1. Specification of substance / mixture and company

Trade name / description:
TMB/Substrate Solution for recomWell

Identified use:
These Products are colorimetric substrate solutions for use in immunological in-vitro tests, based on the enzyme HRP. Reserved for industrial and professional use.

Details of the supplier providing the safety data sheet:

- **Company name:** Mikrogen GmbH
  Floriansbogen 2-4
  82061 Neuried, Germany

- **Informing entity / telephone no.:**
  Tel.: +49(0)89 - 54801-0
  Fax.: +49(0)89 - 54801-100
  E-mail: hendlmeier@mikrogen.de
  Responsible for this SDS: Ms Sonja Hendlmeier

- **EMERGENCY NUMBER:**
  Munich Poison Control Centre: +49(0)89 - 19240

2. Possible hazards

- **Classification in accordance with Regulation (EC) No. 1272/2008 [CLP] modified by (EC) 2016/1179:** Repr. 1B, H360D Because of the preservative it may be dangerous for water organisms.

- **Identifying elements:**

<table>
<thead>
<tr>
<th>Hazard pictogram</th>
<th>Signal word</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image" alt="Hazard pictogram" /></td>
<td>Danger!</td>
</tr>
</tbody>
</table>

- **Hazard-determining components for labelling:** N-Methyl-2-pyrrolidone
- **Hazard warnings:** H360D: May damage the unborn child.
- **Hazard class:** reproductive toxicity Repr. 1B

- **Precautions:**
  - P280 Wear protective gloves/protective clothing/eye protection/face protection.
  - P308+P313: If exposed or concerned: Get medical advice/attention.
3. Composition/details of the components

- **Description:** Watery solution
- **Ingredient:**

<table>
<thead>
<tr>
<th>CAS No.</th>
<th>EC No.</th>
<th>% [Mass]</th>
<th>name</th>
<th>symbol</th>
<th>classification in accordance with Regulation (EC), No. 1272/2008 [CLP]</th>
</tr>
</thead>
<tbody>
<tr>
<td>872-50-4</td>
<td>212-828-1</td>
<td>&lt; 5 %</td>
<td>N-Methyl-2-pyrrolidone</td>
<td></td>
<td>H315, H319, H335, H360D</td>
</tr>
</tbody>
</table>

The full text of H-statements is in article 16.

4. First aid measures

- **General information:**
  Consult a physician. Show this safety data sheet to the doctor in attendance.

- **After inhalation:**
  If breathed in, move the concerned person to fresh air. In case of apnoea, give artificial respiration. Consult a physician.

- **After skin contact:**
  Wash off with plenty of water. Consult a physician.

- **After eye contact:**
  Rinse opened eyes with plenty of water. Consult an ophthalmologist.

- **After swallowing:**
  Never give anything by mouth to an unconscious person. Rinse mouth out and drink water. Consult a physician.

5. Fire-fighting procedures

- **Extinguishing media**
  Suitable extinguishing media
  Use water spray, alcohol resistant foam, solid extinguishing agent or carbon dioxide.

- **Special hazards arising from the substance or mixture**
  The product itself is not inflammable; extinguishing measures should therefore be prepared for an environmental fire. In case of fire toxic vapours, e.g. nitric oxide, can be released.

- **Advice for firefighters**
  Wear breath protective mask and protective clothes if necessary during fire fighting.

6. Accidental release measures

- **Personal precautions:** Avoid breathing vapour/mist/gas. Use personal protective equipment. Care for appropriate ventilation.

- **Environmental precautions:** Keep away from drains, water or soil.

- **Methods and material for containment and cleaning up:** Suck up with inert absorbance material and dispose as hazardous waste. Keep in a suitable, closed container.
7. Handling and storage

- **Handling**
  - **Safe handling:** No special measures necessary if handled and stored correctly.
  - **Protection against fire and explosion:** No special measures necessary.

- **Storage**
  - **Requirements for storage rooms and containers:** Seal opened containers carefully and store upright to prevent any leakage.
  - **Combined storage:**
    - **Storage classification:** 12 (non flammable liquids)
    - **Segregate from:**
      - Class 1 (explosives)
      - Class 4.1A (flammable solids)
      - Class 4.3 (dangerous when wet)
      - Class 6.2 (infectious)
      - Class 7 (radioactive)
  - **Further information about storage conditions:**
    Store separated from foodstuffs.
    Protect from unauthorized access.

