

# Safety data sheet

according to Regulation (EC) No 1907/2006, (EU) No 453/2010

Printing date 11.06.2015

Version number: 2

Revision: 11.06.2015

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

- **1.1 Product identifier**
- **Trade name: TMB-Complete**
- **Other names:** TMB-Complete 1, TMB-Complete 2, TMB-Complete 5
- **1.2 Relevant identified uses of the substance or mixture and uses advised against**  
No further relevant information available.
- **Application of the substance / the mixture:** Preparation for in vitro diagnostic use.
- **Uses advised against:** No information available at present.
- **1.3 Details of the supplier of the safety data sheet**
- **Supplier:**  
TestLine Clinical Diagnostics s.r.o.  
Production of diagnostic sets for human, veterinary, inorganic and organic laboratories.  
Business Address: Křižíkova 68, 612 00 Brno, Czech Republic  
Company Identification Number: 479 13 240  
Phone/Fax: +420 541 243 390  
E-mail: mansfeld@testlinecd.com / Web: www.testlinecd.com
- **Further information obtainable from:** Ing. Karel Královec, Studio2K, E-mail: bl@studio2k.cz
- **1.4 Emergency telephone number**  
Phone: +420 224 919 293 or +420 224 915 402; E-mail: tis@vfn.cz  
Toxicology Information Centre in Prague (TIS), Na Bojišti 1, 120 00 Prague 2  
Permanent medical information service for cases of acute poisoning of humans and animals.  
National helpdesks contact details - <http://echa.europa.eu/cs/support/helpdesks/national-helpdesks/list-of-national-helpdesks>.

## SECTION 2: Hazards identification

- **2.1 Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008**  
The product is not classified as dangerous according to the CLP regulation.
- **2.2 Label elements**
- **Labelling according to Regulation (EC) No 1272/2008:** Void
- **Hazard pictograms:** Void
- **Signal word:** Void
- **Hazard-determining components of labelling:** Not apply.
- **Hazard statements:** Void
- **Precautionary statements:** Void.
- **Additional information:** Void.
- **2.3 Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:**  
The mixture does not contain substances classified as of the date of preparation of the safety data sheet as PBT pursuant to Regulation (EC) No 1907/2006 (REACH).
- **vPvB:**  
The mixture does not contain substances classified as of the date of preparation of the safety data sheet as vPvB pursuant to Regulation (EC) No 1907/2006 (REACH).

## SECTION 3: Composition/information on ingredients

- **3.2 Chemical characterisation: Mixtures**
- **Description:** Mixture of substances listed below with nonhazardous additions.

- **Dangerous components:**

CAS: 54827-17-7 EINECS: 259-364-6	3,3',5,5'-tetramethylbenzidine ⚠ Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335	< 0.06%
CAS: 7722-84-1 EINECS: 231-765-0 Index number: 008-003-00-9	hydrogen peroxide ⚠ Ox. Liq. 1, H271; ⚠ Skin Corr. 1A, H314; ⚠ Acute Tox. 4, H302; Acute Tox. 4, H332	< 0.05%

- **Non dangerous components:**

CAS: 7732-18-5 EINECS: 231-791-2	water, distilled, conductivity or of similar purity	> 95%
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- **SVHC:**  
The product does not contain substances classified as of the date of preparation of the safety data sheet as PBT or vPvB and stated in the Candidate list of substances producing very high concerns for Appendix XIV of Regulation (EC) No 1907/2006 (REACH).
- **Regulation (EC) No 648/2004 on detergents / Labelling for contents:** Not apply.

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- **Additional information:** For the wording of the listed risk phrases refer to section 16.

## SECTION 4: First aid measures

### · 4.1 Description of first aid measures

#### · **General information:**

No special measures required.

In case of doubt, appearance of symptoms or upon any problems, seek medical help and present this safety data sheet or the product label.

#### · **After inhalation:**

Remove person from danger area.

Take care of fresh air supply and seek medical assistance upon subsequent or lasting problems.

#### · **After skin contact:**

Wash the affected skin with water and soap and rinse thoroughly. Upon skin irritation or other problems, consult further procedure with an expert physician.

#### · **After eye contact:**

Open the eye lids, possibly remove contact lenses, and rinse the affected eyes thoroughly with clean flowing water. Upon skin irritation or other problems, consult further procedure with an expert physician.

#### · **After swallowing:**

Thoroughly rinse the mouth with water and do not cause vomiting. Put the affected person in warm and calm conditions. In case of appearance of symptoms or upon any problems, consult further procedure with a physician.

Provide a physician product safety data sheet.

