

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006

The Roche logo, consisting of the word "Roche" in a bold, sans-serif font, enclosed within a hexagonal border.

**HE4**

Version  
1.6

Revision Date:  
13.02.2015

Date of last issue: 08.08.2014  
Date of first issue: 08.11.2012

## SECTION 1: Identification of the substance/mixture and of the company/undertaking

### 1.1 Product identifier

Commercial Product Name : HE4  
Mat.-No./ Genisys-No. : 05950929190

### 1.2 Relevant identified uses of the substance or mixture and uses advised against

Recommended restrictions : For professional users only.  
on use

### 1.3 Details of the supplier of the safety data sheet

Company : Roche Diagnostics Deutschland GmbH  
-  
Sandhoferstrasse 116  
68305 Mannheim  
E-mail address : mannheim.umweltschutz@roche.com  
Telephone : +496217590  
Telefax : +496217592890  
Responsible Department : +49(0)621-759-2012+49(0)621-759-4848+49(0)8856-60-2629

### 1.4 Emergency telephone number

In case of emergencies: : Central Works Security +49(0)621-759-2203  
Roche Diagnostics GmbH  
  
Centre for detoxification: : Mainz +49(0)6131-19240  
Munich +49(0)89-19240

## SECTION 2: Hazards identification

### 2.1 Classification of the substance or mixture

The product is a kit consisting of individual ingredients. The classification of the ingredients can be obtained from section 3. Section Label elements contains the resulting labelling for the kit.

### 2.2 Label elements

**Labelling (REGULATION (EC) No 1272/2008)**

Not a hazardous substance or mixture.

### 2.3 Other hazards

See SECTION 3

## SECTION 3: Composition/information on ingredients

**R1**

**Classification (REGULATION (EC) No 1272/2008)**

Not a hazardous substance or mixture.

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006

Roche

**HE4**

Version  
1.6

Revision Date:  
13.02.2015

Date of last issue: 08.08.2014  
Date of first issue: 08.11.2012

## **Classification (67/548/EEC, 1999/45/EC)**

Not a hazardous substance or mixture.

## **Hazardous components**

Remarks : No hazardous ingredients

## **R2**

## **Classification (REGULATION (EC) No 1272/2008)**

Not a hazardous substance or mixture.

## **Classification (67/548/EEC, 1999/45/EC)**

Not a hazardous substance or mixture.

## **Hazardous components**

Remarks : No hazardous ingredients

## **Beads (MP)**

## **Classification (REGULATION (EC) No 1272/2008)**

Not a hazardous substance or mixture.

## **Classification (67/548/EEC, 1999/45/EC)**

Not a hazardous substance or mixture.

## **Hazardous components**

Remarks : No hazardous ingredients

## **SECTION 4: First aid measures**

### **4.1 Description of first aid measures**

- General advice : Do not leave the victim unattended.
- If inhaled : Move to fresh air.  
If unconscious place in recovery position and seek medical advice.  
If symptoms persist, call a physician.
- In case of skin contact : If on skin, rinse well with water.
- In case of eye contact : Immediately flush eye(s) with plenty of water.  
Remove contact lenses.  
Protect unharmed eye.  
If eye irritation persists, consult a specialist.
- If swallowed : Keep respiratory tract clear.  
Do not give milk or alcoholic beverages.  
Never give anything by mouth to an unconscious person.  
If symptoms persist, call a physician.  
Rinse mouth with water.

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006

The Roche logo, consisting of the word "Roche" in a bold, sans-serif font, enclosed within a hexagonal border.

**HE4**

Version  
1.6

Revision Date:  
13.02.2015

Date of last issue: 08.08.2014  
Date of first issue: 08.11.2012

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

Symptoms : No information available.

## 4.3 Indication of any immediate medical attention and special treatment needed

Treatment : The first aid procedure should be established in consultation with the doctor responsible for industrial medicine.

---

## SECTION 5: Firefighting measures

### 5.1 Extinguishing media

Suitable extinguishing media : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

### 5.2 Special hazards arising from the substance or mixture

Specific hazards during fire-fighting : No information available.

