

Safety Data Sheet according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations Version: 1.0

| SECTION 1: Identification                  |  |   |  |  |
|--|--|---|--|--|
| 1.1. Identification                        |  |   |  |  |
|  |  |   |  |  |
| Trade name                                 | : Tissue Ma  | arking & Margin Dye - Black   |  |  |
| Product code                               | : 3801753  |   |  |  |
| 1.2. Recommended use and restriction       | ons on use   |   |  |  |
| Recommended use                            | : Identifica   | tion of surgical margins  |  |  |
| Restrictions on use                        | : Other use  | 25  |  |  |
| 1.3. Supplier                              |  |   |  |  |
| Leica Biosystems Richmond, Inc             |  |   |  |  |
| 5205 Route 12                              |  |   |  |  |
| Richmond, IL 60071 - USA<br>T 844-534-2262 |  |   |  |  |
| LBSNA-LBS-QA@leicabiosystems.com - leic    | abiosystems.com  |   |  |  |
| 1.4. Emergency telephone number            |  |   |  |  |
|  |  |   |  |  |
| Organisation/Company                       |  | Emergency number  |  |  |
| ChemTrec                                   |  | 800-424-9300  |  |  |
| International Calls (call collect)         |  | +1 703-527-3887   |  |  |
| Australia 24 Hr Poisons Information Centr  | e  | 13 11 26  |  |  |
| SECTION 2: Hazard(s) identification        |  |   |  |  |
| 2.1. Classification of the substance of    | mixture  |   |  |  |
| GHS-US classification                      |  |   |  |  |
| Serious eye damage/eye irritation, Categor | v 2A   | Causes serious eye irritation   |  |  |
| Carcinogenicity, Category 2                | y 2/ (   | Suspected of causing cancer   |  |  |
|  |  |   |  |  |
| 2.2. GHS Label elements, including pr      | ecautionary stat   | ements  |  |  |
| GHS-US labelling                           |  |   |  |  |
| Hazard pictograms (GHS-US)                 | :  |   |  |  |
|  |  |   |  |  |
|  |  |   |  |  |
|  | GHS0   | 7 GH508   |  |  |
| Signal word (GHS-US)                       | : Warning  | , 6,500   |  |  |
| Hazard statements (GHS-US)                 | : Causes se  | erious eye irritation<br>d of causing cancer  |  |  |
| Precautionary statements (GHS-US)          | : Obtain sp<br>Do not ha<br>Wash tho<br>Wear pro<br>If in eyes | becial instructions before use<br>andle until all safety precautions have been read and understood<br>broughly after handling<br>stective gloves/protective clothing/eye protection/face protection.<br>Rinse cautiously with water for several minutes. Remove contact lenses, if present<br>to do. Continue rinsing |  |  |

If exposed or concerned: Get medical advice/attention If eye irritation persists: Get medical advice/attention

Dispose of contents/container in accordance with all local/regional/national/international

Store locked up

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## 2.3. Other hazards which do not result in classification

## No additional information available

2.4. Unknown acute toxicity (GHS US)

Not applicable

## **SECTION 3: Composition/information on ingredients**

### 3.1. Substances

### Not applicable

## 3.2. Mixtures

| Name         | Product identifier | %   | GHS-US classification  |
|--------------|--------------------|-----|--|
| Formaldehyde | (CAS-No.) 50-00-0  | < 1 | Acute Tox. 3 (Oral), H301<br>Acute Tox. 3 (Dermal), H311<br>Acute Tox. 3 (Inhalation:vapour), H331<br>Skin Corr. 1B, H314<br>Skin Sens. 1, H317<br>Muta. 2, H341<br>Carc. 1A, H350 |

