

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006

Roche

CREJ2

Version
1.7

Revision Date:
18.02.2015

Date of last issue: 03.08.2014
Date of first issue: 25.05.2012

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

1.1 Product identifier

Commercial Product Name : CREJ2
Mat.-No./ Genisys-No. : 04810716190

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 : Danger

Hazard statements : H314 Causes severe skin burns and eye damage.
H412 Harmful to aquatic life with long lasting effects.

Supplemental Hazard Statements : EUH001 Explosive when dry.

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Precautionary statements : **Prevention:**
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response:
P303 + P361 + P353 IF ON SKIN (or hair): Remove/ Take off immediately all contaminated clothing. Rinse skin with water/ shower.
P304 + P340 + P310 IF INHALED: Remove person to fresh air and keep comfortable for breathing. Immediately call a POISON CENTER or doctor/ physician.
P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

Additional Labelling:

EUH210 Safety data sheet available on request.

2.3 Other hazards

See SECTION 3

SECTION 3: Composition/information on ingredients

R1 (B)

Classification (REGULATION (EC) No 1272/2008)

Skin corrosion, Category 1B H314: Causes severe skin burns and eye damage.

Chronic aquatic toxicity, Category 3 H412: Harmful to aquatic life with long lasting effects.

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 (%)
potassium hydroxide	1310-58-3 215-181-3	C; R35 Xn; R22	Met. Corr. 1; H290 Acute Tox. 3; H301 Skin Corr. 1A; H314 Aquatic Chronic 2; H411	>= 2,5 - < 5
tri- potassiumphosphate- monohydrate	27176-10-9 231-907-1	Xi; R41 Xi; R38	Skin Irrit. 2; H315 Eye Dam. 1; H318	>= 1 - < 3
Tripotassium hydrogen ethylenediaminetet- raacetate	65501-24-8 241-543-5	Xi; Xi; R36/37/38 R52/53	Skin Irrit. 2; H315 Eye Irrit. 2; H319 STOT SE 3; H335 Aquatic Chronic 3; H412	>= 1 - < 2,5

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For explanation of abbreviations see section 16.

R2 (C)

Classification (REGULATION (EC) No 1272/2008)

Not a hazardous substance or mixture.

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

R 1: Explosive when dry.

R 4: Forms very sensitive explosive metallic compounds.

Hazardous components

Chemical Name	CAS-No. EC-No. Registration number	Classification (67/548/EEC)	Classification (REGULATION (EC) No 1272/2008)	Concentration (%)
picric acid	88-89-1 201-865-9	E; R 3 R 4 T; R23/24/25	Expl. 1.1; H201 Acute Tox. 3; H301 Acute Tox. 3; H331 Acute Tox. 3; H311 Aquatic Chronic 3; H412	>= 1 - < 2,5

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.

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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.
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.

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6.2 Environmental precautions

Environmental precautions : Prevent product from entering drains.
Prevent further leakage or spillage if safe to do so.
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 : Soak up with inert absorbent material (e.g. sand, silica gel, acid binder, universal binder, sawdust).
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 : 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

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SECTION 8: Exposure controls/personal protection

8.1 Control parameters

R1 (B)

Contains no substances with occupational exposure limit values.

R2 (C)

Occupational Exposure Limits

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
picric acid	88-89-1	TWA	0,1 mg/m ³	91/322/EEC
Further information	Existing scientific data on health effects appear to be particularly limited, Indicative			
		AGW (Inhalable fraction)	0,1 mg/m ³	DE TRGS 900
Peak-limit: excursion factor (category)	1;(I)			
Further information	European Union (The EU has established a limit value: deviations in value and peak limit are possible), Skin absorption, A foundation for the derivation of a limit value is not available.			

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.

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SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

R1 (B)

Appearance	: liquid
Colour	: No data available
Odour	: No data available
Odour Threshold	: No data available
pH	: > 13,5
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	: 1,072 g/cm3 (25 °C)
	1,072 g/cm3 (25 °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	: No data available
Odour Threshold	: No data available

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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	: 1,0004 g/cm3
	1,004 g/cm3
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	: No data available

9.2 Other information

R1 (B)

No data available

R2 (C)

No data available

SECTION 10: Stability and reactivity

10.1 Reactivity

No dangerous reaction known under conditions of normal use.