### · 4.2 Most important symptoms and effects, both acute and delayed

Possible toxicological effects resulting from the classification are stated in Section 11.

No further relevant information is available.

### · 4.3 Indication of any immediate medical attention and special treatment needed

Show this safety data sheet to the physician or health professional.

## SECTION 5: Firefighting measures

### · 5.1 Extinguishing media

#### · **Suitable extinguishing agents:**

No extinguishing substances are determined, the mixture is not flammable. Use fire extinguishing methods suitable to surrounding conditions.

#### · **For safety reasons unsuitable extinguishing agents:** No extinguishing substances are determined.

### · 5.2 Special hazards arising from the substance or mixture

No special dangers are determined.

### · 5.3 Advice for firefighters

#### · **Protective equipment:**

No special measures required.

According to size of fire.

#### · **Additional information:** No relevant information is available.

## SECTION 6: Accidental release measures

### · 6.1 Personal precautions, protective equipment and emergency procedures

Ensure adequate ventilation.

Prevent contact of the product with eyes, skin, and clothing, use personal protective equipment.

Prevent the possibility of slipping on the spilled product.

Prevent entry of unauthorised persons.

### · 6.2 Environmental precautions

Do not allow to enter sewers/surface or ground water.

### · 6.3 Methods and material for containment and cleaning up

Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust) and place into suitable and marked vessels.

Possibly wipe the leaked product with a paper towel and place it into a waste vessel.

Thoroughly wash the affected spot and the tools used with a suitable detergent, it is possible to use a larger quantity of water.

Dispose contaminated material as waste according to item 13.

### · 6.4 Reference to other sections

See Section 7 for information on safe handling.

See Section 8 for information on personal protection equipment.

See Section 13 for disposal information.

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## SECTION 7: Handling and storage

### 7.1 Precautions for safe handling

Before use, it is necessary to familiarize oneself with the contents of Sections 2, 6, 8, and 11 of the safety data sheet.

Prevent contact of the product with the skin and eyes, use personal protective means.

Use working methods according to operating instructions.

General hygiene measures for the handling of chemicals are applicable.

Before a pause and after ending the work, wash the hands and take off the polluted working clothes. Keep these clothes separately.

Remove contaminated clothing and protective equipment before entering areas in which food is consumed.

Do not eat, drink, smoke, or snuff during use.

· **Information about fire - and explosion protection:** No special measures required.

### 7.2 Conditions for safe storage, including any incompatibilities

#### Storage

· **Requirements to be met by storerooms and receptacles:**

Secure impermeable floors against the liquids.

Store only in unopened original receptacles.

Vessels already open must be reclosed carefully and stored in the upright position in order to prevent leakage of the contents.

· **Information about storage in one common storage facility:** Keep away from food, drink and animal feedingstuffs.

· **Further information about storage conditions:**

Store in a dry and well ventilated place.

Keep containers tightly sealed.

Protect from exposure to the light.

Store under lock and key and with access restricted to technical experts or their assistants only.

· **Recommended storage temperature:** +2 °C to +8 °C.

### 7.3 Specific end use(s)

The product is intended only for professional use.

Specific use is stated in the manual for use on the product packaging label or in the product documentation.

## SECTION 8: Exposure controls/personal protection

· **Additional information about design of technical facilities:**

Ensure good ventilation. This can be achieved by local suction or general air extraction. If this is insufficient to maintain the concentration under WEL or IOEL values, suitable breathing protection should be worn. Applies only if maximum permissible exposure values are listed here.

### 8.1 Control parameters

· **Ingredients with limit values that require monitoring at the workplace:**

The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.

· **DNELs:** No values available.

· **PNECs:** No values available.

· **Ingredients with biological limit values:** No values available.

· **Additional information:** The lists valid during the making were used as basis.

### 8.2 Exposure controls

· **Personal protective equipment**

· **General protective and hygienic measures:**

The usual precautionary measures are to be adhered to when handling chemicals.

Keep away from foodstuffs, beverages and feed.

Do not eat, drink, smoke or sniff while working.

Immediately remove all soiled and contaminated clothing.

Wash hands before breaks and at the end of work.

Avoid contact with the eyes and skin.

· **Respiratory protection:** Unnecessary during regular use.

· **Protection of hands:**



Protective gloves (EN 374).

Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation.

Preventive skin protection by use of skin-protecting agents is recommended.

· **Material of gloves:**

Not determined.

Use for example:

For example protective surgical gloves.

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The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer.

· **Penetration time of glove material:**

Not determined.

No tests have been performed, glove resistance must be tested before use.

The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

· **Eye protection:**



In case of danger of contact with eyes, use tightly adhering protective goggles (EN 166).

