

	Material Safety Data Sheet (MSDS) According to Commission Regulation (EU) No 453/2010		Polycheck Allergy- Diagnostic (IVD)
issued: 15. May 2004	certified: 	proved: 	issued by:
changed: 29. August 2013	Dr. E. Michels	J. Meyer	I. Claes

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

1.1. Product identifier

Product name: Polycheck Allergy Diagnostic
 GMDN Code: 30278
 EDMA Code: 12 02 01 05

1.2. Relevant identified uses of the substances or mixtures and uses advised against:

Scanner based assay for screening and quantification of allergen specific IgE

1.3. Details of the supplier of the safety data sheet

Biocheck GmbH
 Vorbergweg 41, D 48159 Muenster (Deutschland)
 Telefon: 0251-2150-869, Telefax: 0251-2150-870
 E-mail: office@polycheck.de
 Internet: <http://www.biocheck.de>

1.4. Emergency call: see your local poison information center

2. Hazards identification

2.1. Classification of the substance or mixture:

The classification is according to the latest editions of the EU lists and extended by company and literature data.

2.2. Label elements:

According to the current regulations there is no labelling required. (Guideline 67/548/EWG)

2.3. Other hazards:

none

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3. Composition/information on ingredients

3.1. Substances: for in vitro diagnostic use; Test-Kit

Component	Contents	Hazards	Conc.	Classific.	Risk phrase
Polycheck x-Allergen Cassette	Cellulose membrane carrying natural substances (allergens) with humidity adsorbent (x=different Allergen compositions)	none			
anti-IgE Antibody	Biotinylated antibody in phosphate-buffered saline (pH 7,4)	none			
Enzyme-Labeled anti-Ligand	Streptavidin-conjugate with alkaline phosphatase in phosphate-buffered saline (pH 7,4)	none			
Substrate Solution	BCIP-substrate in water solution (pH 10,0)	none			
Start Solution	Protein in Phosphate-buffered saline (pH 7,4)	none			
Wash Buffer	Tween20-detergent and powder for phosphate-buffered saline (pH 7,4)	none			

Additional information:

Substrat Solution: CAS-No. 6578-06-9

5-Brom-4-chlor-3-indolyhydrogenphosphat-p-toluidin (<1%)

CAS-No. 298-83-9

5,5'-diphenyl-3,3'-bis(4-nitrophenyl)-2,2'-(3,3'-imethoxydiphenyl-4,4'-xylen-ditetrazoliumchlorid) (<1%)

Wash Buffer: no CAS-No.

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4. First aid measures

4.1. Description and first aid measures

general information: ask for medical attention, consult the Material Safety Data Sheet

after inhalation: remove to fresh air; in case of accident or persisting discomfort, obtain medical attention

after skin contact: wash thoroughly with soap and water

after eye contact: irrigate with copious amounts of water; displace contact lenses and in case of heavy irritations ask for medical attention

after swallowing: in case of discomfort ask for medical attention

4.2. Most important symptoms and effects, both acute and delayed

after inhalation: can cause irritations

after skin contact: potential skin irritations

after eye contact: potential redness or streaming eyes

after swallowing: potential sickness and gastrointestinal disease

4.3. Indication of any immediate medical attention and special treatment needed:

none

5. Fire fighting measures

5.1. Extinguishing media: foam, dry chemical powder, carbon dioxide, water spray, all common extinguishing agents are applicable

5.2. Special hazards arising from the substance or mixture:

no special hazards

5.3. Advice for firefighters:

no special protective equipment necessary

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6. Accidental release measures

6.1. **Personal precautions, protective equipment and emergency procedures:**
not required

6.2. **Environmental precautions:** not required

6.3. **Methods and material for containment and cleaning up:**
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).

6.4. **Reference to other sections:** Dispose contaminated material as waste according to item 13.

7. Handling and storage

7.1. **Precautions for safe handling:**
no special measures required

7.2. **Conditions for safe storage, including any incompatibilities:**
no special measures required

7.3. **Specific end use:** see item 1.2

8. Exposure controls and personal protection

8.1. **Control parameters:** not required

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8.2. Exposure parameters:

General protective and hygiene measures:

Keep away from foodstuff and beverages.
Wash hands before breaks and at the end of the working day.

Respiration protection:

Not recommended in rooms with access to fresh air when applied appropriately.

Protection of hands:

Wearing of protective gloves is recommended.

Eye protection:

Not recommended in appropriate applications.

9. Physical and chemical properties

9.1. Information on basic physical and chemical properties

Form: liquid, resp. powder (see also item 2)

Colour: liquid: colourless; Powder: white

Odour characteristics: no odour

Melting point / range: N/A

Boiling point / range: N/A

Ignition temperature: N/A

Self ignition: N/A

Flash point: N/A

Danger of explosion: product does not present an explosion hazard

Explosion limits: N/A

Relative vapour density 20°C: N/A

Density at 20°C: N/A

Solubility in water at 20°C: N/A

9.2. Other information: no other information available

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13. Disposal considerations

13.1. Waste treatment methods: Disposal must be made according to official regulations; can be composed together with household garbage.

14. Transport information

- 14.1. UN number: non dangerous goods
- 14.2. UN proper shipping name: non dangerous goods
- 14.3. Transport hazard class(es): non dangerous goods
- 14.4. Packing group: non dangerous goods
- 14.5. Environmental hazards: non dangerous goods
- 14.6. Special precautions for user: non dangerous goods
- 14.7. Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code: non dangerous goods

15. Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture:

The product has been classified and marked in accordance with EU Directives/Ordinance on hazardous material.

National Regulations

Classification according to VbF: N/A
 Immision hazard class: N/A
 Water hazard class: WGK 1

15.2. Chemical safety assessment: N/A

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16. Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship

Material Safety Data Sheet issued by: Ingeborg Claes

Date of issue of the Material Safety Data Sheet: 29. August 2013