I. Identification

Chemical name and synonyms:	not applicable
Trade name and synonyms:	Specific IgE kit (REF 50-02), Specific IgE kit (basic) (REF 50-02-SP-5, 50-02-SP-10), Specific IgE kit with biotinylated allergens (basic) (REF 50-02-AP-5, 50-02-AP-10, 50-02-AP-10c, 50-02-AP-10e), Specific IgE kit (calibration set) (REF 50-02-CAL), Specific IgE biotinylated allergens (REF 50-10…50-100; 51-01…51-500; 52-100…52-199), Specific IgE Positive controls and Negative controls (REF 51-501…51-503)
Chemical family:	In Vitro Diagnostic Test Kit (Reagents)
Formula:	not applicable
Proper DOT shipping name:	not applicable
DOT hazard classification:	not applicable
Manufacturer:	Astra Biotech GmbH
Manufacturer's Address:	Rudower Chaussee 29 12489 Berlin, Germany
Manufacturer's phone/fax:	+49 - (0)30 - 746 96 509/ +49 - (0)30 - 367 405 135

II. Hazards identification

Chemicals may always cause some special hazards. Therefore they should be handled by trained personnel with necessary care.

III. Composition, Information on Ingredients

Product: Specific IgE kit

Component	Preservative	Concentration of the hazardous substances	Stability at +4 °C
Microplate	Gentamicin sulphate	-	18 months
Wash solution, concentrated	none	-	18 months
Conjugate E-1	Kathon MW	Kathon MW - 0.1 %, active ingredients – 0.015 %	18 months
Conjugate E-2	Kathon MW	Kathon MW - 0.1 %, active ingredients – 0.015 %	18 months
Substrate	-	3,3',5,5'-tetramethylbenzidine - 1.2 mM; Hydrogen superoxide – 3.0 mM	18 months
Stop solution	none	1 M solution	18 months
Calibrators, Control	Kathon MW	Kathon MW - 0.1 %, active ingredients – 0.015 %	18 months

Product: allergens-biotin conjugates

Component	Preservative	Concentration	Stability at +4 °C
Allergens-biotin conjugates	Kathon MW	Kathon MW - 0.1 %, active ingredients – 0.015 %	18 months

Product: Specific Controls

Component	Preservative	Concentration	Stability at +4 °C
Positive Control- Inhalants, Positive Control- Foods, Negative Control	Sodium azide	Sodium azide - 0.07 %	24 months 1 month after reconstituted

Information on substances derived from tissues of human origin

Substance	Description	Source (blood, serum, plasma, tissue, cells etc.)	Hazard/Biohazard
Total IgE positive human plasma	Human Plasma positive inhalants	plasma	Plasma tested and found to be negative for HIV, HBC antigen, HCV, Syphilis and HBsAg
Total IgE positive human plasma	Human Plasma positive foods	plasma	Plasma tested and found to be negative for HIV, HBC antigen, HCV, Syphilis and HBsAg
Total IgE negative human plasma	Human Plasma	plasma	Plasma tested and found to be negative for HIV, HBC antigen, HCV, Syphilis and HBsAg

IV. First aid measures

Symptoms of exposure:
CORROSIVE: Stop solution (1 M hydrochloric acid solution;
POSSIBLE MUTAGEN: TMB Substrate solution;
POSSIBLE IRRITANT: TMB Substrate solution, Conjugate E-1, Conjugate E-2; Calibrators, Control, Allergens-biotin conjugates (Kathon MW - 0.1 %, active ingredients – 0.015 %)

In case of exposure to reagent solutions, we recommend the following emergency first-aid procedures:

1. Skin or Eye contact: wash with tap water for at least 15 minutes. Remove any contaminated clothes. Consult a physician.
2. Inhalation: displace the affected man to the fresh air and call a physician.
3. Ingestion: rinse the mouth with some water and call a physician.

V. Fire-fighting measures

Not applicable.
Usage of the reagents according to protocol should not incur a fire or explosion hazard. In case of fire use water, foam, carbon dioxide or dry chemical, as suitable.

VI. Clean up measures

Use standard laboratory absorbent materials for cleanup. Clean with enough water.

VII. Handling and storage

Hygienic Practice in Storage: store in a cool (2 -8 °C) and dry area away from direct sunlight and incompatible substances.
Hygienic Practice in Handling: handle all the samples and materials in contact with samples according to NCCLS guidelines for preventing transmission of blood-borne infections.

VIII. Exposure control and personnel protection

Eye Protection: recommended
Skin Protection: recommended
Respiratory Equipment: not applicable

Good laboratory practices should be followed when handling all the reagents.

IX. Physical data

pH: Conjugate: 7.3
TMB: 3.65
Stop solution: <1.0
Calibrators 0-5, Control 7.3±0.1
Positive Control- Inhalants, Positive Control- Foods, Negative Control 7.3±0.1

X. Stability and reactivity

TMB Substrate solution contains hydrogen peroxide which is an oxidizing agent, and TMB which is an irritant.

XI. Toxicological information

Hydrochloric acid: LD_{50} (rat) 900 mg/kg body weight
Sodium azide: LC50 Inhalation-rat-37 mg/m^3
LD50 Dermal-rabbit-20 mg/kg

XII. Ecological information:

Biological effects:
Hydrochloric acid is toxic for water organisms by quantitative changes of PH value. LD_{50} 25 mg/L up.
Biological effects:

XIII. Disposal consideration

Dispose in accordance with Local, State and Federal Regulations.

XIV. Transport information

This product can be conveyed without any contingencies. No regulations are to be applied.

XV. Regulatory Information

European Labeling according to Regulation (EC) No 1272/2008.

Name	Percent	CAS-No	hazard Symbols	Risk Phrases
Kathon MW	0.0015 %<=C<0.06 %	55965-84-9	 Warning	H 317 May cause an allergic skin reaction
Sodium azide	0.07 % < 0.1 %	26628-22-8	Article 11 of Directive 1272/2008 of 16 December 2008, Anex I, table 1.1 (category 1-3)	

The following precautions should be observed:

- P261 - Avoid breathing spray;
- P272 - Contaminated work clothing should not be allowed out of the workplace;
- P280 - Wear protective gloves/protective clothing/eye protection;
- P302+P352 - IF ON SKIN: Wash with plenty of soap and water;
- P333+P313 - If skin irritation or rash occurs: Get medical advice/attention;
- P363 - Wash contaminated clothing before reuse;
- P501 - Dispose of contents/container in accordance with national regulation.

XVI. Other information

This product is designed and evaluated for the professional use by qualified laboratory staff. It has to be used only as *in vitro* diagnostic medical device.

XVII. Disclaimer

The knowledge above is believed to be correct and is representing the most available to us information now. However we give no warranty expressed or implied in respect to such information, and we assume no liability resulting from its use. Users should make their own investigations to determine the suitability of the information for their particular purpose. In no way shall the company be liable for any claims, losses or damages of any third party or for lost profits of any special, indirect, incidental, consequential or exemplary damages, howsoever arising, even if the company has been advised of the possibility of such damages.