· **Body protection:**

As needed, use the working protective clothes with long sleeves, possibly overalls, and protective working footwear.

· **Thermal hazards:** Not apply.

· **Limitation and supervision of exposure into the environment:**

Adhere to usual measures for environmental protection, see Section 6.

**SECTION 9: Physical and chemical properties**

· **9.1 Information on basic physical and chemical properties**

· **General Information**

· **Appearance**

**Form:** Fluid.  
**Colour:** Colourless to pale blue.

· **Odour:** Odourless.  
· **Odour threshold:** Not determined.

· **pH-value:** 3.6 - 3.8

· **Change in condition**  
**Melting point/Melting range:** Undetermined.  
**Boiling point/Boiling range:** ~ 100 °C

· **Flash point:** Not applicable.

· **Flammability (solid, gaseous):** Not applicable.

· **Ignition temperature:** Not applicable.

· **Decomposition temperature:** Not determined.

· **Self-igniting:** Product is not selfigniting.

· **Danger of explosion:** Product does not present an explosion hazard.

· **Explosion limits**  
**Lower:** Not determined.  
**Upper:** Not determined.

· **Oxidising properties** Not determined.

· **Vapour pressure:** Not determined.

· **Density:** 1.01 g/cm<sup>3</sup>

· **Vapour density** Not determined.

· **Evaporation rate** Not determined.

· **Solubility in / Miscibility with water:** Unlimited miscible.

· **Partition coefficient (n-octanol/water):** Not determined.

· **Viscosity**  
**Dynamic:** Not determined.  
**Kinematic:** Not determined.

· **Solvent content:**  
**VOC (2010/75/EC):** Not apply.

· **9.2 Other information** No further relevant information available.

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## SECTION 10: Stability and reactivity

- **10.1 Reactivity:** Upon adhering to the determined regulations of storage and use, no reactivity is expected (see Section 7).
- **10.2 Chemical stability:**  
Upon adhering to the determined regulations of storage and use, the product is stable (see Section 7).
- **10.3 Possibility of hazardous reactions:** Upon regular manner of use and storage, no hazardous reactions are created.
- **10.4 Conditions to avoid:**  
Permanent temperature above +8 °C.  
Permanent access light.
- **10.5 Incompatible materials:** No substances and materials are specified.
- **10.6 Hazardous decomposition products:** No decomposition when used as directed.

## SECTION 11: Toxicological information

### 11.1 Information on toxicological effects

#### Acute toxicity

#### LD/LC50 values relevant for classification:

##### 7722-84-1 hydrogen peroxide

Oral	LD50	1193 mg/kg (rat)
Dermal	LD50	> 6500 mg/kg (rabbit) Value applies to hydrogen peroxide solution 70%.
Inhalative	LC50/4 h	> 0.17 mg/l (rat)

- **Primary irritant effect**
- **Skin corrosion/irritation** Based on available data, the classification criteria are not met.
- **Serious eye damage/irritation** Based on available data, the classification criteria are not met.
- **By inhalation:** Based on available data, the classification criterions are not met.
- **By ingestion:** Based on available data, the classification criterions are not met.
- **Additional toxicological information:** No relevant information is available.
- **Acute effects (acute toxicity, irritation and corrosivity):** No acute effects.
- **CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction):**  
Based on available data, the classification criterions are not met.
- **Germ cell mutagenicity**  
Based on available data, the classification criteria are not met.
- **Carcinogenicity**  
Based on available data, the classification criteria are not met.
- **Reproductive toxicity**  
Based on available data, the classification criteria are not met.
- **STOT-single exposure**  
Based on available data, the classification criteria are not met.
- **STOT-repeated exposure**  
Based on available data, the classification criteria are not met.
- **Aspiration hazard**  
Based on available data, the classification criteria are not met.
- **Other information:** No further information is available.

## SECTION 12: Ecological information

### 12.1 Toxicity

#### Aquatic toxicity:

##### 7722-84-1 hydrogen peroxide

EC50/24 h	7.7 mg/l (daphnia)
EC50/48 h	2.4 mg/l (daphnia)
IC50/72 h	2.5 mg/l (algae) (OECD 201 - Alga, Growth Inhibition Test)
LC50/24 h	31.3 mg/l (fish)
LC50/96 h	16.4 mg/l (fish)

- **12.2 Persistence and degradability** No further relevant information available.
- **Behaviour in waste water treatment plants:** No relevant information is available.
- **12.3 Bioaccumulative potential** Bioaccumulation is not expected.
- **12.4 Mobility in soil** No further relevant information available.
- **Additional ecological information**
- **AOX-indication:** No relevant information is available.
- **General notes:** Generally not hazardous for water
- **12.5 Results of PBT and vPvB assessment**
- **PBT:**  
The mixture does not contain substances classified as of the date of preparation of the safety data sheet as the PBT pursuant to Regulation (EC) No 1907/2006 (REACH).