- **Recommended storage temperature:**
  Value +2°C – +8 °C

8. Exposure limitation and controls/personal protection

If the products are used according to the instructions, no air pollution is to be expected. Preventative medical examinations for the workplace should be made available.

- **Control parameters:**

<table>
<thead>
<tr>
<th>CAS No.</th>
<th>EC No.</th>
<th>name</th>
<th>limit value according to BGW (TRGS 903)</th>
</tr>
</thead>
<tbody>
<tr>
<td>872-50-4</td>
<td>212-828-1</td>
<td>N-Methyl-2-pyrrolidone</td>
<td>150 mg/l urine at the end of a shift, parameter: 5-Hydroxy-N-Methyl-2-pyrrolidone</td>
</tr>
</tbody>
</table>

- **Exposure controls:**
  Consider the usual good hygiene and safety practice by handling chemicals. Pregnant women should strictly avoid inhalation or skin contact.

- **Personal protective equipment:**
  Wear personal protective equipment.

- **Respiratory protection:**
  Not required if used according to the intended use. In case of a divergent risk assessment use a full-face respirator with multi-purpose combination respirator cartridge Type ABEK (EN 14387).

- **Gloves:**
  Protective gloves of nitril rubber (Material thickness min. 0,28 mm, AQL 1,5) or nature latex (Material thickness min. 0,22 mm, AQL 1,5), satisfying the norm EN 374

- **Eye/face protection:**
  Safety glasses with side shields conforming to EN 166 (EU)
• **Body protection:**
  Standard laboratory work clothing

• **General protective and hygiene measures:**
  ▪ Do not smoke, eat or drink when working.
  ▪ Keep away from food and drink.
  ▪ Wash hands before breaks and after work.
  ▪ Avoid contact with eyes and skin.
  ▪ Immediately remove soiled or soaked clothing.

---

9. **Physical and chemical properties**

**General information:**

• **Appearance**
  ▪ Form: Liquid
  ▪ Colour: Colourless to slightly blue

• **Smell**
  ▪ Odour threshold: Not determined
  ▪ pH value: 3.6 - 3.8

• **State changes**
  ▪ Melting point / melting range: Not determined
  ▪ Boiling point / boiling range: 100°C

• **Flash point:** Not suitable

• **Flammability (solid, gaseous):** Not suitable

• **Ignition temperature:** Not determined

• **Decomposition temperature:** Not determined

• **Self-ignition:** The product does not self-ignite.

• **Risk of explosion:** The product is not an explosion risk.

• **Explosion limits**
  ▪ Lower: Not determined
  ▪ Upper: Not determined

• **Vapour pressure at 20°C:** Not determined

• **Density:** 1.003 g/ml

• **Relative density:** Not determined

• **Vapour density:** Not determined

• **Evaporation rate:** Not determined

• **Solubility in/miscibility with water:** Completely miscible

• **Distribution coefficient (n-octanol/water):** Not determined

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10. **Stability and reactivity**

• **Conditions to avoid:**
  None if used correctly.

• **Substances to avoid:**
  None known.

• **Hazardous decomposition products:**
  No hazardous decomposition products known.
11. Toxicological information

Information on toxicological effects

**Acute toxicity**

<table>
<thead>
<tr>
<th>Component</th>
<th>Valuation</th>
<th>Value</th>
<th>Species</th>
</tr>
</thead>
<tbody>
<tr>
<td>N-Methyl-2-pyrrolidon</td>
<td>LD50 (oral)</td>
<td>3598 mg/kg</td>
<td>Rat</td>
</tr>
<tr>
<td></td>
<td>LC50 (inhalative)</td>
<td>&gt; 5.1 mg/l</td>
<td>Rat</td>
</tr>
</tbody>
</table>

**Skin corrosion/irritation**

<table>
<thead>
<tr>
<th>Component</th>
<th>Valuation</th>
<th>Value</th>
<th>Species</th>
</tr>
</thead>
<tbody>
<tr>
<td>N-Methyl-2-pyrrolidon</td>
<td>LD50 (dermal)</td>
<td>8000 mg/kg</td>
<td>rabbit</td>
</tr>
</tbody>
</table>

**Serious eye damage/irritation**

Irritation.

**Respiratory or skin sensitization**

No sensitization known.

**Germ cell mutagenicity**

No information available.

**Carcinogenicity**

No information available.

**Reproductive toxicity**

May damage the unborn child: N-Methyl-2-pyrrolidone (Repr. 1B).

**STOT-single exposure**

May cause respiratory irritation.

