

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

1.1 Product identifier

Product Name	ImmunoCAP 100 Tryptase	Article Number	10-9303-01, 10-9303-02
Product Name	ImmunoCAP Tryptase	Article Number	10-9521-01 10-9521-02
Product identifier	Tryptase Conjugate		
Product identifier	Tryptase Curve Control (CC-1 and CC-2)		
Product identifier	ImmunoCAP anti-Tryptase	This part is not included in article number 10-9521-01 and 10-9521-02	

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@thermofisher.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	-

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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.

The products contain products manufactured from human blood components. The source materials have been tested by immunoassay for hepatitis B surface antigen, for antibodies to HIV1 and HIV2 and hepatitis C virus and found negative.

3. Composition/Information on Ingredients

Mixture	CAS No.	EC No.	Conc.	Classification For further information, see section 16
Tryptase conjugate B-galatosidase-anti-Tryptase (mouse monoclonal antibodies) in buffer			>99%	
Sodium azide	26628-22-8	247-852-1	0.05%	T+; N R28 R32 R50/53
Tryptase Curve control (CC-1) Human Tryptase buffer			>99%	
Sodium azide	26628-22-8	247-852-1	0.05%	T+; N R28 R32 R50/53
ImmunoCAP Anti-Tryptase Mouse monoclonal antibodies on cellulose solid phase in buffer			>99%	
Mixture of: 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] (3:1)	55965-84-9		< 0.0015%	T; R 23/24/25, C; R 34 N; R 50-53



4. First Aid Measures

4.1 Description of first aid measures

Skin contact	Gently wash with plenty of soap and water. If skin irritation or rash occurs: Get medical advice/attention.
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	
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4.3 Indication of any immediate medical attention and special treatment needed

None	
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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			
Properties	Tryptase Conjugate	Tryptase Curve Control	ImmunoCAP Anti-Tryptase
Appearance:	Liquid	Liquid	Cellulose solid phase saturated in buffer and with plastic container
Colour:	Blue	Yellowish	Opal
Odour:	None	None	None
Odour threshold:	None	None	None
pH:	7.4	7.0	7.4
Melting point/freezing point:	N/A	N/A	N/A
Initial boiling point or boiling range:	100°C	100°C	N/A
Flash point:	N/A	N/A	N/A
Evaporation rate:	N/A	N/A	N/A
Flammability (solid, gas):	N/A	N/A	N/A
Upper/Lower flammability or Explosive limits:	N/A	N/A	N/A
Vapour pressure:	N/A	N/A	N/A
Vapour density:	N/A	N/A	N/A
Relative density:	1 g/ml	1 g/ml	N/A
Solubility (ies):	Completely soluble	Completely soluble	N/A
Partition coefficient: n-octanol/water:	N/A	N/A	N/A
Auto-ignition temperature:	N/A	N/A	N/A
Decomposition temperature:	N/A	N/A	N/A
Viscosity:	N/A	N/A	N/A
Explosive properties:	N/A	N/A	N/A
Oxidizing properties:	N/A	N/A	N/A
9.2 Other information	None	None	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**11.1. Information on toxicological effects**

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



12. Ecological Information

Tryptase Conjugate and Curve Control and ImmunoCAP Anti-Tryptase

12.1. Toxicity	The potential eco-toxicological hazards associated with this preparation have not been fully characterized.
12.2. Eco toxicity	CAS No. 55965-84-9
Fish	LC50 Rainbow trout 96h 0.1 9 mg/l
Alga	LC50 Bluegill sunfish 96h 0.28 mg/l
Aquatic invertebrates	EC50 Marine alga (Skeletonema costatum) 0.003 mg/l EC50 Alga (Selenastrum capreicornutum)
12.2. Eco toxicity	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	CAS No. 26172-55-4 t½ anaerobic=4.8 h t½ aerobic =17.3 h CAS No. 2682-20-4 t½ aerobic =9.1 h
12.4. Bio accumulative potential	No information available.
12.5. Mobility in soil	CAS No. 55965-84-9 Activated sludge growth inhibition EC 50: 4.5 mg/l.
12.6. Results of PBT and vPvB assessment	No information available
12.7. Other adverse effects	No information available
12.8. Other information	Information given is based on data from raw material.

13. Disposal Considerations

13.1. Waste treatment methods

The product	Conjugate, controls and buffer 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

16. Other Information

<p>Internal No.: 354120 Created: 2008-12-10 Review date: 2013-01-29 Revised: Section 12 updated Replaces date: 2012-11-30</p> <p>List of relevant R phrases in section 3: T (toxic); R28 Very toxic if swallowed, R32 Contact with acids liberates very toxic gas. T (toxic); R 23/24/25 Toxic by inhalation, in contact with skin and if swallowed. C (corrosive); R 34 Causes burns; R 43 May cause sensitization by skin contact N (toxic to the environment); R 50-53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.</p> <p>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 customer'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.</p>
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