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· **vPvB:**

The mixture does not contain substances classified as of the date of preparation of the safety data sheet as the vPvB pursuant to Regulation (EC) No 1907/2006 (REACH).

· **12.6 Other adverse effects** No further relevant information available.

## SECTION 13: Disposal considerations

· **13.1 Waste treatment methods**

· **Recommendation:**

Must not be disposed together with household waste. Do not allow product to reach sewage system.  
Remove product residues according to the corresponding local directives as other waste.  
E.g. put away at suitable waste dumps or remove in suitable waste incineration plants.

· **European waste catalogue:**

The waste codes are recommendations based on the scheduled use of this product. Owing to the user's specific conditions for use and disposal, other waste codes may be allocated under certain circumstances. (2001/118/EC, 2001/119/EC, 2001/573/EC).

The catalogue numbers with the asterisk (\*) mark hazardous waste (N), numbers without the asterisk mark other waste (O).

18 02 06	chemicals other than those mentioned in 18 02 05
15 01 02	plastic packaging

· **Uncleaned packaging**

· **Recommendation:**

Dispose of packaging according to regulations on the disposal of packagings.  
Non contaminated packagings may be reused.  
Dispose of packaging that cannot be cleaned in the same manner as the mixture.  
Empty container completely. Dispose of hazardous waste pursuant to corresponding local directives in adequate equipment.  
Put other waste away according to the material type into collection vessels for sorted waste.

· **Regulations:**

Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste and repealing certain Directives, as amended.  
Law No. 185/2001 Coll., about waste and about a change of some other laws, as amended.  
Decree of the MoE and MoA No. 376/2001 Coll. about the evaluation of hazardous properties of waste, as amended.  
Decree of the MoE No. 381/2001 Coll. MoE, by which the Waste Catalogue, the List of Hazardous Waste and lists of waste and countries for the purposes of export, import, and transit of waste, and the procedure for awarding con-sent for export, import, and transit of waste (Waste Catalogue) is determined, as amended.  
Decree of MoE No. 383/2001 Coll. about the details of waste handling, as amended.

## SECTION 14: Transport information

· <b>14.1 UN-Number</b>	
· <b>ADR, ADN, IMDG, IATA</b>	Void
· <b>14.2 UN proper shipping name</b>	
· <b>ADR, ADN, IMDG, IATA</b>	Void
· <b>14.3 Transport hazard class(es)</b>	
· <b>ADR, ADN, IMDG, IATA</b>	
· <b>Class:</b>	Void
· <b>14.4 Packing group</b>	
· <b>ADR, IMDG, IATA</b>	Void
· <b>14.5 Environmental hazards</b>	
· <b>Marine pollutant:</b>	No
· <b>14.6 Special precautions for user</b>	Unless specified otherwise, general measures for safe transport must be followed.
· <b>14.7 Transport in bulk according to Annex II of Marpol and the IBC Code</b>	Not applicable.
· <b>Transport/Additional information:</b>	Non-dangerous material according to Transport Regulations.
· <b>UN "Model Regulation":</b>	-

## SECTION 15: Regulatory information

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

· **Tactile warning of danger:** Not applicable.

· **Child-resistant fastening:** Not applicable.

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**Trade name: TMB-Complete***(Contd. of page 6)***· Legal regulations of the European Community:**

Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC, as amended.

REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006, as amended.

COMMISSION REGULATION (EU) No 453/2010 of 20 May 2010 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), as amended.

Council Directive 96/82/EC of 9 December 1996 on the control of major-accident hazards involving dangerous substances, as amended.

**· Legal regulations of the Czech Republic:**

Law No 350/2011 Coll., about chemical substances and chemical preparations and about a change of some laws.

Law No 59/2006 Coll., about the prevention of severe accidents, as amended.

Governmental Regulation No 361/2007 Coll., by which the conditions of employee health protection during work are determined.

Law No 258/2000 Coll., about public health protection and about a change of some related laws, as amended.

Law No 201/1966 Coll., about the health care of the people, as amended.

Law No 201/2012 Coll., about atmosphere protection, as amended.

Decree No 355/2002 Coll., by which the emission limits and further conditions of operating of other stationary sources of atmosphere pollution emitting volatile organic substances from processes applying organic solvents and from storage and distribution of petrol are determined.

