

1. Identification of the Substance and of the Company

Product Name	Specific IgE Calibrator Strip	Article number	10-9386-01
Product Name	Specific IgE Calibrator Strip 0 - 100	Article number	10-9459-01
Use of the Preparation	<i>In vitro</i> diagnostic test		

Manufacturer	Phadia AB
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Issued by	Quality & Environmental Management

2. Hazard Identification

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. Reagents manufactured from human components have been tested for hepatitis B and C, for antibodies to HIV1 and HIV2, and found to be negative.
Environmental hazards	The product contains substances with concentrations that are not classified as hazardous to the environment according to EC directive.
Fire and explosion hazards	None.
Physical/chemical hazards	None.

3. Composition/Information on Ingredients

Preparation contains	CAS No.	EINECS No.	Conc.	Classification For further information, see section 16
Human IgE in buffer 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		100% < 0.0004%	T; R 23/24/25, C; R 34 N; R 50-53



4. First Aid Measures

Skin contact	In case of skin contact, wash with plenty of water and soap.
Eye contact	In case of contact with eyes, rinse with plenty of water and seek medical advice.
Ingestion	Rinse mouth with water, and then drink a cup of water or milk.

5. Fire Fighting Measures

Specific hazards	This mixture does not pose a fire hazard.
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6. Accidental Release Measures

Personal precaution	Wear suitable gloves and eye/face protection.
Clean-up method – Small spillage	Wipe up with adsorbent material (e.g. cloth, fleece) discharge according to local regulation.
Clean-up method – Large spillage	Flush into sewer with plenty of water.

7. Handling and Storage

Handling and specific use	See Direction for Use
Storage	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.

8. Exposure Controls/Personal Protection

Occupational exposure control	
Respiratory protection	Not required
Hand protection	Not required under normal laboratory use, in other cases use disposable gloves
Material of gloves	Latex/rubber gloves
Penetration time of glove material	Gloves resistance is not critical when the product is handled according to the directions for use.
Eye protection	Not required under normal laboratory use
Environmental exposure control	
The solution can be disposed with wastewater, when in compliance with local regulations.	



9. Physical and Chemical Properties

Property	Specific IgE Calibrator Strip	Property	Specific IgE Calibrator Strip
Form	Liquid	Upper/Lower Exposition limit	N/A
Colour	Yellow	Vapour pressure:	-
Odour	None	Density	1mg/l
pH	7.0	Solubility in water	Soluble
Boiling point	100°C	Viscosity	-
Flash point:	N/A	Other information	-

10. Stability and Reactivity

Stability	Do not use after expiration date.
Reactivity	Stable at recommended storage conditions

11. Toxicological Information

General	The product contains no substances which at their given concentration, are considered to be hazardous to health.
Acute toxicity	Product does not contain any components known to have any acute toxicity.
Repeated-dose toxicity	Product does not contain any components known to have any effects relating to the repeated-dose toxicity.
Mutagenicity	Product does not contain any components known to have mutagenic effect.
Carcinogenicity	Product does not contain any components known to have carcinogenic effect.
Reproductive toxicity	Product does not contain any components known to be toxic to there productive system and having fertility effect.
Other information	None.

12. Ecological Information

General information	The potential ecotoxicological hazards associated with this preparation has not been fully characterized.
Exotoxicity	Data is lacking on the product.
Mobility	Data is lacking, the product is soluble in water.
Persistence and degradability	Data is lacking on the product.
Bioaccumulative potential	Data is lacking on the product.
Other adverse effects	Data is lacking on the product.



13. Disposal Considerations

The product	The 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

14. Transport Information

The product is not classified as Dangerous Goods in the meaning of current transport regulations (ADR/RID; DGR and IMDG code).

Ambient temperature not to be exceeded during transport: +27°C.

15. Regulatory Information

No classification according to European directive on classification of dangerous preparations 1999/45/EEC.

16. Other Information

Internal No.: 341936

Revised: New layout, changed name of one ingredients to the name used in EU directive 2004/73/EG

Replaces date: April 19, 2006

List of relevant R phrases in section 3:

T toxic ; R 23/24/25 Toxic by inhalation, in contact with skin and if swallowed, C corrosive; R 34 Causes burns; N Dangerous for the environment; R 50-53 Very toxic to aquatic organisms, may cause long term adverse effect in the aquatic environment.

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Doc.no. 341936 Ver. 4.0 Page 5 (5)

