

### 1. Identification of the Substance and of the Company

<b>Product Name</b>	ImmunoCAP® Specific IgE Calibrators	<b>Article Number</b>	10-9460-01 10-9254-01
<b>Product Name</b>	ImmunoCAP® Specific IgE Calibrator Strip	<b>Article Number</b>	10-9459-01 10-9386-01
<b>Use of the Preparation</b>	<i>In vitro</i> diagnostic test		

<b>Manufacturer</b>	Phadia AB
<b>Address</b>	Box 6460, 751 37 Uppsala, SWEDEN
<b>Telephone No.</b>	+46 18 16 50 00
<b>Emergency Tel. No.</b>	+46 18 16 50 00
<b>Issued by</b>	Quality & Environmental Management
<b>e-mail</b>	<a href="mailto:anna-tora.martin@phadia.com">anna-tora.martin@phadia.com</a>

### 2. Hazard Identification

Health hazards	May cause sensitization by skin contact  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	None
Fire and explosion hazards	None.
Physical/chemical hazards	None.

### 3. Composition/Information on Ingredients

Preparations contain	CAS No.	EINECS No.	Conc.	Classification
Human IgE in buffer Mixture of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-2Hisothiazol-3-one [EC no. 220-239-6] (3:1)	- 55965-84-9		>99% <0,004%	- T; R 23/24/25 C; R 34 N; R 50-53

### 4. First Aid Measures

<b>Skin contact</b>	In case of skin contact, wash with plenty of water and soap.
<b>Eye contact</b>	In case of contact with eyes, rinse with plenty of water and seek



	medical advice.
<b>Ingestion</b>	Rinse mouth with water, then drink a cup of water or milk.

### 5. Fire Fighting Measures

Specific hazards	This mixture does not pose a fire hazard.
------------------	---

### 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

<b>Occupational exposure control</b>	
Respiratory protection	Not required
Hand protection	Skin protection not required under normal laboratory use.
Material of gloves	Disposable vinyl gloves is preferred if hand protection is chosen.
Penetration time of glove material	Gloves resistance is not critical when the product is handled according to the directions for use.
Eye protection	Eye protection not required under normal laboratory use.
<b>Environmental exposure control</b>	Curve control and calibrators can be disposed with wastewater, when in compliance with local regulations.



### 9. Physical and Chemical Properties

Property	Calibrators
Form	Liquid
Colour	Yellowish
Odour	
pH	7,0
Boiling point	
Flash point:	N/A
Upper/Lower Explosion limit	N/A
Vapour pressure:	
Density	
Solubility in water	Completely soluble
Viscosity	
Other information	
Form	Liquid

### 10. Stability and Reactivity

Stability	Should not be use after expiration date
Reactivity	Stable at recommended storage conditions

### 11. Toxicological Information

<b>Acute toxicity</b>	Raw material	Oral: LD50 rat female 2.630 mg/kg Oral: LD50 rat male 3.350 mg/kg Inhalation: LD50 rat 4h 0.33mg/l Dermatal: LD50 rabbit >5.000 mg/kg
<b>Sensitization</b>	Raw material	Sensitization (Guinea pig)
<b>Repeated-dose toxicity</b>		-
<b>Carcinogenicity</b>	CAS No 55965-84-9	Product do not contain any components known to have carcinogenic effect.
<b>Reproductive toxicity</b>	CAS No 55965-84-9	Product do not contain any components known to be toxic to the reproductive system and having fertility effect.
<b>Mutagenicity</b>	CAS No 55965-84-9	Product do not contain any components known to have mutagenic effect.
<b>Other information</b>		Information given is based on data from raw material



### 12. Ecological Information

<b>Ecotoxicity</b>		
Fish	CAS No 55965-84-9	LC50 Rainbow trout 96h 0,19mg/l LC50 Bluegill sunfish 96h 0,28mg/l
Alga		EC50 Marine alga (Skeletonema costatum) 0,003mg/l EC50 Alga (Selenastrum capreicornutum)
Aquatic invertebrates		EC50 Daphnia magna 48h 0,16mg/l
<b>Mobility:</b>	CAS No 55965-84-9	Activated sludge growth inhibition EC 50: 4,5mg/l
<b>Persistence and degradability:</b>	CAS No 26172-55-4	t <sub>1/2</sub> anaerobic =4.8 h t <sub>1/2</sub> aerobic =17.3 h
	CAS No 2682-20-4	t <sub>1/2</sub> aerobic =9.1 h
<b>Bioaccumulative potential:</b>		Data is lacking on the product
<b>Other adverse effects:</b>		Data is lacking on the product
<b>Other information</b>		Information given is based on data from raw material

### 13. Disposal Considerations

The product	Controls 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 06 chemicals consisting of or containing dangerous substances.

### 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

Classification according to European directive on classification of dangerous preparations 1999/45/EEC.

#### Calibrators

Mixture of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-2-Isothiazol-3-one [EC no. 220-239-6] (3:1)

#### Hazard warning symbols and designations



Xi: Irritant  
R 43 May cause sensitization by skin contact  
S 24 Avoid contact with skin  
S 37 Use suitable gloves

### 16. Other Information

Classification and risk phrases used in section 3 according to European directive on classification of dangerous preparations 1999/45/EEC.

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.

**Internal No.:** 348677

**Issue date:** 2006-02-10

**Revised:** New layout, general update, added art.No 10-9459-01 and 10-9386 Specific IgE Calibrtor Strip

**Replaces date:** 2006-03-07

**DISCLAIMER:** The information contained in the SDS (Safety Data Sheet) is believed to be correct as of its date of issuance. By making the SDS available, Phadia does not make any express or implied warranty (including any warranty of merchantability or fitness for a particular purpose) regarding the SDS, its accuracy or the product to which it relates. 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.



Document name SPECIFIC IGE CALIBRATORS SDS Number 348677 Version 3.0

Issued by Anna-Tora Martin 2008-Dec-9 15:40 CET

Approved by Anna-Tora Martin 2008-Dec-9 15:40 CET

Valid by 2008-Dec-9 15:40 CET