The full wording of Law No 254/2001 Coll. about waters and about a change of some laws (Water Law), announced in the Collection of Laws under No 273/2010.

Law No 477/2001 Coll., about packaging and about a change of some laws (Packaging Law), as amended.

**· 15.2 Chemical safety assessment** A Chemical Safety Assessment has not been carried out.**SECTION 16: Other information****· Warning:**

The safety data sheet contains data needed for securing safety and health protection during work and environmental protection. The stated data correspond to the current state of knowledge and experience and is in accordance with valid legal regulations. It cannot be deemed as a guarantee of the properties, suitability, and usefulness of the product for specific application and therefore no contractual legal relationships are hereby created.

The safety data sheet is the property of the physical or legal entity stated in Section 1 and is protected by copy-right. All copying, distribution or sales without the consent of the owner is forbidden.

**· Relevant phrases:**

H271 May cause fire or explosion; strong oxidiser.

H302 Harmful if swallowed.

H314 Causes severe skin burns and eye damage.

H315 Causes skin irritation.

H319 Causes serious eye irritation.

H332 Harmful if inhaled.

H335 May cause respiratory irritation.

**· Training hints:**

Pursuant to article No 35 of the European Parliament and Council Regulation (ES) No 1907/2006, the employer must allow employees or their representatives access to information from the safety data sheet of the substance or preparation, which the employees use or to the effects of which they may be exposed during their work.

Physical entities performed individual activities within the scope of handling of this hazardous product are trained and regularly, at least once a year, retrained.

Product information sources: safety data sheet, product or technical information, safety instructions, and other expert documents for the product, issued by the supplier.

**· Recommended restriction of use:**

The product is to be used only for the purpose, for which it is designed. It is up to the user's responsibility to adhere to the product usage conditions and to respect the safety instructions for health and environmental protection.

The product is designed only for professional purposes. It must not be used in households. The product can only be handled by a person older than 18 years, who is sufficiently informed about the work procedures, hazardous properties of the product, and also about the necessary safety measures.

**· Further information:** This product must be stored, sold, and used in accordance with valid hygienic regulations.**· Classification according to Regulation (EC) No 1272/2008**

Classification of the mixture was performed according to the methods given in Annex I to Regulation (EC) No 1272/2008 (CLP).

**· Department issuing SDS:** Studio2K, Ing. Karel Královec, Phone: +420 354 526 677, E-mail: info@studio2k.cz*(Contd. on page 8)*

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· **First issue of SDS:** 23.07.2014

· **Internal code formula:** 811.011

· **Documents used to prepare SDS:**

The original documents provided by the supplier or manufacturer related to the product (mixture), eventually to individual substances contained.

· **Abbreviations and acronyms:**

ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

GHS: Globally Harmonised System of Classification and Labelling of Chemicals

EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society)

VOC: Volatile Organic Compounds (USA, EU)

DNEL: Derived No-Effect Level (REACH)

PNEC: Predicted No-Effect Concentration (REACH)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic

SVHC: Substances of Very High Concern

vPvB: very Persistent and very Bioaccumulative

Ox. Liq. 1: Oxidising Liquids, Hazard Category 1

Acute Tox. 4: Acute toxicity, Hazard Category 4

Skin Corr. 1A: Skin corrosion/irritation, Hazard Category 1A

Skin Irrit. 2: Skin corrosion/irritation, Hazard Category 2

Eye Irrit. 2: Serious eye damage/eye irritation, Hazard Category 2

STOT SE 3: Specific target organ toxicity - Single exposure, Hazard Category 3

· **Sources:**

The safety data sheet was prepared in accordance with the European Parliament and Council Regulation (EC) No 1272/2008 (CLP) and according to the requirements of the European Parliament and Council Regulation (EC) No 1907/2006 about the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency - head IV, article 31, appendix II (instructions for safety data sheet compiling), as amended by the Commission Regulation (EU) No. 453/2010 dated 20 May 2010.

The classification of the mixture was performed pursuant to the European Parliament and Council Regulation (EC) No 1272/2008 (CLP). The data provided by the manufacturers or importers of individual mixture components stated in their safety data sheets served as the basis.

The missing ecotoxicology and toxicology data was obtained from the ESIS (European chemical Substances Information System), specifically from the IUCLID (International Uniform Chemical Information Database). As needed, data from further available chemical databases was used.

· **Safety data sheet revision:**

Safety data sheet revision because of the addition of certain data or information.

Change of chapters: 3, 11, 13, 16.

This release of the safety data sheet is its 1 revision and replaces the safety data sheet published on: 23.07.2014.

· **\* Data compared to the previous version altered.**

· © Studio2K & DR SoftWare ChemGes