

Safety Data Sheet
Malic acid



Revision 8

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

1.1. Product identifier

Commercial name: **Malic acid**
REACH registration number: 01-2119906954-31-0000
Index number: NOT AVAILABLE
International Chemical Identification: Malic acid
CAS number: 6915-15-7
EC number: 230-022-8

Distributed By:



2 Madison Ave. Larchmont, NY 10538
Ph: 914-834-1881 Fax: 914-834-4611

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

Industrial use:

Intermediates, mixtures and formulated, pH-regulating agents.

Professional use:

Mixtures and formulated, pH-regulating agents, fertilizers, metal surface treatment products, non - metal surface treatment products, flocculant agents, precipitants, neutralization agents, disinfectants, Washing and cleaning products, cosmetics, personal care products, water softeners, water treatment chemicals, Laboratory chemicals.

Consumers use:

Food/feed additives, Cosmetic products, personal care products, Water softeners, Disinfectant, Washing and cleaning products, disinfectant solutions for hemodialysis equipment,

1.3. Details of the supplier of the safety data sheet

Producer: Polynt S.p.A.
Via Enrico Fermi 51
24020 Scanzorosciate (BG)
ITALY
Telephone number: +39 035 652 111
msds@polynt.com

Supplier: Polynt S.p.A.
Via Enrico Fermi 51
24020 Scanzorosciate (BG)
ITALY
Telephone number: +39 035 652 111

1.4. Emergency telephone number

+39 035 652 276

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Reg CE 1272/2008

Hazard statement Code(s)

Serious eye damage/eye irritation
H319: Causes serious eye irritation.

Hazard Class and Category Code(s)

Eye Irrit. 2

Reg CE 548/1967 o Reg CE 45/1999

Xi - Irritant; R36 - Irritating to eyes.

2.2. Label elements

Labelling according to Regulation 1272/2008/EC.

Contains: Malic acid
INDEX N° Not available

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CAS N° 6915-15-7

EC N° 230-022-8

Pictograms:



WARNING

Hazard statement:

H319: Causes serious eye irritation.

Precautionary statements:

P264: Wash eyes thoroughly after handling.

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

P280: Wear protective gloves/eye protection/face protection. (see MSDS).

P337+P313: If eye irritation persists: Get medical advice/attention.

(*)2.3. Other hazards

Dust explosion hazards (See Section 9.2)

SECTION 3: Composition/information on ingredients

3.1. Substances

Malic acid

International Chemical Identification: Malic acid

Index No: NOT AVAILABLE

Chemical formula: C4H6O5

Concentration range: >= 99,0 %

Registration number: 01-2119906954-31-0000

CAS No: 6915-15-7

EC No: 230-022-8

SECTION 4: First aid measures

4.1. Description of first aid measures

Inhalation:

Remove to fresh air. If breathing is irregular or stopped, administer artificial respiration.

Skin:

After contact with skin, wash immediately with plenty of soap and water. Consult a physician.

Eye:

In the case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

Call a physician immediately.

Ingestion:

Call a physician immediately. Clean mouth with water. Do not induce vomiting without medical advice. Never give anything by mouth to an unconscious person.

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

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Irritating to eyes and skin.

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

See section 4.1.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Appropriate fire-fighting equipment:

Foam, powder, water spray.

Inappropriate fire-fighting equipment

Do not use water jets as they can disperse and spread fire.

5.2. Special hazards arising from the substance or mixture

In combustion emits toxic fumes of carbon dioxide / carbon monoxide.

5.3. Advice for firefighters

In the event of fire, wear self-contained breathing apparatus.

Water mist may be used to cool closed containers.

Use personal protective equipment to protect skin/eyes.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Move any people not authorised to contain the emergency out of the area.

Avoid coming in contact with the substance or handling containers without adequate protection.

Use the personal protective equipment described in section 8.

Use a respirator in the event of emissions/spillage of large quantities.

Eliminate all sources of ignition.

Remove all incompatible materials as outlined in section 10.5 of SDS.

Avoid dust formation.

6.2. Environmental precautions

Contain the spillage as far as possible.

Prevent spilled materials getting into the drainage system, wells, surface water or groundwater.

In the case of leaks into a water course, drains, or if the product has contaminated the ground or vegetation, contact the local authorities.

6.3. Methods and material for containment and cleaning up

Do not use equipment that can generate sources of ignition when cleaning. Clean the spilled material mechanically and put it in an appropriate container for disposal in accordance with section 13. After collection, ventilate and clean the affected area with water before granting access. Do not flush the water used for cleaning into watercourses or down drains.

