

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006

Roche

**TP2**

Version  
1.8

Revision Date:  
21.02.2015

Date of last issue: 03.08.2014  
Date of first issue: 14.06.2012

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

### 1.1 Product identifier

Commercial Product Name : TP2  
Mat.-No./ Genisys-No. : 03183734190

### 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)

Hazard pictograms :



Signal word : Warning

Hazard statements : H290 May be corrosive to metals.  
H315 Causes skin irritation.  
H319 Causes serious eye irritation.  
H411 Toxic to aquatic life with long lasting effects.

Precautionary statements : **Prevention:**  
P273 Avoid release to the environment.

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P280  
P280  
**Response:**  
P362 + P364

Wear eye protection/ face protection.  
Wear protective gloves.

Take off contaminated clothing and wash it  
before reuse.

## 2.3 Other hazards

See SECTION 3

## SECTION 3: Composition/information on ingredients

### R1(A / B)

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

Corrosive to metals, Category 1

H290: May be corrosive to metals.

Skin irritation, Category 2

H315: Causes skin irritation.

Eye irritation, Category 2

H319: Causes serious eye irritation.

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

Corrosive

R35: Causes severe burns.

#### Hazardous components

Chemical Name	CAS-No. EC-No. Registration number	Classification (67/548/EEC)	Classification (REGULATION (EC) No 1272/2008)	Concentration (%)
sodium hydroxide	1310-73-2 215-185-5	C; R35	Met. Corr. 1; H290 Skin Corr. 1A; H314	>= 1 - < 2

For explanation of abbreviations see section 16.

### R2 (C)

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

Corrosive to metals, Category 1

H290: May be corrosive to metals.

Skin irritation, Category 2

H315: Causes skin irritation.

Eye irritation, Category 2

H319: Causes serious eye irritation.

Chronic aquatic toxicity, Category 2

H411: Toxic to aquatic life with long lasting effects.

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

Corrosive

R35: Causes severe burns.

Dangerous for the environment

R51/53: Toxic to aquatic organisms, may cause  
long-term adverse effects in the aquatic environ-  
ment.

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## Hazardous components

Chemical Name	CAS-No. EC-No. Registration number	Classification (67/548/EEC)	Classification (REGULATION (EC) No 1272/2008)	Concentration (%)
sodium hydroxide	1310-73-2 215-185-5	C; R35	Met. Corr. 1; H290 Skin Corr. 1A; H314	$\geq 1 - < 2$
Copper(II)sulfate- pentahydrate	7758-99-8 231-847-6	Xn; R22 Xi; R36/38 N; R50-R53	Acute Tox. 4; H302 Skin Irrit. 2; H315 Eye Irrit. 2; H319 Aquatic Acute 1; H400 Aquatic Chronic 1; H410	$\geq 0,25 - < 1$

For explanation of abbreviations see section 16.

## SECTION 4: First aid measures

### 4.1 Description of first aid measures

- General advice : Move out of dangerous area.  
Consult a physician.  
Show this safety data sheet to the doctor in attendance.  
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 : Immediate medical treatment is necessary as untreated wounds from corrosion of the skin heal slowly and with difficulty.  
If on skin, rinse well with water.  
If on clothes, remove clothes.
- In case of eye contact : Small amounts splashed into eyes can cause irreversible tissue damage and blindness.  
In the case of contact with eyes, rinse immediately with plenty of water and seek medical advice.  
Continue rinsing eyes during transport to hospital.  
Remove contact lenses.  
Protect unharmed eye.  
Keep eye wide open while rinsing.  
If eye irritation persists, consult a specialist.
- If swallowed : Clean mouth with water and drink afterwards plenty of water.  
Keep respiratory tract clear.  
Do NOT induce vomiting.  
Do not give milk or alcoholic beverages.  
Never give anything by mouth to an unconscious person.  
If symptoms persist, call a physician.  
Take victim immediately to hospital.

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Rinse mouth with water.

## 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.

Unsuitable extinguishing media : High volume water jet

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

Specific hazards during fire-fighting : Do not allow run-off from fire fighting to enter drains or water courses.

### 5.3 Advice for firefighters

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

Further information : Collect contaminated fire extinguishing water separately. This must not be discharged into drains.  
Fire residues and contaminated fire extinguishing water must be disposed of in accordance with local regulations.