### Full text of hazard classes and H-statements : see section 16

| SECTION 4: First-aid measures             |  |
|---|--|
| 4.1. Description of first aid measures    |  |
| First-aid measures general                | : IF exposed or concerned: Get medical advice/attention.   |
| First-aid measures after inhalation       | : Remove person to fresh air and keep comfortable for breathing.   |
| First-aid measures after skin contact     | : Rinse skin with water/shower. Remove/Take off immediately all contaminated clothing.   |
| First-aid measures after eye contact      | : Rinse eyes with water as a precaution.   |
| First-aid measures after ingestion        | : Call a poison center or a doctor if you feel unwell.   |
| 4.2. Most important symptoms and eff      | ects (acute and delayed)   |
| No additional information available       |  |
| 4.3. Immediate medical attention and      | special treatment, if necessary  |
| Treat symptomatically.                    |  |
| SECTION 5: Fire-fighting measures         |  |
| 5.1. Suitable (and unsuitable) extinguis  | hing media   |
| Suitable extinguishing media              | : Water spray. Dry powder. Foam. Carbon dioxide.   |
| 5.2. Specific hazards arising from the cl | hemical  |
| Fire hazard                               | : Highly flammable liquid and vapour.  |
| Reactivity                                | : Highly flammable liquid and vapour.  |
| 5.3. Special protective equipment and     | precautions for fire-fighters  |
| Protection during firefighting            | : Do not attempt to take action without suitable protective equipment. Self-contained breathing apparatus. Complete protective clothing. |
| SECTION 6: Accidental release measures    | 5  |
| 6.1. Personal precautions, protective e   | quipment and emergency procedures  |
| 6.1.1. For non-emergency personnel        |  |
| Emergency procedures                      | : Ventilate spillage area. No open flames, no sparks, and no smoking.  |
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| 6.1.2.  | For emergency responders  |  |
|---|---|--|
| Protect   | ive equipment :   | Do not attempt to take action without suitable protective equipment. For further   |
|   |   | information refer to section 8: "Exposure controls/personal protection".   |
| 6.2.  | Environmental precautions   |  |
| Avoid re  | elease to the environment.  |  |
| 6.3.  | Methods and material for containment  | and cleaning up  |
| Method  | Is for cleaning up :  | Take up liquid spill into absorbent material. Notify authorities if product enters sewers or public waters.  |
| Other ir  | nformation :  | Dispose of materials or solid residues at an authorized site.  |
| 6.4.  | Reference to other sections   |  |
| For furt  | her information refer to section 13.  |  |
| SECTIO  | ON 7: Handling and storage  |  |
| 7.1.  | Precautions for safe handling   |  |
| Precaut   | ions for safe handling :  | Ensure good ventilation of the work station. Keep away from heat, hot surfaces, sparks,<br>open flames and other ignition sources. No smoking. Ground/bond container and receiving<br>equipment. Use only non-sparking tools. Take precautionary measures against static<br>discharge. Flammable vapours may accumulate in the container. Use explosion-proof<br>equipment. Wear personal protective equipment. Obtain special instructions before use. Do<br>not handle until all safety precautions have been read and understood. |
| Hygiene   | e measures :  | Do not eat, drink or smoke when using this product. Always wash hands after handling the product.  |
| 7.2.  | Conditions for safe storage, including a  | ny incompatibilities   |
| Technic   | al measures :   | Ground/bond container and receiving equipment.   |
|   |   |  |
| Storage   | conditions :  | Store in a well-ventilated place. Keep cool. Keep container tightly closed. Store locked up.   |
|   |   |  |
|   | conditions :<br>ON 8: Exposure controls/personal prof<br>Control parameters   |  |
| <b>SECTIO</b><br>8.1.   | ON 8: Exposure controls/personal proto<br>Control parameters  |  |
| SECTIC<br>8.1.<br>Forma   | N 8: Exposure controls/personal pro   |  |
| SECTIC<br>8.1.<br>Forma   | ON 8: Exposure controls/personal pro<br>Control parameters<br>Idehyde (50-00-0)   |  |
