

**TBILI**

Version 1.3

Revision Date 09-18-2014

Print Date 12-06-2014

**SECTION 1. IDENTIFICATION**

Product name : TBILI  
Mat.-No./ Genisys-No. : 11822713216

**Manufacturer or supplier's details**

Company name of supplier : Roche Diagnostics  
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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 : H290 May be corrosive to metals.  
H314 Causes severe skin burns and eye damage.

Precautionary statements : **Prevention:**  
P234 Keep only in original container.  
P264 Wash skin thoroughly after handling.  
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): Remove/ Take off immediately all contaminated clothing. Rinse skin with water/ shower.  
P304 + P340 IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing.  
P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy

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to do. Continue rinsing.  
P310 Immediately call a POISON CENTER or doctor/ physician.  
P363 Wash contaminated clothing before reuse.  
P390 Absorb spillage to prevent material damage.

**Storage:**

P405 Store locked up.  
P406 Store in corrosive resistant stainless steel container with a resistant inner liner.

**Disposal:**

P501 Dispose of contents/ container to an approved waste disposal plant.

**Other hazards**

None known.

**SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS****R1/F1****GHS Classification**

Serious eye damage, Category 1

H318: Causes serious eye damage.

**Hazardous components**

| Chemical Name                  | CAS-No.    | Concentration (%) |
|--------------------------------|------------|-------------------|
| Betaines, C12-14-alkyldimethyl | 66455-29-6 | >= 1 - < 5        |

**R2/F2****GHS Classification**

Corrosive to metals, Category 1

H290: May be corrosive to metals.

Skin corrosion, Category 1

H314: Causes severe skin burns and eye damage.

Serious eye damage, Category 1

H318: Causes serious eye damage.

**Hazardous components**

No hazardous ingredients

**SECTION 4. 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.

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- If on skin, rinse well with water.  
If on clothes, remove clothes.
- In case of eye contact : Small amounts splashed into eyes can cause irreversible tissue damage and blindness.  
In the case of contact with eyes, rinse immediately with plenty of water and seek medical advice.  
Continue rinsing eyes during transport to hospital.  
Remove contact lenses.  
Protect unharmed eye.  
Keep eye wide open while rinsing.  
If eye irritation persists, consult a specialist.
- If swallowed : Clean mouth with water and drink afterwards plenty of water.  
Keep respiratory tract clear.  
Do NOT induce vomiting.  
Do not give milk or alcoholic beverages.  
Never give anything by mouth to an unconscious person.  
If symptoms persist, call a physician.  
Take victim immediately to hospital.
- 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.

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**SECTION 5. FIREFIGHTING MEASURES**

- Suitable extinguishing media : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
- Unsuitable extinguishing media : High volume water jet
- Specific hazards during firefighting : Do not allow run-off from fire fighting to enter drains or water courses.
- 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.
- Special protective equipment for firefighters : Wear self-contained breathing apparatus for firefighting if necessary.

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**SECTION 6. ACCIDENTAL RELEASE MEASURES**

- Personal precautions, protective equipment and emergency procedures : Use personal protective equipment.  
Refer to protective measures listed in sections 7 and 8.
- Environmental precautions : Prevent product from entering drains.  
Prevent further leakage or spillage if safe to do so.

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Local authorities should be advised if significant spillages cannot be contained.

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

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**SECTION 7. HANDLING AND STORAGE**

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.

Conditions for safe storage : Keep container tightly closed in a dry and well-ventilated place.  
Containers which are opened must be carefully resealed and kept upright to prevent leakage.  
Observe label precautions.  
Electrical installations / working materials must comply with the technological safety standards.

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**SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION****R1/F1****Components with workplace control parameters**

Contains no substances with occupational exposure limit values.

**R2/F2****Components with workplace control parameters**

Contains no substances with occupational exposure limit values.

**Personal protective equipment**

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 | : | Eye wash bottle with pure water<br>Tightly fitting safety goggles   |

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Wear face-shield and protective suit for abnormal processing problems.

- Skin and body protection : impervious clothing  
Choose body protection according to the amount and concentration of the dangerous substance at the work place.
- Hygiene measures : When using do not eat or drink.  
When using do not smoke.  
Wash hands before breaks and at the end of workday.

**SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES*****R1/F1***

- Appearance : liquid
- pH : 4.1, (25 °C)
- 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 : 1.013 g/cm<sup>3</sup> (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.

***R2/F2***

- Appearance : liquid
- pH : 1.2
- 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.

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|                           |  |
|---------------------------|--|
| Upper explosion limit     | : No data available  |
| Lower explosion limit     | : No data available  |
| 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. |

**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 decomposition if stored and applied as directed.         |
| Conditions to avoid                | : No data available   |
| Incompatible materials             | : No data available   |
| Hazardous decomposition products   | : No data available   |

**SECTION 11. TOXICOLOGICAL INFORMATION*****R1/F1*****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<br>Method: Calculation method |
|---------------------|---|

**Skin corrosion/irritation**

Not classified based on available information.

**Product:**

Remarks: May cause skin irritation and/or dermatitis.

**Components:****Betaines, C12-14-alkyldimethyl:**

Result: Irritating to skin.

Remarks: May cause skin irritation in susceptible persons.

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**Serious eye damage/eye irritation**

Causes serious eye damage.

**Product:**

Remarks: May cause irreversible eye damage.

**Components:****Betaines, C12-14-alkyldimethyl:**

Result: Risk of serious damage 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.

**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.

**Components:****Betaines, C12-14-alkyldimethyl:**

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

**STOT - repeated exposure**

Not classified based on available information.

**Components:****Betaines, C12-14-alkyldimethyl:**

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

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**Aspiration toxicity**

Not classified based on available information.

