

N-MID Osteocalcin Elecsys cobas e 100

Version 1.3

Revision Date 09-19-2014

Print Date 12-06-2014

SECTION 1. IDENTIFICATION

Product name : N-MID Osteocalcin Elecsys cobas e 100

Mat.-No./ Genisys-No. : 12149133160

Manufacturer or supplier's details

Company name of supplier : Roche Diagnostics

-

Address : 9115 Hague Road
46250 Indianapolis IN

Telephone : 1-800-428-5074

Emergency telephone number:

In case of emergencies: : CHEMTREC 1-800-424-9300 (U.S. or
Canada)
1-703-527-3887 (International)

Recommended use of the chemical and restrictions on use

Restrictions on use : For professional users only.

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification

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.

GHS Label element

Not a hazardous substance or mixture.

Other hazards

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Beads (MP)

GHS Classification

Not a hazardous substance or mixture.

Hazardous components

Chemical Name	CAS-No.	Concentration (%)
sucrose	57-50-1	>= 1 - < 5

R1

GHS Classification

Not a hazardous substance or mixture.

Hazardous components

No hazardous ingredients

N-MID Osteocalcin Elecsys cobas e 100

Version 1.3

Revision Date 09-19-2014

Print Date 12-06-2014

R2**GHS Classification**

Not a hazardous substance or mixture.

Hazardous components

No hazardous ingredients

SECTION 4. 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.
Most important symptoms and effects, both acute and delayed	: No information available.
Notes to physician	: The first aid procedure should be established in consultation with the doctor responsible for industrial medicine.

SECTION 5. FIREFIGHTING MEASURES

Suitable extinguishing media	: Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Specific hazards during firefighting	: No information available.
Further information	: Standard procedure for chemical fires. Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Special protective equipment for firefighters	: Wear self-contained breathing apparatus for firefighting if necessary.

SECTION 6. ACCIDENTAL RELEASE MEASURES

N-MID Osteocalcin Elecsys cobas e 100

Version 1.3

Revision Date 09-19-2014

Print Date 12-06-2014

Personal precautions, protective equipment and emergency procedures : Refer to protective measures listed in sections 7 and 8.

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

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

SECTION 7. HANDLING AND STORAGE

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

Conditions for safe storage : Electrical installations / working materials must comply with the technological safety standards.

Materials to avoid : No materials to be especially mentioned.

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Beads (MP)

Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
sucrose	57-50-1	TWA	10 mg/m ³	ACGIH
		TWA (Respirable)	5 mg/m ³	NIOSH REL
		TWA (total)	10 mg/m ³	NIOSH REL
		TWA (total dust)	15 mg/m ³	OSHA Z-1
		TWA (respirable fraction)	5 mg/m ³	OSHA Z-1
		TWA (Total dust)	15 mg/m ³	OSHA P0
		TWA (respirable dust fraction)	5 mg/m ³	OSHA P0

R1

Components with workplace control parameters

Contains no substances with occupational exposure limit values.

R2

Components with workplace control parameters

Contains no substances with occupational exposure limit values.

Personal protective equipment

N-MID Osteocalcin Elecsys cobas e 100

Version 1.3

Revision Date 09-19-2014

Print Date 12-06-2014

Respiratory protection	: No personal respiratory protective equipment normally required.
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.
Eye protection	: Safety glasses
Skin and body protection	: Protective suit
Hygiene measures	: Handle in accordance with good industrial hygiene and safety practice.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES
Beads (MP)

Appearance	: liquid
Colour	: colourless
Odour	: none
pH	: 7.4
Melting point/range	: No data available
Boiling point/boiling range	: No data available
Flash point	: does not flash
Upper explosion limit	: No data available
Lower explosion limit	: No data available
Density	: 1.01 g/cm ³ (20 °C)
Solubility(ies)	
Water solubility	: completely miscible
Auto-ignition temperature	: No data available
Thermal decomposition	: No data available
Oxidizing properties	: The substance or mixture is not classified as oxidizing.