## SECTION 6: Accidental release measures

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

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

### 6.2 Environmental precautions

Environmental precautions : Prevent product from entering drains.  
Prevent further leakage or spillage if safe to do so.  
If the product contaminates rivers and lakes or drains inform respective authorities.

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

Methods for cleaning up : Soak up with inert absorbent material (e.g. sand, silica gel, acid binder, universal binder, sawdust).  
Keep in suitable, closed containers for disposal.

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## 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 : Do not breathe vapours/dust.  
Avoid contact with skin and eyes.  
For personal protection see section 8.  
Smoking, eating and drinking should be prohibited in the application area.  
Dispose of rinse water in accordance with local and national regulations.  
To prevent leaks or spillages from spreading, provide a suitable liquid retention system.
- Advice on protection against fire and explosion : Normal measures for preventive fire protection.
- Hygiene measures : When using do not eat or drink. When using do not smoke.  
Wash hands before breaks and at the end of workday.

### 7.2 Conditions for safe storage, including any incompatibilities

- Requirements for storage areas and containers : Keep container tightly closed in a dry and well-ventilated place. Containers which are opened must be carefully re-sealed and kept upright to prevent leakage. Electrical installations / working materials must comply with the technological safety standards.
- Further information on storage conditions : See label, package insert or internal guidelines
- Storage class (TRGS 510) : 8B, Non-combustible, corrosive hazardous materials
- 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(A / B)**

Contains no substances with occupational exposure limit values.

#### **R2 (C)**

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Contains no substances with occupational exposure limit values.

## 8.2 Exposure controls

### Personal protective equipment

Eye protection : Eye wash bottle with pure water  
Tightly fitting safety goggles  
Wear face-shield and protective suit for abnormal processing problems.

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 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 : impervious clothing  
Choose body protection according to the amount and concentration of the dangerous substance at the work place.

## SECTION 9: Physical and chemical properties

### 9.1 Information on basic physical and chemical properties

#### **R1(A / B)**

Appearance : liquid

Colour : No data available

Odour : none

Odour Threshold : No data available

pH : 13,4

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

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Vapour pressure : No data available  
Relative vapour density : No data available  
Relative density : No data available  
Density : 1,0251 g/cm<sup>3</sup> (20 °C)

Solubility(ies)  
Water solubility : soluble

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.

## **R2 (C)**

Appearance : liquid

Colour : No data available  
Odour : none

Odour Threshold : No data available  
pH : 13,2

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 : 1,0342 g/cm<sup>3</sup> (20 °C)

Solubility(ies)  
Water solubility : soluble

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

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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(A / B)***

No data available

### ***R2 (C)***

No data available

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## 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 : No decomposition if stored and applied as directed.

### 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

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## SECTION 11: Toxicological information

### 11.1 Information on toxicological effects

#### ***R1(A / B)***

#### **Acute toxicity**

Not classified based on available information.



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## **Skin corrosion/irritation**

Causes skin irritation.

### **Components:**

#### **sodium hydroxide:**

Remarks: Extremely corrosive and destructive to tissue.

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

Causes serious eye irritation.

### **Components:**

#### **sodium hydroxide:**

Remarks: May cause irreversible eye damage.

## **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.

### **Components:**

#### **sodium hydroxide:**

Genotoxicity in vitro : Test Type: Ames test  
Result: negative

## **Carcinogenicity**

Not classified based on available information.

## **Reproductive toxicity**

Not classified based on available information.

### **Components:**

#### **sodium hydroxide:**

Effects on fertility :  
Remarks: No data available

## **STOT - single exposure**

Not classified based on available information.

### **Components:**

#### **sodium hydroxide:**

Assessment: The substance or mixture is not classified as specific target organ toxicant, single exposure.

## **STOT - repeated exposure**

Not classified based on available information.

### **Components:**

#### **sodium hydroxide:**

Assessment: The substance or mixture is not classified as specific target organ toxicant, repeated exposure.

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## Aspiration toxicity

Not classified based on available information.

**R2 (C)**

## Acute toxicity

Not classified based on available information.

### Components:

#### **Copper(II)sulfate-pentahydrate:**

Acute oral toxicity : Acute toxicity estimate: 500 mg/kg  
Method: Expert judgement

Acute dermal toxicity : Acute toxicity estimate: > 2.001 mg/kg  
Method: Expert judgement

## Skin corrosion/irritation

Causes skin irritation.