### 5.3 Advice for firefighters

Special protective equipment for firefighters : Wear self-contained breathing apparatus for firefighting if necessary.

Further information : Standard procedure for chemical fires.  
Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

---

## SECTION 6: Accidental release measures

### 6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions : Refer to protective measures listed in sections 7 and 8.

### 6.2 Environmental precautions

Environmental precautions : Local authorities should be advised if significant spillages cannot be contained.

### 6.3 Methods and material for containment and cleaning up

Methods for cleaning up : Wipe up with absorbent material (e.g. cloth, fleece).  
Keep in suitable, closed containers for disposal.

### 6.4 Reference to other sections

Treat recovered material as described in the section "Disposal considerations".

---

## SECTION 7: Handling and storage

### 7.1 Precautions for safe handling

Advice on safe handling : For personal protection see section 8.  
Smoking, eating and drinking should be prohibited in the ap-

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006

**Roche**

**HE4**

Version  
1.6

Revision Date:  
13.02.2015

Date of last issue: 08.08.2014  
Date of first issue: 08.11.2012

plication area.

Advice on protection against fire and explosion : Normal measures for preventive fire protection.

Hygiene measures : Handle in accordance with good industrial hygiene and safety practice.

## 7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers : Electrical installations / working materials must comply with the technological safety standards.

Further information on storage conditions : See label, package insert or internal guidelines

Advice on common storage : No materials to be especially mentioned.

Storage class (TRGS 510) : 12, Non Combustible Liquids

Other data : No decomposition if stored and applied as directed.

## 7.3 Specific end use(s)

Specific use(s) : Laboratory chemicals

## SECTION 8: Exposure controls/personal protection

### 8.1 Control parameters

#### **R1**

Contains no substances with occupational exposure limit values.

#### **R2**

Contains no substances with occupational exposure limit values.

#### **Beads (MP)**

Contains no substances with occupational exposure limit values.

### 8.2 Exposure controls

#### **Personal protective equipment**

Eye protection : Safety glasses

Hand protection

Material : Protective gloves

Remarks : The selected protective gloves have to satisfy the specifications of EU Directive 89/686/EEC and the standard EN 374 derived from it. This recommendation is only valid for the product mentioned in the safety data sheet and provided by

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006

Roche

**HE4**

Version  
1.6

Revision Date:  
13.02.2015

Date of last issue: 08.08.2014  
Date of first issue: 08.11.2012

us and for the application specified by us. Please observe the instructions regarding permeability and breakthrough time which are provided by the supplier of the gloves. Also take into consideration the specific local conditions under which the product is used, such as the danger of cuts, abrasion, and the contact time. The suitability for a specific workplace should be discussed with the producers of the protective gloves.

Skin and body protection : Protective suit

Respiratory protection : No personal respiratory protective equipment normally required.

## SECTION 9: Physical and chemical properties

### 9.1 Information on basic physical and chemical properties

#### **R1**

Appearance : liquid

Colour : colourless

Odour : none

Odour Threshold : No data available

pH : 6,5

Melting point/range : No data available

Boiling point/boiling range : No data available

Flash point : does not flash

Evaporation rate : No data available

Flammability (solid, gas) : The product is not flammable., Does not sustain combustion.

Upper explosion limit : No data available

Lower explosion limit : No data available

Vapour pressure : No data available

Relative vapour density : No data available

Relative density : No data available

Density : 1,033 g/cm<sup>3</sup>

Solubility(ies)

Water solubility : completely miscible

Partition coefficient: n-octanol/water : No data available

Ignition temperature : No data available

Auto-ignition temperature : No data available

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006

**Roche**

## HE4

Version  
1.6

Revision Date:  
13.02.2015

Date of last issue: 08.08.2014  
Date of first issue: 08.11.2012

Decomposition temperature : No data available  
Viscosity : No data available  
Explosive properties : No data available  
Oxidizing properties : The substance or mixture is not classified as oxidizing.