N-MID Osteocalcin Elecsys cobas e 100

Version 1.3

Revision Date 09-19-2014

Print Date 12-06-2014

R1

Appearance	: liquid
Colour	: colourless
Odour	: none
pH	: 6.0
Melting point/range	: No data available
Boiling point/boiling range	: No data available
Flash point	: does not flash
Flammability (solid, gas)	: The product is not flammable.
Upper explosion limit	: No data available
Lower explosion limit	: No data available
Density	: 1.03 g/cm ³
Solubility(ies)	
Water solubility	: completely miscible
Auto-ignition temperature	: No data available
Thermal decomposition	: No data available
Oxidizing properties	: The substance or mixture is not classified as oxidizing.

R2

Appearance	: liquid
Odour	: none
pH	: 6.0
Melting point/range	: No data available
Boiling point/boiling range	: No data available
Flash point	: does not flash
Flammability (solid, gas)	: The product is not flammable.
Upper explosion limit	: No data available
Lower explosion limit	: No data available
Density	: 1.03 g/cm ³
Solubility(ies)	
Water solubility	: completely miscible

N-MID Osteocalcin Elecsys cobas e 100

Version 1.3

Revision Date 09-19-2014

Print Date 12-06-2014

Auto-ignition temperature	: No data available
Thermal decomposition	: No data available
Oxidizing properties	: The substance or mixture is not classified as oxidizing.

SECTION 10. STABILITY AND REACTIVITY

Reactivity	: No dangerous reaction known under conditions of normal use.
Chemical stability	: Stable under normal conditions.
Possibility of hazardous reactions	: Stable under recommended storage conditions. No hazards to be specially mentioned.
Conditions to avoid	: No data available
Incompatible materials	: No data available
Hazardous decomposition products	: No data available

SECTION 11. TOXICOLOGICAL INFORMATION

Beads (MP)

Information on likely routes of exposure

Acute toxicity

Not classified based on available information.

Product:

Acute oral toxicity	: Acute toxicity estimate : > 5,000 mg/kg Method: Calculation method
---------------------	---

Components:

sucrose:

Acute oral toxicity	: LD50 Oral (Rat): 29,700 mg/kg LD50 Oral (Mouse): 14,000 mg/kg
Acute inhalation toxicity	: Acute toxicity estimate : > 30 mg/l Method: Expert judgement
Acute dermal toxicity	: Acute toxicity estimate : > 5,001 mg/kg Method: Expert judgement

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.

N-MID Osteocalcin Elecsys cobas e 100

Version 1.3

Revision Date 09-19-2014

Print Date 12-06-2014

Respiratory sensitisation: Not classified based on available information.

Germ cell mutagenicity

Not classified based on available information.

Carcinogenicity

Not classified based on available information.

IARC

No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

ACGIH

No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by ACGIH.

OSHA

No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by OSHA.

NTP

No component of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

Reproductive toxicity

Not classified based on available information.

STOT - single exposure

Not classified based on available information.

Product:

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

Components:**sucrose:**

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

STOT - repeated exposure

Not classified based on available information.

Product:

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

Components:**sucrose:**

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

Aspiration toxicity

Not classified based on available information.

Components:**sucrose:**

N-MID Osteocalcin Elecsys cobas e 100

Version 1.3

Revision Date 09-19-2014

Print Date 12-06-2014

No data available

Further information**Components:****sucrose:**

Remarks: Health injuries are not known or expected under normal use.

R1**Information on likely routes of exposure****Acute toxicity**

Not classified based on available information.

Product:

Acute oral toxicity : Acute toxicity estimate : > 5,000 mg/kg
Method: Calculation method

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.

IARC

No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

ACGIH

No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by ACGIH.

OSHA

No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by OSHA.

NTP

No component of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

Reproductive toxicity

Not classified based on available information.

STOT - single exposure

Not classified based on available information.