6.4. Reference to other sections

See sections 8 and 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Recommendations for safe use:

Provide sufficient air exchange and/or exhaust in work rooms.

Avoid contact with skin and eyes.

Avoid accumulation of electrostatic charges, to prevent risk of powders exploding.

Avoid formation of respirable particles.

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Advice on general occupational hygiene:

Do not eat, drink or smoke when using this product.
Wash face and hands thoroughly after handling.
Take off contaminated clothing and wash before reuse.

7.2. Conditions for safe storage, including any incompatibilities

Eliminate all sources of combustion.
Keep container hermetically closed in a dry and well ventilated environment.
Avoid the formation of dust.
Keep away from incompatible materials (see point 10.5).
Keep away from food, feed and beverages.

7.3. Specific end use(s)

None identified.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

DERIVED NO EFFECT LEVEL (DNEL) / DERIVED MINIMUM EFFECT LEVEL (DMEL) :

Workers:

Short-term systemic effects:

Inhalation: DNEL: 8,8 mg/m³ Assessment factor 50
Dermal: DNEL: 40 mg/kg bw/day Assessment factor 50

Long-term systemic effects:

Inhalation: DNEL: 10,6 mg/m³ Assessment factor 50
Dermal: DNEL: 12 mg/kg bw/day Assessment factor 50

General population:

Short-term systemic effects:

Oral: DNEL 20 mg/kg bw/day Assessment factor 100
Inhalation: DNEL 2,2 mg/m³ Assessment factor 100
Dermal: DNEL 20 mg/kg bw/day Assessment factor 100

Long-term systemic effects:

Oral: DNEL 6 mg/kg bw/day Assessment factor 100
Inhalation: DNEL 2,6 mg/m³ Assessment factor 100
Dermal: DNEL 6 mg/kg bw/day Assessment factor 100

PREDICTED NO EFFECT CONCENTRATION (PNEC) :

Environment:

Water:

PNEC water (freshwater): 0.1 mg/L Assessment factor 1000
PNEC water (marine water): 0.01 mg/L Assessment factor 10000
PNEC water (intermittent releases): 1 mg/L Assessment factor 100

Soil:

PNEC soil: 0.275 mg/kg soil dw

Sediment:

PNEC sediment (freshwater): 0.275 mg/kg sediment dw
PNEC sediment (marine water): 0.027 mg/kg sediment dw

STP:

PNEC STP: 3 mg/L Assessment factor 100

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Occupational Exposure limit values:

National: Undetermined

European: Undetermined

8.2. Exposure controls

Appropriate engineering controls:

See annexe of this file.

Eye / face protection:

Goggles or protective visor.

Skin protection / of the Hand:

The material the gloves are made of must be impermeable and stable when in contact with the substance. No specific information available on the suitability of the material and thickness of the gloves. Consult the glove manufacturer for specific information on the suitability of the gloves. Replace the gloves in the case of internal contamination, when punctured, or if external contamination cannot be removed. The actual duration of protection depends on the conditions of use.

Skin protection / of the body:

Use suitable protective clothing for chemical substances.

Respiratory protection:

Mask with P3 dust filter if solid or type A filter for vapours and organic gases with a boiling point > 65°C if molten. (EN 149)

Environmental exposure controls:

See annexe of this file.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

a1) **Appearance:** Solid crystalline powder

a2) **Color:** White

b) **Odour:** Characteristics

c) **Odour threshold:** NOT AVAILABLE

d) **pH:** NOT AVAILABLE

e1) **Melting point:** 131 °C @ 1013 hPa

f1) **Initial boiling point:** NOT APPLICABLE

g) **Flash point:** NOT AVAILABLE

h) **Evaporation rate:** NOT APPLICABLE

i) **Flammability (solid, gas):** Not flammable

j1) **Upper flammability limits:** NOT AVAILABLE

j2) **Lower flammability limits:** NOT AVAILABLE

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- j3) Upper explosive limits: NOT AVAILABLE
- j4) Lower explosive limits: 187.5 g/m³
- k) Vapour pressure: 0.00039 Pa @ 25°C
- l) Vapour density: NOT AVAILABLE
- m) Relative density: 1.615 @ 20°C
- n) Water solubility: 647 g/l @ 20°C
- o) Partition coefficient: n-octanol/water: -1.26 @ 25°C
- p) Auto-ignition temperature: NOT AVAILABLE
- q) Decomposition temperature: NOT AVAILABLE
- r) Viscosity: NOT APPLICABLE
- s) Explosive properties: NOT EXPLOSIVE
- t) Oxidising properties: NOT OXIDIZING

(*)9.2. Other information

Parameters:

Test Results:

