

Version 1.3 Revision Date 09-18-2014 Print Date 12-06-2014

SECTION 1. IDENTIFICATION

Product name : HSV-2 IgG

Mat.-No./ Genisys-No. : 05572193160

Chemical nature : Handle as potentially infectious.

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

Hazard pictograms



Signal word : Danger

Hazard statements : H317 May cause an allergic skin reaction.

H334 May cause allergy or asthma symptoms or breathing

difficulties if inhaled.

Precautionary statements : **Prevention:**

P261 Avoid breathing dust/ fume/ gas/ mist/ vapours/ spray.
P272 Contaminated work clothing should not be allowed out of

the workplace.

P280 Wear protective gloves.

P285 In case of inadequate ventilation wear respiratory

protection. **Response:**

P302 + P352 IF ON SKIN: Wash with plenty of soap and water. P304 + P341 IF INHALED: If breathing is difficult, remove victim

to fresh air and keep at rest in a position comfortable for

breathing.



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P333 + P313 If skin irritation or rash occurs: Get medical advice/

attention.

P342 + P311 If experiencing respiratory symptoms: Call a

POISON CENTER or doctor/ physician.

P363 Wash contaminated clothing before reuse.

Disposal:

P501 Dispose of contents/ container to an approved waste

disposal plant.

Other hazards

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

R1/R2

GHS Classification

Not a hazardous substance or mixture.

Hazardous components

No hazardous ingredients

Beads (MP)

GHS Classification

Not a hazardous substance or mixture.

Hazardous components

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

Cal 1 / Cal 2

GHS Classification

Respiratory sensitisation, Category 1 H334: May cause allergy or asthma symptoms or

breathing difficulties if inhaled.

Skin sensitisation, Category 1 H317: May cause an allergic skin reaction.

Chemical nature : Handle as potentially infectious.

Hazardous components

Chemical Name	CAS-No.	Concentration (%)
2-methyl-2H-isothiazol-3-one hydrochloride	26172-54-3	>= 0.1 - < 1

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.



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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

Personal precautions, protective equipment and emergency procedures

: Avoid dust formation.

Environmental precautions : Local authorities should be advised if significant spillages

cannot be contained.

Methods and materials for

containment and cleaning up

: Pick up and arrange disposal without creating dust.

Sweep up and shovel.

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.



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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

R1/R2

Components with workplace control parameters

Contains no substances with occupational exposure limit values.

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/m3	ACGIH
		TWA	5 mg/m3	NIOSH REL
		(Respirable)		
		TWA (total)	10 mg/m3	NIOSH REL
		TWA (total	15 mg/m3	OSHA Z-1
		dust)		
		TWA (respirable fraction)	5 mg/m3	OSHA Z-1
		TWA (Total dust)	15 mg/m3	OSHA P0
		TWA (respirable dust fraction)	5 mg/m3	OSHA P0

Cal 1 / Cal 2

Components with workplace control parameters

Contains no substances with occupational exposure limit values.

Personal protective equipment

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.

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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

R1/R2

Appearance : liquid

Colour : colourless

Odour : none

pH : 6.5

Melting point/range : No data available

Boiling point/boiling range : No data available

Flash point : No data available

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

Upper explosion limit : No data available

Lower explosion limit : No data available

Density : 1.008 g/cm3

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.

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



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Upper explosion limit : No data available

Lower explosion limit : No data available

Density : 1.01 g/cm3 (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.

Cal 1 / Cal 2

Appearance : solid

Colour : light yellow

Odour : none

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

Solubility(ies)

Water solubility : soluble

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

No hazards to be specially mentioned.

Stable under recommended storage conditions.

reactions

Conditions to avoid : No data available

Incompatible materials : No data available



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Hazardous decomposition

products

: No data available

SECTION 11. TOXICOLOGICAL INFORMATION

R1/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.



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Aspiration toxicity

Not classified based on available 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.

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.



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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:

No data available

Further information

Components:

sucrose:

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

Cal 1 / Cal 2

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.

Components:



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2-methyl-2H-isothiazol-3-one hydrochloride:

Result: Causes burns.

Serious eye damage/eye irritation

Not classified based on available information.

Respiratory or skin sensitisation

Skin sensitisation: May cause an allergic skin reaction.

Respiratory sensitisation: May cause allergy or asthma symptoms or breathing difficulties if

inhaled.

Components:

2-methyl-2H-isothiazol-3-one hydrochloride:

Assessment: May cause sensitisation by skin contact.

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.

OSHANo 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.

SECTION 12. ECOLOGICAL INFORMATION

R1/R2

Ecotoxicity

Product:



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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).

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 h

Toxicity to fish (Chronic

toxicity)

: > 1 mg/l

Ecotoxicology Assessment

Acute aguatic 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



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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).

Cal 1 / Cal 2

Ecotoxicity

Product:

Ecotoxicology Assessment

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

Other organisms relevant to

the environment

: No data available

Components:

2-methyl-2H-isothiazol-3-one hydrochloride:

Ecotoxicology Assessment

Acute aquatic toxicity : This product has no known ecotoxicological effects.

Chronic aquatic toxicity : This product has no known ecotoxicological effects.

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



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

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods

Waste from residues : Special treatment as infectious material is mandatory in

compliance with local regulations (disinfection and

incineration).

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

R1/R2

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).



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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

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

This product does not contain any Hazardous Chemicals listed under the U.S. CleanWater 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 %

New Jersey Right To Know

water 7732-18-5 90 - 100 %

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.

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).

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. CleanWater Act, Section 311, Table 116.4A.

This product does not contain any Hazardous Chemicals listed under the U.S. CleanWater 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



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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 7365-45-9
 1 - 5 %

 ylethanesulphonic acid
 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.

Cal 1 / Cal 2

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).

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. CleanWater Act, Section 311, Table 116.4A.

This product does not contain any Hazardous Chemicals listed under the U.S. CleanWater 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

Human serum /-plasma / -hemolysate, liquid Not Assigned 90 - 100 % 4-(2-hydroxyethyl)piperazin-1- 7365-45-9 5 - 10 % ylethanesulphonic acid

New Jersey Right To Know



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> Human serum /-plasma / -hemolysate, liquid Not Assigned 90 - 100 % 4-(2-hydroxyethyl)piperazin-1-7365-45-9 5 - 10 % ylethanesulphonic acid

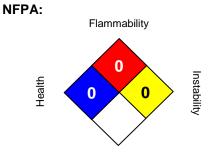
California Prop 65

: 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

R1/R2



Special hazard.

HMIS III:

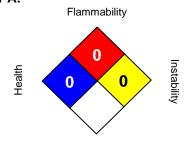
HEALTH	0
FLAMMABILITY	0
PHYSICAL HAZARD	0

0 = not significant, 1 =Slight,

2 = Moderate, 3 = High

4 = Extreme, * = Chronic

Beads (MP) NFPA:



Special hazard.

HMIS III:

HEALTH	0
FLAMMABILITY	0
PHYSICAL HAZARD	0

0 = not significant, 1 = Slight,

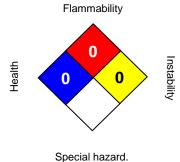
2 = Moderate, 3 = High 4 = Extreme, * = Chronic

Cal 1 / Cal 2



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NFPA:



HMIS III:

HEALTH	0
FLAMMABILITY	0
PHYSICAL HAZARD	0

0 = not significant, 1 = Slight,

2 = Moderate, 3 = High 4 = Extreme, * = Chronic

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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.