### **R2**

Appearance : liquid  
Colour : colourless  
Odour : none  
Odour Threshold : No data available  
pH : 7,4  
Melting point/range : No data available  
Boiling point/boiling range : No data available  
Flash point : does not flash  
Evaporation rate : No data available  
Flammability (solid, gas) : The product is not flammable., Does not sustain combustion.  
Upper explosion limit : No data available  
Lower explosion limit : No data available  
Vapour pressure : No data available  
Relative vapour density : No data available  
Relative density : No data available  
Density : 1,033 g/cm3  
Solubility(ies)  
Water solubility : completely miscible  
Partition coefficient: n-octanol/water : No data available  
Ignition temperature : No data available  
Auto-ignition temperature : No data available  
Decomposition temperature : No data available  
Viscosity : No data available  
Explosive properties : No data available  
Oxidizing properties : The substance or mixture is not classified as oxidizing.

### **Beads (MP)**

Appearance : liquid  
Colour : colourless

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006

Roche

**HE4**

Version  
1.6

Revision Date:  
13.02.2015

Date of last issue: 08.08.2014  
Date of first issue: 08.11.2012

Odour	: none
Odour Threshold	: No data available
pH	: 7,4
Melting point/range	: No data available
Boiling point/boiling range	: No data available
Flash point	: does not flash
Evaporation rate	: No data available
Flammability (solid, gas)	: Does not sustain combustion.
Upper explosion limit	: No data available
Lower explosion limit	: No data available
Vapour pressure	: No data available
Relative vapour density	: No data available
Relative density	: No data available
Density	: 1,01 g/cm <sup>3</sup> (20 °C)
Solubility(ies)	
Water solubility	: completely miscible
Partition coefficient: n-octanol/water	: No data available
Ignition temperature	: No data available
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
Viscosity	: No data available
Explosive properties	: No data available
Oxidizing properties	: The substance or mixture is not classified as oxidizing.

## 9.2 Other information

### **R1**

No data available

### **R2**

No data available

### **Beads (MP)**

No data available

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006

**Roche**

**HE4**

Version  
1.6

Revision Date:  
13.02.2015

Date of last issue: 08.08.2014  
Date of first issue: 08.11.2012

---

## SECTION 10: Stability and reactivity

### 10.1 Reactivity

No dangerous reaction known under conditions of normal use.

### 10.2 Chemical stability

Stable under normal conditions.

### 10.3 Possibility of hazardous reactions

Hazardous reactions : Stable under recommended storage conditions.  
No hazards to be specially mentioned.

### 10.4 Conditions to avoid

Conditions to avoid : No data available

### 10.5 Incompatible materials

Materials to avoid : No data available

### 10.6 Hazardous decomposition products

No data available

---

## SECTION 11: Toxicological information

### 11.1 Information on toxicological effects

**R1**

#### Acute toxicity

Not classified based on available information.

#### Skin corrosion/irritation

Not classified based on available information.

#### Serious eye damage/eye irritation

Not classified based on available information.

#### Respiratory or skin sensitisation

Skin sensitisation: Not classified based on available information.

Respiratory sensitisation: Not classified based on available information.

#### Germ cell mutagenicity

Not classified based on available information.

#### Carcinogenicity

Not classified based on available information.

#### Reproductive toxicity

Not classified based on available information.

#### STOT - single exposure

Not classified based on available information.



# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006

The Roche logo, consisting of the word "Roche" in a bold, sans-serif font, enclosed within a hexagonal border.

**HE4**

Version  
1.6

Revision Date:  
13.02.2015

Date of last issue: 08.08.2014  
Date of first issue: 08.11.2012

## **STOT - repeated exposure**

Not classified based on available information.

## **Aspiration toxicity**

Not classified based on available information.

## **R2**

## **Acute toxicity**

Not classified based on available information.

## **Skin corrosion/irritation**

Not classified based on available information.

## **Serious eye damage/eye irritation**

Not classified based on available information.

## **Respiratory or skin sensitisation**

Skin sensitisation: Not classified based on available information.

Respiratory sensitisation: Not classified based on available information.

## **Germ cell mutagenicity**

Not classified based on available information.

## **Carcinogenicity**

Not classified based on available information.

## **Reproductive toxicity**

Not classified based on available information.