Sample Characterisation:

Particle Size Distribution of sample (µm): =< 70
Moisture content (%): 0.12

Dust Explosion risk:

Minimum Ignition Energy (MIE), (mJ):
Without inductance (Electrostatic) (<25 µH): > 1000
With inductance (Mechanical) (1mH): 80-100

Explosion severity (20 litre sphere):

Maximum explosion pressure P_{max} (barg): 6.4 at 2375 g/m³
(dP/dt)_{max} (bar/s): 256 at 2167 g/m³
K_{st} value (bar.m/s): 69
St class: 1
Ambient Temperature (°C): 20

SECTION 10: Stability and reactivity

10.1. Reactivity

Stable under normal conditions.

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

None known in normal conditions.

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10.4. Conditions to avoid

Avoid the build-up of electrostatic charges.
Avoid exposure to heat sources.
Avoid the formation of dust.

10.5. Incompatible materials

Oxidizing agents, alkalis, alkali metals, amines and carbonates.
Unsuitable container materials: iron, zinc, aluminium. Aqueous solutions of Malic Acid can release explosive hydrogen gas if in contact with these active metals.

10.6. Hazardous decomposition products

Unknown

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity:

Oral:

Method:

equivalent or similar to OECD Guideline 401 (Acute Oral Toxicity)
rat (Wistar) male/female oral: gavage

Results:

LD50: 3500 mg/kg bw based on: test mat.

Inhalation:

Method:

Read-across from supporting substance (structural analogue or surrogate)
OECD Guideline 403 (Acute Inhalation Toxicity)
EU Method B.2 (Acute Toxicity (Inhalation))
rat (Sprague-Dawley) male/female, Inhalation: dust (nose only)

Results:

LC50 (4h): 1306 mg/m³ air based on: test mat.

Dermal:

Method:

Read-across from supporting substance (structural analogue or surrogate)
Others. Rabbit(New Zealand White) Coverage: occlusive.

Results:

LD50: 20000 mg/kg bw

Conclusions: not classified

Skin corrosion/irritation:

Method:

Read-across from supporting substance (structural analogue or surrogate)
OECD Guideline 404 (Acute Dermal Irritation / Corrosion)
Rabbit(small white Russian); Coverage: occlusive (shaved)

Results:

Slightly irritating

Serious eye damage/eye irritation:

Method:

Read-across from supporting substance (structural analogue or surrogate)
OECD Guideline 405 (Acute Eye Irritation / Corrosion) Rabbit(small white Russian)

Results:

Irritating Category 2

Respiratory or skin sensitisation:

Respiratory Sensitisation: Not available

Skin Sensitisation:

Method:

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Read-across from supporting substance (structural analogue or surrogate)
OECD Guideline 406 (Skin Sensitisation) guinea pig (Dunkin-Hartley) female,
Induction: intradermal and epicutaneous.

Results:

Not sensitising

Germ cell mutagenicity:

In vitro:

Bacterial reverse mutation assay (e.g. Ames test) (gene mutation).

Method:

equivalent or similar to OECD Guideline 471 (Bacterial Reverse Mutation Assay)
S. typhimurium TA 1535, TA 1537, TA 98 and TA 100, S. typhimurium, other:
TA 92 and TA 94. (met. act.: with and without).

Results: negative.

Mammalian cell gene mutation assay (gene mutation).

Method:

OECD Guideline 476 (In vitro Mammalian Cell Gene Mutation Test).
mouse lymphoma L5178Y cells. (met. act.: with and without).

Results: negative.

Mammalian chromosome aberration test (chromosome aberration):

Method:

equivalent or similar to OECD Guideline 473 (In vitro Mammalian Chromosome
Aberration Test). Chinese hamster lung fibroblasts (V79) (met. act.: without)

Results: negative.

Carcinogenicity: not available

Reproductive toxicity:

Effects on sexual function and fertility:

Oral:

Method:

equivalent or similar to OECD Guideline 416 (Two-Generation Reproduction
Toxicity Study); rat male/female, Oral: feed.

Results:

NOAEL (P): 10000 ppm (male/female) based on: test mat.

LOAEL (F2): 10000 ppm (male/female) based on: test mat.

Effects on development of the offspring:

Oral:

Method:

equivalent or similar to OECD Guideline 414 (Prenatal Developmental Toxicity Study)
rat (Wistar). Oral: gavage.