N-MID Osteocalcin Elecsys cobas e 100

Version 1.3

Revision Date 09-19-2014

Print Date 12-06-2014

STOT - repeated exposure

Not classified based on available information.

Aspiration toxicity

Not classified based on available information.

R2**Information on likely routes of exposure****Acute toxicity**

Not classified based on available information.

Product:

Acute oral toxicity : Acute toxicity estimate : > 5,000 mg/kg
Method: Calculation method

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.

IARC

No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

ACGIH

No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by ACGIH.

OSHA

No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by OSHA.

NTP

No component of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

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.

N-MID Osteocalcin Elecsys cobas e 100

Version 1.3

Revision Date 09-19-2014

Print Date 12-06-2014

SECTION 12. ECOLOGICAL INFORMATION
Beads (MP)
Ecotoxicity
Product:

Ecotoxicology Assessment

Toxicity Data on Soil

: Not expected to adsorb on soil.

Components:
sucrose:

Toxicity to fish

: LC50: > 100 mg/l
Exposure time: 96 hToxicity to fish (Chronic
toxicity)

: > 1 mg/l

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

Persistence and degradability

No data available

Bioaccumulative potential
Components:
sucrose:
Partition coefficient: n-
octanol/water

: log Pow: -3.67

Mobility in soil

No data available

Other adverse effects

No data available

Product:

Regulation

40 CFR Protection of Environment; Part 82 Protection of
Stratospheric Ozone - CAA Section 602 Class I Substances

Remarks

This product neither contains, nor was manufactured with a
Class I or Class II ODS as defined by the U.S. Clean Air Act
Section 602 (40 CFR 82, Subpt. A, App.A + B).
R1

N-MID Osteocalcin Elecsys cobas e 100

Version 1.3

Revision Date 09-19-2014

Print Date 12-06-2014

Ecotoxicity

Product:

Ecotoxicology Assessment

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

Other organisms relevant to the environment : No data available

Persistence and degradability

No data available

Bioaccumulative potential

No data available

Mobility in soil

No data available

Other adverse effects

No data available

Product:

Regulation

40 CFR Protection of Environment; Part 82 Protection of Stratospheric Ozone - CAA Section 602 Class I Substances

Remarks

This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A + B).

R2

Ecotoxicity

Product:

Ecotoxicology Assessment

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

Other organisms relevant to the environment : No data available

Persistence and degradability

No data available

Bioaccumulative potential

No data available

Mobility in soil

No data available

Other adverse effects

No data available

Product:

Regulation

40 CFR Protection of Environment; Part 82 Protection of Stratospheric Ozone - CAA Section 602 Class I Substances

Remarks

This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act

N-MID Osteocalcin Elecsys cobas e 100

Version 1.3

Revision Date 09-19-2014

Print Date 12-06-2014

Section 602 (40 CFR 82, Subpt. A, App.A + B).

SECTION 13. DISPOSAL CONSIDERATIONS**Disposal methods**

Waste from residues : 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**International Regulation****IATA-DGR**

Not regulated as a dangerous good

IMDG-Code

Not regulated as a dangerous good

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

Not applicable for product as supplied.

National Regulations**49 CFR**

Not regulated as a dangerous good

SECTION 15. REGULATORY INFORMATION***Beads (MP)*****EPCRA - Emergency Planning and Community Right-to-Know Act****CERCLA Reportable Quantity**

This material does not contain any components with a CERCLA RQ.

SARA 304 Extremely Hazardous Substances Reportable Quantity

This material does not contain any components with a section 304 EHS RQ.

SARA 302

: No chemicals in this material are subject to the reporting requirements of SARA Title III, Section 302.

SARA 313

: This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

Clean Air Act

This product does not contain any hazardous air pollutants (HAP), as defined by the U.S. Clean Air Act Section 12 (40 CFR 61).

This product does not contain any chemicals listed under the U.S. Clean Air Act Section 112(r) for Accidental Release Prevention (40 CFR 68.130, Subpart F).