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| SECTIO<br>8.1.<br>Forma<br>Not ap   | ON 8: Exposure controls/personal prof<br>Control parameters<br>Aldehyde (50-00-0)<br>Oplicable<br>Appropriate engineering controls  |  |
| SECTIO<br>8.1.<br>Forma<br>Not ap<br>8.2.<br>Approp   | ON 8: Exposure controls/personal proto<br>Control parameters<br>Aldehyde (50-00-0)<br>Oplicable<br>Appropriate engineering controls<br>riate engineering controls :   | tection  |
| SECTIO<br>8.1.<br>Forma<br>Not ap<br>8.2.<br>Approp   | ON 8: Exposure controls/personal proto<br>Control parameters<br>Aldehyde (50-00-0)<br>Oplicable<br>Appropriate engineering controls<br>riate engineering controls :   | Ensure good ventilation of the work station.<br>Avoid release to the environment.  |
| SECTIO<br>8.1.<br>Forma<br>Not ap<br>8.2.<br>Approp<br>Environ<br>8.3.  | ON 8: Exposure controls/personal protocontrol parameters   Control parameters   aldehyde (50-00-0)   oplicable   Appropriate engineering controls   riate engineering controls   :   mental exposure controls   | Ensure good ventilation of the work station.<br>Avoid release to the environment.  |
| SECTIO<br>8.1.<br>Forma<br>Not ap<br>8.2.<br>Approp<br>Environ<br>8.3.<br>Hand p  | ON 8: Exposure controls/personal prof   Control parameters   aldehyde (50-00-0)   oplicable   Appropriate engineering controls   riate engineering controls   riate engineering controls   smental exposure controls   Individual protection measures/Person  | Ensure good ventilation of the work station.<br>Avoid release to the environment.  |
| SECTIO<br>8.1.<br>Forma<br>Not ap<br>8.2.<br>Approp<br>Environ<br>8.3.<br>Hand pr<br>Protection   | N 8: Exposure controls/personal prof   Control parameters   Aldehyde (50-00-0)   oplicable   Appropriate engineering controls   riate engineering controls   riate engineering controls   mental exposure controls   Individual protection measures/Person   rotection:   | Ensure good ventilation of the work station.<br>Avoid release to the environment.  |
| SECTIO<br>8.1.<br>Forma<br>Not ap<br>8.2.<br>Approp<br>Environ<br>8.3.<br>Hand pr<br>Protection   | ON 8: Exposure controls/personal prof   Control parameters   aldehyde (50-00-0)   oplicable   Appropriate engineering controls   riate engineering controls   riate engineering controls   smental exposure controls   Individual protection measures/Person   rotection:   ive gloves   tection:                               | Ensure good ventilation of the work station.<br>Avoid release to the environment.  |
| SECTIO<br>8.1.<br>Forma<br>Not ap<br>8.2.<br>Approp<br>Environ<br>8.3.<br>Hand pu<br>Protecti<br>Eye pro<br>Safety g                      | ON 8: Exposure controls/personal prof   Control parameters   aldehyde (50-00-0)   oplicable   Appropriate engineering controls   riate engineering controls   riate engineering controls   smental exposure controls   Individual protection measures/Person   rotection:   ive gloves   tection:                               | Ensure good ventilation of the work station.<br>Avoid release to the environment.  |
| SECTIO<br>8.1.<br>Forma<br>Not ap<br>8.2.<br>Approp<br>Environ<br>8.3.<br>Hand p<br>Protecti<br>Eye pro<br>Safety g<br>Skin an            | ON 8: Exposure controls/personal prof   Control parameters   aldehyde (50-00-0)   oplicable   Appropriate engineering controls   riate engineering controls   riate engineering controls   smental exposure controls   Individual protection measures/Person   rotection:   tive gloves   tection:   glasses                    | Ensure good ventilation of the work station.<br>Avoid release to the environment.  |
| SECTIO<br>8.1.<br>Forma<br>Not ap<br>8.2.<br>Approp<br>Environ<br>8.3.<br>Hand p<br>Protecti<br>Eye pro<br>Safety g<br>Skin an<br>Wear su | N 8: Exposure controls/personal prof   Control parameters   aldehyde (50-00-0)   oplicable   Appropriate engineering controls   riate engineering controls   riate engineering controls   imental exposure controls   Individual protection measures/Person   rotection:   ive gloves   tection:   glasses   d body protection: | Ensure good ventilation of the work station.<br>Avoid release to the environment.  |