Results:

NOEL (maternal toxicity): 350 mg/kg bw/day

NOEL (developmental toxicity): 350 mg/kg bw/day

Conclusions: not classified

Specific target organ toxicity (STOT) - Single exposure:

not available

Specific target organ toxicity (STOT) - Repeated exposure:

Oral:

Method:

equivalent or similar to OECD Guideline 452 (Chronic Toxicity Studies)
rat male/female, chronic (oral: feed), Exposure: 104 weeks (Continuous (in feed))

Results:

NOEL: 5000 ppm (male/female) based on: test mat.

LOEL: 50000 ppm (male/female) based on: test mat.

Value used for CSA: NOAEL: 600 mg/kg bw/day

Conclusions: not classified

Aspiration hazard: not available

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SECTION 12: Ecological information

12.1. Toxicity

Toxicity to aquatic environment:

Short-term toxicity to the aquatic environment:

Fish:

Method:

OECD Guideline 203 (Fish, Acute Toxicity Test)
Danio rerio; freshwater; semi-static

Results:

LC50 (96 h): > 100 mg/L test mat. (nominal)
NOEC: 100 mg/L

Aquatic invertebrates:

Method:

OECD Guideline 202 (Daphnia sp. Acute Immobilisation Test)
Daphnia sp. freshwater; static.

Results:

LC50 (48h): 240 mg/L test mat. based on: mortality
EC50: 240 mg/L

Algae or other aquatic plants:

Method:

Read-across from supporting substance (structural analogue or surrogate)
OECD Guideline 201 (Alga, Growth Inhibition Test)
Pseudokirchnerella subcapitata (algae); freshwater; static.

Results:

EC50 (72 h): > 100 mg/L test mat. (nominal) based on: biomass
EC50 (72 h): > 100 mg/L test mat. (nominal) based on: growth rate
NOEC (72 h): 100 mg/L test mat. (nominal) based on: biomass
NOEC (72 h): 100 mg/L test mat. (nominal) based on: growth rate
Value used for CSA: EC10/LC10 or NOEC: 100 mg/L

Aquatic microorganisms:

Method:

Read-across from supporting substance (structural analogue or surrogate)
OECD Guideline 209 (Activated Sludge, Respiration Inhibition Test)
activated sludge of a predominantly domestic sewage; freshwater; static

Results:

EC50 (3 h): > 300 mg/L test mat. (nominal) based on: respiration rate

Long-term toxicity to aquatic environmental: not available

Toxicity to the Terrestrial environment: not available

12.2. Persistence and degradability

Degradability:

Abiotic degradation: not available

Biotic degradation:

Aquatic environment:

Method:

OECD Guideline 301 C (Ready Biodegradability: Modified MITI Test (I))
Test type: ready biodegradability, activated sludge (adaptation not specified)

Results:

readily biodegradable
% Degradation of test substance:
73% after 14 d (O₂ consumption) (BOD)
99% after 14 d (TOC removal) (TOC)
100% after 14 d (Test mat. analysis) (HPLC)

Value used for CSA: Readily biodegradable

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12.3. Bioaccumulative potential

Bioaccumulation:

Log Pow: 1,26

Aquatic environment:

Method:

Weight of evidence. ECHA Guidance on information requirements and chemical safety assessment - Chapter R.06: QSARs and grouping of chemicals - May 2008

Results:

BCF: 1 L/kg (whole body w.w.)

Value used for CSA: BCF: 1 L/kg ww (L/kg ww or dimensionless)

Terrestrial environment: Data not available

Conclusions: These data indicate that the substance is not bioaccumulative (B).

12.4. Mobility in soil

Adsorption/desorption:

In accordance with REACH Regulation 1907/2006, Annex VIII - 9.3.1 Column 2, screening tests for adsorption/desorption do not need to be conducted as the substance has a low potential for adsorption based on a log Kow of - 1.26

Volatilisation:

Method:

Others: Weight of evidence

Results:

Henry's Law constant: 0.000000086 Pa m³/mol at 25 °C

Distribution among environmental compartments:

Method:

Weight of evidence. Calculation programme: EPI Suite (v.4.10).

Calculation according to Mackay, Level III

Media: air - biota - sediment(s) - soil - water;

Results:

Percent distribution in media:

Air (%): 0,0001

Water (%): 26,4

Soil (%): 73,6

Sediment (%): 0,0344

12.5. Results of PBT and vPvB assessment

Substance is not Persistent (P) (see section 12.2)

Substance is not bioaccumulative (B) (see section 12.3)

Substance is not classified toxic (T)

Conclusions:

Based on available information, the substance is not PBT vPvB.

12.6. Other adverse effects

No other known.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Recycle if possible, or send to an authorized incinerator. Follow the instructions in sections 6 and 7 when handling waste spillages, taking the steps indicated in the same sections. We recommend recycling containers instead of disposal. Observe the local and national legislation in force.