**Components:****Betaines, C12-14-alkyldimethyl:**

No data available

**R2/F2****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**

Causes severe burns.

**Product:**

Remarks: Extremely corrosive and destructive to tissue.

**Serious eye damage/eye irritation**

Causes serious eye damage.

**Product:**

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.

**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.

**STOT - repeated exposure**

Not classified based on available information.

**Aspiration toxicity**

Not classified based on available information.

**SECTION 12. ECOLOGICAL INFORMATION****R1/F1****Ecotoxicity****Product:**

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

**Components:****Betaines, C12-14-alkyldimethyl:**

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**

No data available

**Mobility in soil**

No data available

**Other adverse effects****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

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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).

**Components:****Betaines, C12-14-alkyldimethyl:**

Adsorbed organic bound halogens (AOX) : Remarks: Not applicable

Additional ecological information : No data available

**R2/F2****Ecotoxicity****Product:**

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**

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).

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**SECTION 13. DISPOSAL CONSIDERATIONS****Disposal methods**

Waste from residues : 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.

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Contaminated packaging : Empty remaining contents.  
Dispose of as unused product.  
Empty containers should be taken to an approved waste handling site for recycling or disposal.  
Do not re-use empty containers.

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**SECTION 14. TRANSPORT INFORMATION****International Regulation****IATA-DGR**

UN/ID No. : UN 1789  
Proper shipping name : Hydrochloric acid  
Class : 8  
Packing group : III  
Labels : Corrosives  
Packing instruction (cargo aircraft) : 856  
Packing instruction (passenger aircraft) : 852

**IMDG-Code**

UN number : UN 1789  
Proper shipping name : Hydrochloric acid  
Class : 8  
Packing group : III  
Labels : 8  
EmS Code : F-A, S-B  
Marine pollutant : no

**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**

UN/ID/NA number : UN 1789  
Proper shipping name : Hydrochloric acid  
Class : 8  
Packing group : III  
Labels : Class 8 - Corrosive  
ERG Code : 157  
Marine pollutant : no

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**SECTION 15. REGULATORY INFORMATION****R1/F1****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.

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**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).

The following chemical(s) are listed under the U.S. Clean Air Act Section 111 SOCM I Intermediate or Final VOC's (40 CFR 60.489):

|                           |           |        |
|---------------------------|-----------|--------|
| Sodium acetate trihydrate | 6131-90-4 | 1.02 % |
|---------------------------|-----------|--------|

**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 % |
| Betaines, C12-14-alkyldimethyl | 66455-29-6 | 1 - 5 %    |

**New Jersey Right To Know**

|                                |            |            |
|--------------------------------|------------|------------|
| water                          | 7732-18-5  | 90 - 100 % |
| Betaines, C12-14-alkyldimethyl | 66455-29-6 | 1 - 5 %    |
| Sodium acetate trihydrate      | 6131-90-4  | 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/F2****EPCRA - Emergency Planning and Community Right-to-Know Act****CERCLA Reportable Quantity**

| Components    | CAS-No.   | Component RQ (lbs) | Calculated product RQ (lbs) |
|---------------|-----------|--------------------|-----------------------------|
| Natriumnitrit | 7632-00-0 | 100                | *                           |

\*: 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.

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**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 SOCM Intermediate or Final VOC's (40 CFR 60.489).

**Clean Water Act**

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

|                   |           |          |
|-------------------|-----------|----------|
| hydrogen chloride | 7647-01-0 | 0.3648 % |
| sodium nitrite    | 7632-00-0 | 0.052 %  |

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

|                   |           |          |
|-------------------|-----------|----------|
| hydrogen chloride | 7647-01-0 | 0.3648 % |
| sodium nitrite    | 7632-00-0 | 0.052 %  |

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

**Massachusetts Right To Know**

|                   |           |           |
|-------------------|-----------|-----------|
| hydrogen chloride | 7647-01-0 | 0.1 - 1 % |
|-------------------|-----------|-----------|

**Pennsylvania Right To Know**

|                   |           |            |
|-------------------|-----------|------------|
| water             | 7732-18-5 | 90 - 100 % |
| hydrogen chloride | 7647-01-0 | 0.1 - 1 %  |
| sodium nitrite    | 7632-00-0 | 0 - 0.1 %  |

**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.

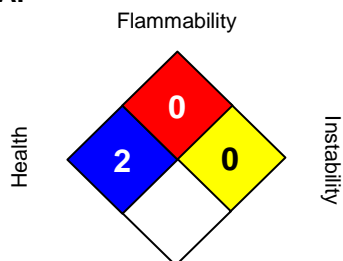
**SECTION 16. OTHER INFORMATION****Further information****R1/F1**

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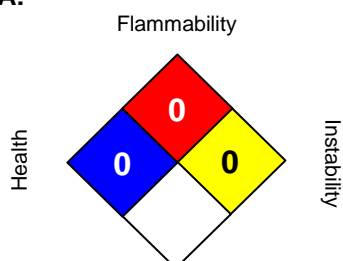
**NFPA:**

Special hazard.

**HMIS III:**

|                        |          |
|------------------------|----------|
| <b>HEALTH</b>          | <b>2</b> |
| <b>FLAMMABILITY</b>    | <b>0</b> |
| <b>PHYSICAL HAZARD</b> | <b>0</b> |

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

**R2/F2  
NFPA:**

Special hazard.

**HMIS III:**

|                        |          |
|------------------------|----------|
| <b>HEALTH</b>          | <b>0</b> |
| <b>FLAMMABILITY</b>    | <b>0</b> |
| <b>PHYSICAL HAZARD</b> | <b>0</b> |

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.