## **STOT - single exposure**

Not classified based on available information.

## **STOT - repeated exposure**

Not classified based on available information.

## **Aspiration toxicity**

Not classified based on available information.

## **Beads (MP)**

## **Acute toxicity**

Not classified based on available information.

## **Skin corrosion/irritation**

Not classified based on available information.

## **Serious eye damage/eye irritation**

Not classified based on available information.

## **Respiratory or skin sensitisation**

Skin sensitisation: Not classified based on available information.

Respiratory sensitisation: Not classified based on available information.

## **Germ cell mutagenicity**

Not classified based on available information.

## **Carcinogenicity**

Not classified based on available information.

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006

The Roche logo, consisting of the word "Roche" in a bold, sans-serif font, enclosed within a hexagonal border.

**HE4**

Version  
1.6

Revision Date:  
13.02.2015

Date of last issue: 08.08.2014  
Date of first issue: 08.11.2012

## **Reproductive toxicity**

Not classified based on available information.

## **STOT - single exposure**

Not classified based on available information.

## **STOT - repeated exposure**

Not classified based on available information.

## **Aspiration toxicity**

Not classified based on available information.

## **SECTION 12: Ecological information**

### **12.1 Toxicity**

#### **R1**

No data available

#### **R2**

No data available

#### **Beads (MP)**

No data available

### **12.2 Persistence and degradability**

#### **R1**

No data available

#### **R2**

No data available

#### **Beads (MP)**

No data available

### **12.3 Bioaccumulative potential**

#### **R1**

No data available

#### **R2**

No data available

#### **Beads (MP)**

No data available

### **12.4 Mobility in soil**

#### **R1**

No data available

#### **R2**

No data available

#### **Beads (MP)**

No data available

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006

Roche

**HE4**

Version  
1.6

Revision Date:  
13.02.2015

Date of last issue: 08.08.2014  
Date of first issue: 08.11.2012

## 12.5 Results of PBT and vPvB assessment

**R1**

Not relevant

**R2**

Not relevant

**Beads (MP)**

Not relevant

## 12.6 Other adverse effects

**R1**

No data available

**R2**

No data available

**Beads (MP)**

No data available

## SECTION 13: Disposal considerations

### 13.1 Waste treatment methods

Product : Can be disposed as waste water, when in compliance with local regulations.

Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal.  
Do not re-use empty containers.

## SECTION 14: Transport information

### 14.1 UN number

Not regulated as a dangerous good

### 14.2 UN proper shipping name

Not regulated as a dangerous good

### 14.3 Transport hazard class(es)

Not regulated as a dangerous good

### 14.4 Packing group

Not regulated as a dangerous good

### 14.5 Environmental hazards

Not regulated as a dangerous good

### 14.6 Special precautions for user

Remarks : Not dangerous goods in the meaning of ADR/RID, ADNR, IMDG-Code, ICAO/IATA-DGR

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006

Roche

**HE4**

Version  
1.6

Revision Date:  
13.02.2015

Date of last issue: 08.08.2014  
Date of first issue: 08.11.2012

## 14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Remarks : Not applicable

## SECTION 15: Regulatory information

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

Seveso II - Directive 2003/105/EC amending Council Directive 96/82/EC on the control of major-accident hazards involving dangerous substances

Not applicable

Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances.

Not applicable

Water contaminating class : WGK 1 slightly water endangering  
(Germany)

### **R1**

**Labelling (REGULATION (EC) No 1272/2008)**

Not a hazardous substance or mixture.

### **R2**

**Labelling (REGULATION (EC) No 1272/2008)**

Not a hazardous substance or mixture.

### **Beads (MP)**

**Labelling (REGULATION (EC) No 1272/2008)**

Not a hazardous substance or mixture.

### 15.2 Chemical Safety Assessment

A Chemical Safety Assessment is not required for this substance when it is used in the specified applications.

## SECTION 16: Other information

### Further information

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



**HE4**

Version  
1.6

Revision Date:  
13.02.2015

Date of last issue: 08.08.2014  
Date of first issue: 08.11.2012

---

DE / EN