

SECTION 1: Identification

1.1. Identification

Trade name : Tissue Marking & Margin Dye - Non Black
Product code : 3801751, 3801752, 3801754, 3801755, 3801756, 3801757

1.2. Recommended use and restrictions on use

Recommended use : Identification of surgical margins
Restrictions on use : Other uses

1.3. Supplier

Leica Biosystems Richmond, Inc
5205 Route 12
Richmond, IL 60071 - USA
T 844-534-2262
LBSNA-LBS-QA@leicabiosystems.com - leicabiosystems.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 Centre	13 11 26

SECTION 2: Hazard(s) identification

2.1. Classification of the substance or mixture

GHS-US classification

Serious eye damage/eye irritation, Category 2A Causes serious eye irritation
Carcinogenicity, Category 2 Suspected of causing cancer

2.2. GHS Label elements, including precautionary statements

GHS-US labelling

Hazard pictograms (GHS-US) :



Signal word (GHS-US) : Warning

Hazard statements (GHS-US) : Causes serious eye irritation
Suspected of causing cancer

Precautionary statements (GHS-US) : Obtain special instructions before use
Do not handle until all safety precautions have been read and understood
Wash thoroughly after handling
Wear protective gloves/protective clothing/eye protection/face protection.
If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing
If exposed or concerned: Get medical advice/attention
If eye irritation persists: Get medical advice/attention
Store locked up
Dispose of contents/container in accordance with all local/regional/national/international

Tissue Marking & Margin Dye - Non Black

Safety Data Sheet

according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

regulations

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 Acute Tox. 3 (Dermal), H311 Acute Tox. 3 (Inhalation:vapour), H331 Skin Corr. 1B, H314 Skin Sens. 1, H317 Muta. 2, H341 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 effects (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) extinguishing media

Suitable extinguishing media : Water spray. Dry powder. Foam. Carbon dioxide.

5.2. Specific hazards arising from the chemical

- 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

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

Emergency procedures : Ventilate spillage area. No open flames, no sparks, and no smoking.

Tissue Marking & Margin Dye - Non Black

Safety Data Sheet

according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

6.1.2. For emergency responders

Protective 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 release to the environment.

6.3. Methods and material for containment and cleaning up

Methods for cleaning up : Take up liquid spill into absorbent material. Notify authorities if product enters sewers or public waters.

Other information : Dispose of materials or solid residues at an authorized site.

6.4. Reference to other sections

For further information refer to section 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : Ensure good ventilation of the work station. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Ground/bond container and receiving equipment. Use only non-sparking tools. Take precautionary measures against static discharge. Flammable vapours may accumulate in the container. Use explosion-proof equipment. Wear personal protective equipment. Obtain special instructions before use. Do not handle until all safety precautions have been read and understood.

Hygiene 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 any incompatibilities

Technical measures : Ground/bond container and receiving equipment.

Storage conditions : Store in a well-ventilated place. Keep cool. Keep container tightly closed. Store locked up.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Formaldehyde (50-00-0)

Not applicable

8.2. Appropriate engineering controls

Appropriate engineering controls : Ensure good ventilation of the work station.

Environmental exposure controls : Avoid release to the environment.

8.3. Individual protection measures/Personal protective equipment

Hand protection:

Protective gloves

Eye protection:

Safety glasses

Skin and body protection:

Wear suitable protective clothing

Respiratory protection:

In case of insufficient ventilation, wear suitable respiratory equipment

Tissue Marking & Margin Dye - Non Black

Safety Data Sheet

according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Liquid
Colour	: Black
Odour	: ammonia
Odour threshold	: No data available
pH	: 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

Tissue Marking & Margin Dye - Non Black

Safety Data Sheet

according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

10.6. Hazardous decomposition products

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

SECTION 11: Toxicological information

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. Photodegradation in the air.
Biochemical oxygen demand (BOD)	0.64 g O ₂ /g substance
Chemical oxygen demand (COD)	1.06 g O ₂ /g substance
ThOD	1.068 g O ₂ /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.

Tissue Marking & Margin Dye - Non Black

Safety Data Sheet

according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

12.4. Mobility in soil

No additional information available

12.5. Other adverse effects

No additional information available

SECTION 13: Disposal considerations

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 information

Department of Transportation (DOT)

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 Quantity (TPQ)	500 lb
---	--------

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

Tissue Marking & Margin Dye - Non Black

Safety Data Sheet

according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

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)

U.S. - California - Proposition 65 - Carcinogens List	U.S. - California - Proposition 65 - Developmental Toxicity	U.S. - California - Proposition 65 - Reproductive Toxicity - Female	U.S. - California - Proposition 65 - Reproductive Toxicity - Male	No significant risk 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