### Components:

#### **sodium hydroxide:**

Remarks: Extremely corrosive and destructive to tissue.

#### **Copper(II)sulfate-pentahydrate:**

Result: Irritating to skin.

Remarks: May cause skin irritation in susceptible persons.

## Serious eye damage/eye irritation

Causes serious eye irritation.

### Components:

#### **sodium hydroxide:**

Remarks: May cause irreversible eye damage.

#### **Copper(II)sulfate-pentahydrate:**

Result: Irritating to eyes.

Remarks: May cause irreversible eye damage.

## Respiratory or skin sensitisation

Skin sensitisation: Not classified based on available information.

Respiratory sensitisation: Not classified based on available information.

### Components:

#### **Copper(II)sulfate-pentahydrate:**

Assessment: May be harmful in contact with skin.

## Germ cell mutagenicity

Not classified based on available information.

### Components:

#### **sodium hydroxide:**

Genotoxicity in vitro : Test Type: Ames test  
Result: negative

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## **Carcinogenicity**

Not classified based on available information.

## **Reproductive toxicity**

Not classified based on available information.

## **Components:**

### **sodium hydroxide:**

Effects on fertility

:

Remarks: No data available

## **STOT - single exposure**

Not classified based on available information.

## **Components:**

### **sodium hydroxide:**

Assessment: The substance or mixture is not classified as specific target organ toxicant, single exposure.

### **Copper(II)sulfate-pentahydrate:**

Assessment: The substance or mixture is not classified as specific target organ toxicant, single exposure.

## **STOT - repeated exposure**

Not classified based on available information.

## **Components:**

### **sodium hydroxide:**

Assessment: The substance or mixture is not classified as specific target organ toxicant, repeated exposure.

## **Aspiration toxicity**

Not classified based on available information.

## **Components:**

### **Copper(II)sulfate-pentahydrate:**

No data available

## **SECTION 12: Ecological information**

### **12.1 Toxicity**

#### ***R1(A / B)***

## **Components:**

### **sodium hydroxide:**

Toxicity to fish

: LC50 (Oncorhynchus mykiss (rainbow trout)): 45,4 mg/l  
Exposure time: 96 h

LC50 (Leuciscus idus (Golden orfe)): ca. 7 mg/l

Toxicity to daphnia and other  
aquatic invertebrates

: EC50 (Daphnia magna (Water flea)): 40,38 mg/l  
Exposure time: 48 h

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Ecotoxicology Assessment  
Acute aquatic toxicity : This product has no known ecotoxicological effects.  
Chronic aquatic toxicity : This product has no known ecotoxicological effects.  
Toxicity Data on Soil : Not expected to adsorb on soil.  
Other organisms relevant to the environment : No data available

### **R2 (C)**

#### **Components:**

##### **sodium hydroxide:**

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): 45,4 mg/l  
Exposure time: 96 h  
LC50 (Leuciscus idus (Golden orfe)): ca. 7 mg/l  
Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 40,38 mg/l  
Exposure time: 48 h

Ecotoxicology Assessment  
Acute aquatic toxicity : This product has no known ecotoxicological effects.  
Chronic aquatic toxicity : This product has no known ecotoxicological effects.  
Toxicity Data on Soil : Not expected to adsorb on soil.  
Other organisms relevant to the environment : No data available

##### **Copper(II)sulfate-pentahydrate:**

Toxicity to fish : LC50 (Leuciscus idus (Golden orfe)): 0,8 mg/l  
Exposure time: 96 h  
LC50 (Fish): 0,1 - 2,5 mg/l  
Exposure time: 96 h  
Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 0,024 mg/l  
Exposure time: 48 h  
M-Factor (Acute aquatic toxicity) : 10  
Ecotoxicology Assessment  
Chronic aquatic toxicity : Very toxic to aquatic life with long lasting effects.  
Toxicity Data on Soil : Not expected to adsorb on soil.  
Other organisms relevant to the environment : No data available

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## 12.2 Persistence and degradability

**R1(A / B)**

No data available

**R2 (C)**

No data available

## 12.3 Bioaccumulative potential

**R1(A / B)**

No data available

**R2 (C)**

No data available

## 12.4 Mobility in soil

**R1(A / B)**

No data available

**R2 (C)**

No data available

## 12.5 Results of PBT and vPvB assessment

**R1(A / B)**

Not relevant

**R2 (C)**

Not relevant

## 12.6 Other adverse effects

**R1(A / B)**

No data available

**R2 (C)**

### Components:

#### **Copper(II)sulfate-pentahydrate:**

Additional ecological information

: Remarks: An environmental hazard cannot be excluded in the event of unprofessional handling or disposal.  
Very toxic to aquatic life with long lasting effects.