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| <b>SECTION 9: Physical and chemical prope</b>   | rties               |  |
|---|---------------------|--|
| 9.1. Information on basic physical and c  | hemical properties  |  |
| Physical state  | : Liquid            |  |
| Colour  | : Black             |  |
| Odour   | : ammonia           |  |
| Odour threshold   | : No data available |  |
| рН  | : 8.5 - 10          |  |
| Melting point   | : Not applicable    |  |
| Freezing point  | : No data available |  |
| Boiling point   | : No data available |  |
| Flash point   | : ≥212 °F           |  |
| Relative evaporation rate (butylacetate=1)  | : No data available |  |
| Flammability (solid, gas)   | : Not applicable.   |  |
| Vapour pressure   | : No data available |  |
| Relative vapour density at 20 °C  | : No data available |  |
| Relative density  | : No data available |  |
| Density   | : 1.02 - 1.14       |  |
| Solubility  | : No data available |  |
| Log Pow   | : No data available |  |
| Auto-ignition temperature   | : No data available |  |
| Decomposition temperature   | : No data available |  |
| Viscosity, kinematic  | : No data available |  |
| Viscosity, dynamic  | : No data available |  |
| Explosive limits  | : No data available |  |
| Explosive properties  | : No data available |  |
| Oxidising properties  | : No data available |  |
| 9.2. Other information  |                     |  |
| No additional information available   |                     |  |
| SECTION 10: Stability and reactivity  |                     |  |
| 10.1. Reactivity  |                     |  |
| Highly flammable liquid and vapour.   |                     |  |
| 10.2. Chemical stability  |                     |  |
| Stable under normal conditions.   |                     |  |
| 10.3. Possibility of hazardous reactions  |                     |  |
| No dangerous reactions known under normal conditions of use.                                    |                     |  |
| 10.4. Conditions to avoid   |                     |  |
| Avoid contact with hot surfaces. Heat. No flames, no sparks. Eliminate all sources of ignition. |                     |  |
| 10.5. Incompatible materials  |                     |  |
| No additional information available   |                     |  |
|   |                     |  |

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### 10.6. Hazardous decomposition products

Under normal conditions of storage and use, hazardous decomposition products should not be produced.

| SECTIO | N 11: Toxicological information      |  |  |
|--------|--------------------------------------|--|--|
| 11 1   | Information on toxicological offects |  |  |

#### 11.1. Information on toxicological effects

Acute toxicity

: Not classified

| Formaldehyde (50-00-0)            |                                  |
|-----------------------------------|----------------------------------|
| ATE US (oral)                     | 100 mg/kg bodyweight             |
| ATE US (dermal)                   | 300 mg/kg bodyweight             |
| ATE US (vapours)                  | 3 mg/l/4h                        |
| Skin corrosion/irritation         | : Not classified                 |
|                                   | pH: 8.5 - 10                     |
| Serious eye damage/irritation     | : Causes serious eye irritation. |
|                                   | pH: 8.5 - 10                     |
| Respiratory or skin sensitisation | : Not classified                 |
| Germ cell mutagenicity            | : Not classified                 |
| Carcinogenicity                   | : Suspected of causing cancer.   |

| Formaldehyde (50-00-0)                             |   |                             |
|--|---|-----------------------------|
| IARC group   |   | 1 - Carcinogenic to humans  |
| National Toxicity Program (NTP) Status             |   | 2 - Known Human Carcinogens |
| Reproductive toxicity                              | : | Not classified              |
| Specific target organ toxicity (single exposure)   | : | Not classified              |
| Specific target organ toxicity (repeated exposure) | : | Not classified              |
| Aspiration hazard                                  | : | Not classified              |

| SECTION   | 12: Ecological information |                            |
|-----------|----------------------------|----------------------------|
| 12.1.     | Toxicity                   |                            |
| Ecology - | general                    | : Harmful to aquatic life. |