N-MID Osteocalcin Elecsys cobas e 100

Version 1.3

Revision Date 09-19-2014

Print Date 12-06-2014

This product does not contain any chemicals listed under the U.S. Clean Air Act Section 111 SOCMI Intermediate or Final VOC's (40 CFR 60.489).

Clean Water Act

This product does not contain any Hazardous Substances listed under the U.S. Clean Water Act, Section 311, Table 116.4A.

This product does not contain any Hazardous Chemicals listed under the U.S. Clean Water Act, Section 311, Table 117.3.

This product does not contain any toxic pollutants listed under the U.S. Clean Water Act Section 307

Massachusetts Right To Know

No components are subject to the Massachusetts Right to Know Act.

Pennsylvania Right To Know

water	7732-18-5	90 - 100 %
sucrose	57-50-1	1 - 5 %

New Jersey Right To Know

water	7732-18-5	90 - 100 %
sucrose	57-50-1	1 - 5 %
4-(2-hydroxyethyl)piperazin-1-ylethanesulphonic acid	7365-45-9	1 - 5 %

California Prop 65 : This product does not contain any chemicals known to State of California to cause cancer, birth defects, or any other reproductive harm.

R1

EPCRA - Emergency Planning and Community Right-to-Know Act

CERCLA Reportable Quantity

Components	CAS-No.	Component RQ (lbs)	Calculated product RQ (lbs)
Sodium phosphate dibasic dihydrate	10028-24-7	5000	*

*: Calculated RQ exceeds reasonably attainable upper limit.

SARA 304 Extremely Hazardous Substances Reportable Quantity

This material does not contain any components with a section 304 EHS RQ.

SARA 302 : No chemicals in this material are subject to the reporting requirements of SARA Title III, Section 302.

SARA 313 : This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

Clean Air Act

This product does not contain any hazardous air pollutants (HAP), as defined by the U.S. Clean Air Act Section 12 (40 CFR 61).

This product does not contain any chemicals listed under the U.S. Clean Air Act Section 112(r) for Accidental Release Prevention (40 CFR 68.130, Subpart F).

This product does not contain any chemicals listed under the U.S. Clean Air Act Section 111 SOCMI Intermediate or Final VOC's (40 CFR 60.489).

Clean Water Act

N-MID Osteocalcin Elecsys cobas e 100

Version 1.3

Revision Date 09-19-2014

Print Date 12-06-2014

The following Hazardous Substances are listed under the U.S. CleanWater Act, Section 311, Table 116.4A:

Sodium phosphate dibasic dihydrate	10028-24-7	0.7 %
------------------------------------	------------	-------

The following Hazardous Chemicals are listed under the U.S. CleanWater Act, Section 311, Table 117.3:

Sodium phosphate dibasic dihydrate	10028-24-7	0.7 %
------------------------------------	------------	-------

This product does not contain any toxic pollutants listed under the U.S. Clean Water Act Section 307

Massachusetts Right To Know

No components are subject to the Massachusetts Right to Know Act.

Pennsylvania Right To Know

water	7732-18-5	90 - 100 %
Sodium phosphate dibasic dihydrate	10028-24-7	0.1 - 1 %

New Jersey Right To Know

water	7732-18-5	90 - 100 %
Albumins, blood serum	9048-46-8	1 - 5 %

California Prop 65 : This product does not contain any chemicals known to State of California to cause cancer, birth defects, or any other reproductive harm.

R2

EPCRA - Emergency Planning and Community Right-to-Know Act

CERCLA Reportable Quantity

Components	CAS-No.	Component RQ (lbs)	Calculated product RQ (lbs)
Sodium phosphate dibasic dihydrate	10028-24-7	5000	*

*: Calculated RQ exceeds reasonably attainable upper limit.

SARA 304 Extremely Hazardous Substances Reportable Quantity

This material does not contain any components with a section 304 EHS RQ.