## SECTION 13: Disposal considerations

### 13.1 Waste treatment methods

Product

: The product should not be allowed to enter drains, water courses or the soil.  
Do not contaminate ponds, waterways or ditches with chemical or used container.  
Send to a licensed waste management company.

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Contaminated packaging : Empty remaining contents.  
Dispose of as unused product.  
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

**ADR** : UN 1824  
**IMDG** : UN 1824  
**IATA** : UN 1824

### 14.2 UN proper shipping name

**ADR** : Sodium hydroxide solution  
**IMDG** : Sodium hydroxide solution  
**IATA** : Sodium hydroxide solution

### 14.3 Transport hazard class(es)

**ADR** : 8  
**IMDG** : 8  
**IATA** : 8

### 14.4 Packing group

**ADR**  
Packing group : III  
Classification Code : C5  
Labels : 8  
Tunnel restriction code : E  
**IMDG**  
Packing group : III  
Labels : 8  
EmS Code : F-A, S-B  
**IATA**  
Packing instruction (cargo aircraft) : 856  
Packing instruction (passenger aircraft) : 852  
Packing instruction (LQ) : Y841  
Packing group : III  
Labels : Corrosives

### 14.5 Environmental hazards

**ADR**  
Environmentally hazardous : no  
**IMDG**  
Marine pollutant : no

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## 14.6 Special precautions for user

Remarks : No data available

## 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

		Quantity 1	Quantity 2
9b	Dangerous for the environment	200 t	500 t

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

E2	ENVIRONMENTAL HAZARDS	200 t	500 t
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Water contaminating class : WGK 2 water endangering (Germany)

### R1(A / B)

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

Hazard pictograms :



Signal word : Warning

Hazard statements	H290	May be corrosive to metals.
	H315	Causes skin irritation.
	H319	Causes serious eye irritation.

Precautionary statements	<b>Prevention:</b>	
	P234	Keep only in original container.
	P264	Wash skin thoroughly after handling.
	P280	Wear eye protection/ face protection.
	P280	Wear protective gloves.
	<b>Response:</b>	
	P337 + P313	If eye irritation persists: Get medical advice/ attention.
	P390	Absorb spillage to prevent material damage.

### R2 (C)

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

Hazard pictograms

:



Signal word

: Warning

Hazard statements

: H290 May be corrosive to metals.  
H315 Causes skin irritation.  
H319 Causes serious eye irritation.  
H411 Toxic to aquatic life with long lasting effects.

Precautionary statements

: **Prevention:**  
P273 Avoid release to the environment.  
P280 Wear eye protection/ face protection.  
P280 Wear protective gloves.  
**Response:**  
P337 + P313 If eye irritation persists: Get medical advice/ attention.  
P390 Absorb spillage to prevent material damage.  
P391 Collect spillage.

## 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

### Full text of R-Phrases

R22 : Harmful if swallowed.  
R35 : Causes severe burns.  
R36/38 : Irritating to eyes and skin.  
R50 : Very toxic to aquatic organisms.  
R53 : May cause long-term adverse effects in the aquatic environment.

### Full text of H-Statements

H290 : May be corrosive to metals.  
H302 : Harmful if swallowed.  
H314 : Causes severe skin burns and eye damage.  
H315 : Causes skin irritation.  
H319 : Causes serious eye irritation.  
H400 : Very toxic to aquatic life.  
H410 : Very toxic to aquatic life with long lasting effects.

### Full text of other abbreviations

Acute Tox. : Acute toxicity  
Aquatic Acute : Acute aquatic toxicity  
Aquatic Chronic : Chronic aquatic toxicity  
Eye Irrit. : Eye irritation  
Met. Corr. : Corrosive to metals  
Skin Corr. : Skin corrosion  
Skin Irrit. : Skin irritation



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## 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.

DE / EN