### 12.2. Persistence and degradability

| Formaldehyde (50-00-0)          |  |
|---------------------------------|--|
| Persistence and degradability   | Readily biodegradable in water. No (test)data on mobility of the components available.<br>Photodegradation in the air. |
| Biochemical oxygen demand (BOD) | 0.64 g O <sub>2</sub> /g substance   |
| Chemical oxygen demand (COD)    | 1.06 g O <sub>2</sub> /g substance   |
| ThOD                            | 1.068 g O₂/g substance   |
| BOD (% of ThOD)                 | 0.6  |

## 12.3. Bioaccumulative potential

| Formaldehyde (50-00-0)    |                                  |
|---------------------------|----------------------------------|
| Log Pow                   | -0.78 - 0.0                      |
| Bioaccumulative potential | Bioaccumulation: not applicable. |

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## 12.4. Mobility in soil

No additional information available

### 12.5. Other adverse effects

No additional information available

| SECTION 13: Disposal consideration                                     | ons   |
|--|---|
| 13.1. Disposal methods   |   |
| Waste treatment methods  | : Dispose of contents/container in accordance with licensed collector's sorting instructions. |
| Additional information   | : Flammable vapours may accumulate in the container.  |
| SECTION 14: Transport informatio<br>Department of Transportation (DOT) | n   |
| In accordance with DOT   |   |
| Not applicable   |   |
| Transport by sea   |   |
|  |   |

Not applicable

### Air transport

Not applicable

| SECTION 15: Regulatory information |  |  |  |
|------------------------------------|--|--|--|
| 15.1. US Federal regulations       |  |  |  |
|                                    |  |  |  |

| Formaldehyde (50-00-0)  |        |  |
|---|--------|--|
| Listed on the United States TSCA (Toxic Substances Control Act) inventory |        |  |
| Subject to reporting requirements of United States SARA Section 313       |        |  |
| CERCLA RQ   | 100 lb |  |
| SARA Section 302 Threshold Planning                                       | 500 lb |  |
| Quantity (TPQ)  |        |  |

### 15.2. International regulations

## CANADA

### Formaldehyde (50-00-0)

Listed on the Canadian DSL (Domestic Substances List)

### **EU-Regulations**

No additional information available

### **National regulations**

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### Formaldehyde (50-00-0)

| Listed on IARC (International Agency for Research on Cancer) |
|--|
| Listed as carcinogen on NTP (National Toxicology Program)    |
| Listed on EPA Hazardous Air Pollutant (HAPS)                 |

### 15.3. US State regulations

| Formaldehyde (50-00-0)                                   | naldehyde (50-00-0)  |   |   |                                     |  |
|--|--|---|---|-------------------------------------|--|
| U.S California -<br>Proposition 65 -<br>Carcinogens List | U.S California -<br>Proposition 65 -<br>Developmental Toxicity | U.S California -<br>Proposition 65 -<br>Reproductive Toxicity -<br>Female | U.S California -<br>Proposition 65 -<br>Reproductive Toxicity -<br>Male | No significant risk<br>level (NSRL) |  |
| Yes  | No   | No  | No  | 40 μg/day                           |  |

### Formaldehyde (50-00-0)

U.S. - New Jersey - Right to Know Hazardous Substance List

### **SECTION 16: Other information**

### Full text of H-statements:

| H301 | Toxic if swallowed                      |  |  |  |
|------|---|--|--|--|
| H311 | Toxic in contact with skin              |  |  |  |
| H314 | Causes severe skin burns and eye damage |  |  |  |
| H317 | May cause an allergic skin reaction     |  |  |  |
| H331 | Toxic if inhaled                        |  |  |  |
| H341 | Suspected of causing genetic defects    |  |  |  |
| H350 | May cause cancer                        |  |  |  |

### SDS US Leica

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product