration date for the complete package is stated on the outer label and the recommended storage temperature is 2-8 °C. Each component is stable until the date stated on the respective label.
7.3. Specific end use(s)	See Directions For Use



8. Exposure Controls/Personal Protection

8.1. Control parameters	Occupational exposure limits values are not available
8.2. Exposure controls	Not required
Appropriate engineering controls	The mixture should be used according to Direction for Use
Individual protection measures such as personal protective equipment	Latex/rubber gloves are recommended Gloves resistance is not critical when the product is handled according to the directions for use. Safety glasses and respiratory protection are not required during normal usage.

Environmental exposure control	Preparation can be disposed with wastewater, when in compliance with local regulations.
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9. Physical and Chemical Properties

9.1. Information on basic physical and chemical properties			
Properties	Mixture	Properties	Mixture
Appearance:	Liquid	Vapour pressure:	N/A
Colour:	Yellowish	Vapour density:	N/A
Odour:	None	Relative density:	1 g/ml
Odour threshold:	None	Solubility (ies):	Completely soluble
pH:	7,0	Partition coefficient: n-octanol/water:	N/A
Melting point/freezing point:	N/A	Auto-ignition temperature:	N/A
Initial boiling point or boiling range:	100°C	Decomposition temperature:	N/A
Flash point:	N/A	Viscosity:	N/A
Evaporation rate:	N/A	Explosive properties:	N/A
Flammability (solid, gas):	N/A	Oxidising properties:	N/A
Upper/Lower flammability or Explosive limits:	N/A		
9.2 Other information	None		



10. Stability and Reactivity

10.1. Reactivity	Stable at recommended storage conditions
10.2. Chemical stability	The preparation should not be use after expiration date.
10.3. Possibility of hazardous reactions	None
10.4. Conditions to avoid	Not stable at temperatures below +2°C
10.5. Incompatible materials	None
10.6. Hazardous decomposition products	None

11. Toxicological Information

General	The product contains no substances which at their given concentration, are considered to be hazardous to health.
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12. Ecological Information

12.1. Toxicity	The potential eco-toxicological hazards associated with this preparation have not been fully characterized.
12.2. Ecotoxicity	Sodium azide
Bacteria	Photobacterium phosphoreum EC50: 38,5 ml, Pseudomonas fluorescens EC50: 2,6 mg/l
Fish	L. macrochirus LC50: 0,7 mg/l /96h
Daphnia	Daphnia pulex EC50: 4,2 mg/l / 96h
Algae	IC50: 272 mg/l
12.3. Persistence and degradability	Data is lacking on the product.
12.4. Bioaccumulative potential	Data is lacking, the product is soluble in water.
12.5. Mobility in soil	Data is lacking on the product.
12.6. Results of PBT and vPvB assessment	Data is lacking on the product.
12.7. Other adverse effects	Data is lacking on the product.
12.8. Other information	None



13. Disposal Considerations

13.1. Waste treatment methods

The product	Calibrators solution can be disposed with wastewater, when in compliance with local regulations.
Emptied packaging	Packaging waste made of plastic and paper boxes can be sorted and recycled according to local regulations.
Emptying instruction	Plastic bottles empties well, free of drip and hands over to plastic recycling. Paper boxes are hand over to relevant material recycling.
European waste catalogue	18 01 07 chemicals other than those mentioned in 18 01 06.

14. Transport Information

14.1. UN number	N/A
14.2. UN proper shipping name	N/A
14.3. Transport hazard class(es)	The product is not classified as Dangerous Goods in the meaning of current transport regulations (ADR/RID; DGR and IMDG code).
14.4. Packing group	N/A
14.5. Environmental hazards	N/A
14.6. Special precautions for user	N/A
14.7. Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code	N/A

15. Regulatory Information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture	
15.2. Chemical safety assessment	Not required
No classification according to regulation (EC) No 1272/2008 on classification, labeling and packaging of substances and mixtures.	



16. Other Information

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T (toxic); R28 Very toxic if swallowed, R32 Contact with acids liberates very toxic gas.

N (toxic to the environment); R 50-53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

DISCLAIMER: The information contained in this Safety Data Sheet is believed to be correct as of its date of issuance. The information characterizes the product from a safety perspective and is not meant to be a specification. It is the costumer's responsibility to ensure the product is suitable for its intended use. Anyone using this information agrees that Phadia shall not be held liable (based on its negligence or otherwise) for any personal injury or other damage relating to, or arising from such use, including direct, incidental, or consequential damage and such user agrees to indemnify Phadia for any claims arising out of its use.



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