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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

SECTION 11: Toxicological information

11.1 Information on toxicological effects

R1 (B)

Acute toxicity

Not classified based on available information.

Components:

potassium hydroxide:

Acute oral toxicity : LD50 (Rat): 273 mg/kg

tri-potassiumphosphate-monohydrate:

Acute oral toxicity : LD50 Oral (Rat): 4.500 mg/kg

Acute dermal toxicity : LD50 Dermal (Rabbit): 4.640 mg/kg

Skin corrosion/irritation

Causes severe burns.

Components:

potassium hydroxide:

Remarks: Extremely corrosive and destructive to tissue.

tri-potassiumphosphate-monohydrate:

Result: Irritating to skin.

Remarks: May cause skin irritation in susceptible persons.

Tripotassium hydrogen ethylenediaminetetraacetate:

Result: Irritating to skin.

Remarks: May cause skin irritation in susceptible persons.

Serious eye damage/eye irritation

Causes serious eye damage.

Components:

potassium hydroxide:

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Remarks: May cause irreversible eye damage.

tri-potassiumphosphate-monohydrate:

Remarks: May cause irreversible eye damage.

Tripotassium hydrogen ethylenediaminetetraacetate:

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.

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.

Components:

potassium hydroxide:

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

tri-potassiumphosphate-monohydrate:

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

Tripotassium hydrogen ethylenediaminetetraacetate:

Exposure routes: Inhalation

Assessment: May cause respiratory irritation.

STOT - repeated exposure

Not classified based on available information.

Components:

potassium hydroxide:

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

tri-potassiumphosphate-monohydrate:

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

Tripotassium hydrogen ethylenediaminetetraacetate:

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

Aspiration toxicity

Not classified based on available information.

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Components:

potassium hydroxide:

No data available

tri-potassiumphosphate-monohydrate:

No data available

Tripotassium hydrogen ethylenediaminetetraacetate:

No data available

R2 (C)

Acute toxicity

Components:

picric acid:

Acute oral toxicity : LD50 (Rat): 200 mg/kg

Acute inhalation toxicity : Acute toxicity estimate: > 0,5 mg/l
Test atmosphere: dust/mist
Method: Expert judgement

Acute dermal toxicity : Acute toxicity estimate: 300 mg/kg
Method: Expert judgement

Skin corrosion/irritation

Components:

picric acid:

Remarks: This information is not available.

Serious eye damage/eye irritation

Components:

picric acid:

Remarks: This information is not available.

STOT - single exposure

Components:

picric acid:

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

Aspiration toxicity

Components:

picric acid:

No data available

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SECTION 12: Ecological information

12.1 Toxicity

R1 (B)

Components:

potassium hydroxide:

Toxicity to fish : LC50 (Fish): > 10 mg/l
Exposure time: 96 h

LC50 (Fish): < 100 mg/l
Exposure time: 96 h

LC50 (Gambusia affinis (Mosquito fish)): 80 mg/l
Exposure time: 24 h

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 270 mg/l
Exposure time: 24 h

Ecotoxicology Assessment
Toxicity Data on Soil : Not expected to adsorb on soil.

Other organisms relevant to the environment : No data available

tri-potassiumphosphate-monohydrate:

Ecotoxicology Assessment
Toxicity Data on Soil : Not expected to adsorb on soil.

Other organisms relevant to the environment : No data available

Tripotassium hydrogen ethylenediaminetetraacetate:

Ecotoxicology Assessment
Chronic aquatic toxicity : Harmful 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

R2 (C)

Components:

picric acid:

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): 106 - 114 mg/l
Exposure time: 96 h

LC50 (Lepomis macrochirus (Bluegill sunfish)): 160 - 180 mg/l
Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 80 - 102 mg/l
Exposure time: 48 h

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Toxicity to algae : EC50 (*Desmodesmus subspicatus* (green algae)): 575 mg/l
Exposure time: 72 h

EC50 (*Pseudokirchneriella subcapitata* (microalgae)): 324 mg/l
Exposure time: 72 h

Ecotoxicology Assessment
Toxicity Data on Soil : Not expected to adsorb on soil.