SARA 302 : No chemicals in this material are subject to the reporting requirements of SARA Title III, Section 302.

SARA 313 : This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

Clean Air Act

This product does not contain any hazardous air pollutants (HAP), as defined by the U.S. Clean Air Act Section 12 (40 CFR 61).

This product does not contain any chemicals listed under the U.S. Clean Air Act Section 112(r) for Accidental Release Prevention (40 CFR 68.130, Subpart F).

This product does not contain any chemicals listed under the U.S. Clean Air Act Section 111 SOCMI Intermediate or Final VOC's (40 CFR 60.489).

Clean Water Act

N-MID Osteocalcin Elecsys cobas e 100

Version 1.3

Revision Date 09-19-2014

Print Date 12-06-2014

The following Hazardous Substances are listed under the U.S. CleanWater Act, Section 311, Table 116.4A:

Sodium phosphate dibasic dihydrate	10028-24-7	0.7 %
------------------------------------	------------	-------

The following Hazardous Chemicals are listed under the U.S. CleanWater Act, Section 311, Table 117.3:

Sodium phosphate dibasic dihydrate	10028-24-7	0.7 %
------------------------------------	------------	-------

This product does not contain any toxic pollutants listed under the U.S. Clean Water Act Section 307

Massachusetts Right To Know

No components are subject to the Massachusetts Right to Know Act.

Pennsylvania Right To Know

water	7732-18-5	90 - 100 %
Sodium phosphate dibasic dihydrate	10028-24-7	0.1 - 1 %

New Jersey Right To Know

water	7732-18-5	90 - 100 %
Albumins, blood serum	9048-46-8	1 - 5 %

California Prop 65

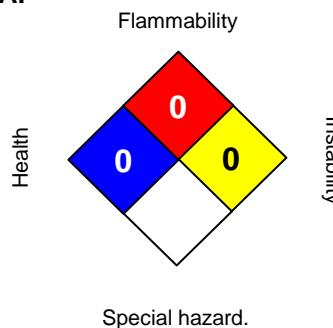
: This product does not contain any chemicals known to State of California to cause cancer, birth defects, or any other reproductive harm.

SECTION 16. OTHER INFORMATION

Further information

Beads (MP)

NFPA:



HMIS III:

HEALTH	0
FLAMMABILITY	0
PHYSICAL HAZARD	0

0 = not significant, 1 =Slight,
2 = Moderate, 3 = High
4 = Extreme, * = Chronic

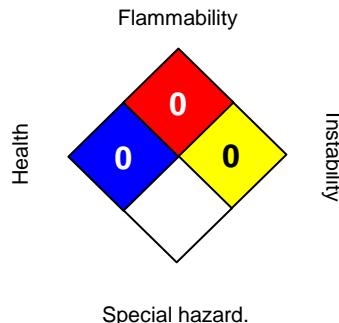
R1

N-MID Osteocalcin Elecsys cobas e 100

Version 1.3

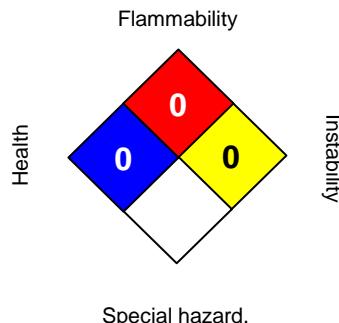
Revision Date 09-19-2014

Print Date 12-06-2014

NFPA:**HMIS III:**

HEALTH	0
FLAMMABILITY	0
PHYSICAL HAZARD	0

0 = not significant, 1 =Slight,
 2 = Moderate, 3 = High
 4 = Extreme, * = Chronic

R2**NFPA:****HMIS III:**

HEALTH	0
FLAMMABILITY	0
PHYSICAL HAZARD	0

0 = not significant, 1 =Slight,
 2 = Moderate, 3 = High
 4 = Extreme, * = Chronic

Revision Date

: 09-19-2014

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.