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SECTION 14: Transport information

14.1. UN number

NOT APPLICABLE

14.2. UN proper shipping name

NOT APPLICABLE

14.3. Transport hazard class(es)

NOT APPLICABLE

14.4. Packing group

NOT APPLICABLE

14.5. Environmental hazards

NOT APPLICABLE

14.6. Special precautions for user

NOT APPLICABLE

ADR/RID

- Tunnel restriction code: NOT APPLICABLE
- Category - limited quantities per transport unit: NOT APPLICABLE
- LQ code - limited quantities per pack unit: NOT APPLICABLE
- E code excepted quantities: NOT APPLICABLE

IMDG

- LQ code - limited quantities per pack unit: NOT APPLICABLE
- E code excepted quantities: NOT APPLICABLE
- Ems: NOT APPLICABLE

ICAO/IATA

- Packing Instructions / max. net quantities per package per plane - combi and cargo: NOT APPLICABLE
- Packing Instructions / max. net quantities per package in limited quantity regime: NOT APPLICABLE
- EQ code for excepted quantities regime: NOT APPLICABLE

14.7. Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code

NOT APPLICABLE

SECTION 15: Regulatory information

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

European Regulation 1907/2006/EC (Reach)
European Regulation 1272/2008/EC (CLP)
European Regulation 453/2010/EU
DIRECTIVE 548/1967/EEC;
DIRECTIVE 45/1999/EC;
DIRECTIVE 24/1998/EC;
DIRECTIVE 37/2004/EC;
DIRECTIVE 92/1999/EC;
DIRECTIVE 82/1996/EC;

15.2. Chemical safety assessment

CSR/CSA: yes

SECTION 16: Other information

Safety Data Sheet compiled according to Regulation 453/2010/EU.

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Exposure Scenarios in local languages will be published as soon as they are available.

(*) on the left indicate the modifications with respect to the last version.

References:

GESTIS International Limit Values.

Acronyms:

ACGIH: American Conference of Governmental Industrial Hygienist.
ADN: European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways.
ADR: European Agreement concerning the International Carriage of Dangerous Goods by Road.
ASTM: American Society of Testing and Materials.
B: Bioaccumulabile.
BCF: BioConcentration Factor.
BSAF: Biological Soil Accumulation Factor.
CSA: Chemical Safety Assessment.
CSR: Chemical Safety Report.
DIN: Deutsches Institut für Normung.
DMEL: Derived Minimal Effect Level.
DNEL: Derived No Effect Level.
Ec: Effective concentration.
EC50: Effective Concentration 50 (that produces an effect (other than death) for 50% of organisms test).
ECx: Effective Concentration 50 (that produces an effect (other than death) for X% of organisms test).
EPA: Environmental Protection Agency.
IATA: International Air Transport Association.
IBC: International code for the construction and equipment of ships carrying dangerous Bulk Chemicals.
ICAO: International Civil Air-transport Organisation.
IMGD: International Maritime Dangerous Goods code.
ISO: International Standards Organisation.
KoC: organic carbon/water partition coefficient (adsorption coefficient).
KoW: n-octanol/water partition coefficient.
LC50: Lethal Concentration for 50% of animal test.
LCx: Lethal Concentration for X% of animal test.
LD50: Lethal Dose for 50% test animal.
LDx: Lethal Dose for X% test animal.
LLNA: Local Lymph Node Assay.
LOAEC: Lowest Observed Adverse Effect Concentration.
LOAEL: Lowest Observed Adverse Effect Level.
LOEC: Lowest Observed Effect Concentration.
LOEL: Lowest Observed Effect Level.
MARPOL: International Convention for the Prevention of Pollution from Ships.
NOAEC: No Observed Adverse Effects Concentration.
NOAEL: No Observed Adverse Effect Level.
NOEC: No Observed Effect Concentration.
NOEL: No Observed Effect Level.
OECD-OCSE: Organisation for Economic Co-operation and Development.
P: Persistent.
PBT: Persistent Bioaccumulabile and Toxic.
PNEC: Predicted No Effect Concentration.
(Q)SAR: Quantitative Structure-Activity Relationship.
RID: Regulations concerning the International carriage of Dangerous goods by rail.
SDS: Safety Data Sheet.
STP: Sewage Treatment Plant.
TLV: Threshold Limit Value.
TLV-C: Threshold Limit Value - Ceiling.
TLV-STEL: Threshold Limit Value - Short Term Exposure Limit.
TLV-TWA: Threshold Limit Value - Time Weighted Average.
vPvB: very Persistent and very Bio-accumulative.

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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.