Other organisms relevant to the environment : No data available

12.2 Persistence and degradability

R1 (B)

No data available

R2 (C)

No data available

12.3 Bioaccumulative potential

R1 (B)

No data available

R2 (C)

Components:

picric acid:

Partition coefficient: n-octanol/water : log Pow: 1,33

12.4 Mobility in soil

R1 (B)

No data available

R2 (C)

No data available

12.5 Results of PBT and vPvB assessment

R1 (B)

Not relevant

R2 (C)

Not relevant

12.6 Other adverse effects

R1 (B)

Components:

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tri-potassiumphosphate-monohydrate:

Additional ecological information : Remarks: No data available

Tripotassium hydrogen ethylenediaminetetraacetate:

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

R2 (C)

No data available

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

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 1814
IMDG : UN 1814
IATA : UN 1814

14.2 UN proper shipping name

ADR : Potassium hydroxide solution
IMDG : Potassium hydroxide solution
IATA : Potassium hydroxide solution

14.3 Transport hazard class(es)

ADR : 8
IMDG : 8
IATA : 8

14.4 Packing group

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ADR

Packing group : II
Classification Code : C5
Labels : 8
Tunnel restriction code : E

IMDG

Packing group : II
Labels : 8
EmS Code : F-A, S-B

IATA

Packing instruction (cargo aircraft) : 855
Packing instruction (passenger aircraft) : 851
Packing instruction (LQ) : Y840
Packing group : II
Labels : Corrosives

14.5 Environmental hazards

ADR

Environmentally hazardous : no

IMDG

Marine pollutant : no

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
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 (B)

Labelling (REGULATION (EC) No 1272/2008)

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Hazard pictograms

:



Signal word

: Danger

Hazard statements

: H314
H412

Causes severe skin burns and eye damage.
Harmful to aquatic life with long lasting effects.

Precautionary statements

: **Prevention:**

P273

Avoid release to the environment.

P280

Wear protective gloves/ protective clothing/
eye protection/ face protection.

Response:

P301 + P330 + P331 IF SWALLOWED: Rinse mouth. Do
NOT induce vomiting.

P303 + P361 + P353 IF ON SKIN (or hair): Take off immedi-
ately all contaminated clothing. Rinse skin
with water/shower.

P304 + P340 + P310 IF INHALED: Remove person to fresh
air and keep comfortable for breathing. Im-
mediately call a POISON CENTER or doc-
tor/ physician.

P305 + P351 + P338 IF IN EYES: Rinse cautiously with wa-
ter for several minutes. Remove contact
lenses, if present and easy to do. Continue
rinsing.

Hazardous components which must be listed on the label:

1310-58-3 potassium hydroxide

R2 (C)

Labelling (REGULATION (EC) No 1272/2008)

Supplemental Hazard
Statements

: EUH001

Explosive when dry.

Not a hazardous substance or mixture.

Additional Labelling:

EUH210 Safety data sheet available on request.

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

R 3

: Extreme risk of explosion by shock, friction, fire or other
sources of ignition.

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R 4	: Forms very sensitive explosive metallic compounds.
R22	: Harmful if swallowed.
R23/24/25	: Toxic by inhalation, in contact with skin and if swallowed.
R35	: Causes severe burns.
R36/37/38	: Irritating to eyes, respiratory system and skin.
R38	: Irritating to skin.
R41	: Risk of serious damage to eyes.
R52/53	: Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

Full text of H-Statements

H201	: Explosive; mass explosion hazard.
H290	: May be corrosive to metals.
H301	: Toxic if swallowed.
H311	: Toxic in contact with skin.
H314	: Causes severe skin burns and eye damage.
H315	: Causes skin irritation.
H318	: Causes serious eye damage.
H319	: Causes serious eye irritation.
H331	: Toxic if inhaled.
H335	: May cause respiratory irritation.
H411	: Toxic to aquatic life with long lasting effects.
H412	: Harmful to aquatic life with long lasting effects.

Full text of other abbreviations

Acute Tox.	: Acute toxicity
Aquatic Chronic	: Chronic aquatic toxicity
Expl.	: Explosives
Eye Dam.	: Serious eye damage
Eye Irrit.	: Eye irritation
Met. Corr.	: Corrosive to metals
Skin Corr.	: Skin corrosion
Skin Irrit.	: Skin irritation
STOT SE	: Specific target organ toxicity - single exposure

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