**STOT-repeated exposure**

No specific target organ toxicant, repeated exposure.

**Aspiration hazard**

No information available.

**Further toxicological information**

Product-specific toxicological data is not known.

**Further data**

- Quantitative data on the toxicity of the mixtures are not available.
- Calculation of ATE according to (EC) 1272/2008, Appendix I: see section 15.1
- Hazardous properties cannot be excluded but are unlikely when the products are handled appropriately.
- Further data: Handle in accordance with good industrial hygiene and safety practice.

12. Environmental information

- **N-Methyl-2-pyrrolidone:**
<table>
<thead>
<tr>
<th>Spezies</th>
<th>Art</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>bluegill</td>
<td>LC50 (mg/l/96h)</td>
<td>832</td>
</tr>
<tr>
<td>gold orfe</td>
<td>LC50 (mg/l/96h)</td>
<td>&gt; 500</td>
</tr>
<tr>
<td>green alga</td>
<td>IC50 (mg/l/72h)</td>
<td>&gt; 500</td>
</tr>
<tr>
<td>invertebrates (Daphnia magna)</td>
<td>EC50 (mg/l/48h)</td>
<td>4897</td>
</tr>
</tbody>
</table>

- **Persistence and degradability**
  For N-Methyl-2-pyrrolidone: > 90% / 20 d
  Easily biologically degradable.
Bioaccumulative potential
Distribution: log P(o/w): ≤ 4 (for N-Methyl-2-pyrrolidone)
There is no bioaccumulation expected.

Mobility in soil
No data available.

Result of PBT and vPvB relevant
None of the components is listed as PBT or vPvB relevant.

Other adverse effects
No further effects known. If used appropriately, no ecological problems are to be expected.

13. Disposal considerations
- **Product:**
  Disposal should be made in accordance with national and local regulations and laws.

- **Packaging:**
  Emptied packaging can be given to local recycling or waste disposal.

14. Transport information
Not subject to transport regulations according to ADR, RID, IATA and IMDG.

15. Regulatory information
- **Safety, health and environmental regulations/legislation specific for the substance or mixture:**
  
  - The calculated toxicity (ATE) of the mixtures according (EC) 1272/2008, Annex I: 65,900 mg/kg body weight, no classification as toxic
  
  - According EC 1272/2008, Annex I no classification as hazardous to water. (calculated L(E)C50 of the mixtures: 8,800 mg/l)
  
  - Water endangering class according to VwVwS (Germany): Water endangering class 1

- **Employment limitations:**
  - Reference is made to the restrictions of employment specified in the Youth Employment Act and the Maternity Protection Act. Other regulations, limitations and prohibitive regulations: Substance of very high concern (SVHC) according (EC) 1907/2006 (REACH), Article 57: N-Methyl-2- pyrrolidone (CAS 872-50-4).

- **Chemical safety assessment:**
  - No data available.
16. Other information

Further information
- The information is based upon our present knowledge. It is intended to describe our products in terms of safety requirement but does not represent any undertaking as regards product quality, nor does it constitute any contractual legal obligation.

- **Section issuing the data sheet:** Department of Occupational Safety and Environmental Protection

- **Contact:** Ms Hendlmeier

- **Abbreviations and acronyms:**
  - RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail)
  - ICAO: International Civil Aviation Organization
  - 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 Harmonized System of Classification and Labelling of Chemicals
  - EINECS: European Inventory of Existing Commercial Chemical Substances
  - CAS: Chemical Abstracts Service (division of the American Chemical Society)
  - VbF: Verordnung über brennbare Flüssigkeiten, Österreich (Ordinance on the storage of combustible liquids, Austria)
  - Fully text to the H-Sentences according CLP mentioned in heading 3:
    - H315 Causes skin irritation.
    - H319 Causes serious eye irritation.
    - H334 May cause allergy or asthma symptoms of breathing difficulties if inhaled.
    - H360D May damage the unborn child.
  - Categories of the Acute Toxicity (ATE) according EC 1272/2008:
    - Category 1 0< ATE ≤5 (oral in mg/kg body weight)
    - Category 2 5< ATE ≤50 (oral in mg/kg body weight)
    - Category 3 50< ATE ≤300 (oral in mg/kg body weight)
    - Category 4 300< ATE ≤2,000 (oral in mg/kg body weight)
  - **Changes with respect to the previous version:** Changes in the articles 2 and 15 due to the regulation (EC) 2016/1179 modifying (EC) 1272/2008.