

Living up to Life



BIOSYSTEMS

Safety Data Sheet

10% Neutral Buffered Formalin

SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND THE COMPANY/ UNDERTAKING

1.1 Product Identifier

Trade Name 10% Neutral Buffered Formalin
Product # 3800598 3800600 3800650 3800604EG 3800811C
SDS # 120
SDS Date August 22, 2013

1.2 Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

Product Use: Tissue Fixation
Uses Advised Against: All other uses.

1.3 Details of the Supplier of the Substance or Mixture

Manufacturer/Preparer: Leica Biosystems Richmond, Inc. Leica Biosystems Canada, Inc.
5205 Route 12 83 Terracon Place
Richmond, IL 60071 Winnipeg, Manitoba R2J 4B3
800-225-8867 800-665-7425

1.4 Emergency Telephone Number

Emergency Spill Information 1-800- 424-9300 (CHEMTREC)
+1 703-527-3887 International calls (call collect)
Other Product Information: 1-800-225-8867

SECTION 2: HAZARDS IDENTIFICATION

2.1 Classification of the Substance or Mixture

CLP/GHS Classification (1272/2008):

Physical:	Health:	Environmental
Not Hazardous	Eye Damage Category 1 Skin Irritation Category 2 Skin Sensitization Category 1 Carcinogenicity Category 1A Specific Target Organ Toxicity – Single Exposure Category 1	Not Hazardous

EU Classification (67/548/EEC): Xn, Xi, R36/37/38, R43, R40, R20/21/22

2.2 Label Elements

DANGER! Contains methanol, formaldehyde



Hazard Phrases

H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H318	Causes serious eye damage.
H350	May cause cancer.
H370	Causes damage to nervous system and eyes.

Precautionary Phrases

P201	Obtain special instructions before use.
P202	Do not handle until all safety precautions have been read and understood.
P260	Do not breathe mist/vapours/spray.
P264	Wash thoroughly after handling.
P270	Do not eat, drink or smoke when using this product.
P272	Contaminated work clothing should not be allowed out of the workplace.
P280	Wear protective gloves/protective clothing/eye protection/face protection.
P305 + P351 + P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P310	Immediately call a POISON CENTER or doctor/physician.
P302 + P352	IF ON SKIN: Wash with plenty of soap and water.
P333 + P313	If skin irritation or rash occurs: Get medical advice/attention.
P362	Take off contaminated clothing and wash before reuse.
P308 + P313	IF exposed or concerned: Get medical advice/ attention.
P405	Store locked up.
P501	Dispose of contents/container in accordance with local and national regulations.

2.3 Other Hazards: None

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Chemical Name	CAS Number / EINECS Number / REACH Reg. Number	% (w/w)	EU Classification (67/548/EEC)	CLP/GHS Classification (1272/2008)
Formaldehyde	50-00-0 200-001-8	<6	T, Xn (Carc. Cat. 3), C, Xi R40, R23/24/25, R34, R43	Carcinogenicity Category 1A (H350), Acute Toxicity Category 3 (H301, H311, H331) Skin Corrosion Category 1B (H314) Eye Corrosion Category 1 (H318) Skin Sensitization Category 1 (H317) Aquatic Acute Toxicity Category 3 (H402)
Methanol	67-56-1 200-659-6	<2	F, T R11, R23/24/25, R39/23/24/25	Flammable Liquid Category 2 (H225) Acute Toxicity Category 3 (H301, H311, H331)

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SECTION 4: FIRST AID MEASURES

4.1 Description of First Aid Measures

First Aid

Eye contact: Immediately flush eye with water for at least 15 minutes while lifting the upper and lower lids. Get immediate medical attention.

Skin contact: Remove contaminated clothing. Wash thoroughly with soap and water. Get medical attention if irritation persists. Launder before reuse.

Inhalation: Remove victim to fresh air. If breathing is difficult have qualified individual administer oxygen and get immediate medical attention. If breathing stops, give artificial respiration. Get immediate medical attention.

Ingestion: Do not induce vomiting unless directed to do so by medical personnel. If the victim is conscious and alert, have them rinse their mouth with water. Never give anything by mouth to an unconscious or drowsy person. Get immediate medical attention.

See Section 11 for more detailed information on health effects.

4.2 Most Important symptoms and effects, both acute and delayed: May cause severe eye irritation or burns. May cause skin irritation. May cause an allergic skin reaction. Inhalation of vapors may cause nose, throat or upper respiratory tract irritation and nervous system effects including dizziness, drowsiness, nausea, vomiting, visual disturbances and unconsciousness. Potential Cancer Hazard. Risk of cancer depends on the level and duration of exposure.

4.3 Indication of any immediate medical attention and special treatment needed: Immediate medical treatment is required for eye contact and ingestion.

SECTION 5: FIREFIGHTING MEASURES

5.1 Extinguishing Media:

Use dry chemical, foam, carbon dioxide (CO₂), or water spray.

5.2 Special Hazards Arising from the Substance or Mixture

Unusual Fire and Explosion Hazards: None known.

Combustion Products: Oxides of carbon, smoke.

5.3 Advice for Fire-Fighters: Self-contained breathing apparatus and protective clothing should be worn in fighting large fires involving chemicals. Determine the need to evacuate or isolate the area according to your local emergency plan. Use water spray to keep fire exposed containers cool.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal Precautions, Protective Equipment and Emergency Procedures:

Wear appropriate protective equipment. Ventilate the area.

6.2 Environmental Precautions:

Prevent entry in storm sewers and waterways. Report spill as required by local and federal regulations.

6.3 Methods and Material for Containment and Cleaning Up:

Small Spill and Leak: Dilute with water and mop, or absorb with inert dry material and place in an appropriate waste disposal container. Use D-Formalizer® pads or F.C.G.® Formaldehyde Control Granules to reduce formaldehyde exposure.

Large Spill and Leak: Stop leak if it is safe to do so. Absorb with DRY earth or non-combustible material. Ensure airborne concentrations of formaldehyde do not exceed published exposure limits. Additional protective equipment may be required,

6.4 Reference to Other Sections:

Refer to Section 8 for personal protective equipment and Section 13 for disposal information.

SECTION 7: HANDLING and STORAGE

7.1 Precautions for Safe Handling:

Prevent eye and skin contact. Do not breathe vapors or mists. Use only with adequate ventilation. Wash thoroughly after handling. Remove contaminated clothing and launder before re-use. Keep containers closed when not in use.

Some countries may have special requirements for handling formaldehyde. In the United States refer to OSHA 1910.1048 for requirements for handling and use of formaldehyde solutions.

7.2 Conditions for Safe Storage, Including any Incompatibilities:

Protect containers from physical damage. Store in a cool area. Keep containers closed when not in use. Store away from oxidizers.

Empty containers retain product residues. Do not cut, weld, braze, etc. on or near empty containers. Follow all SDS precautions in handling empty containers

7.3 Specific end use(s):

Industrial uses: None identified

Professional uses: Tissue Fixation

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control Parameters:

Chemical Name	US OEL	EU IOEL	UK OEL	Germany OEL
Formaldehyde	0.75 ppm TWA, 2 ppm STEL OSHA PEL 0.3 ppm Ceiling ACGIH TLV	None Established	2 ppm TWA 2 ppm Ceiling	0.3 ppm TWA 0.6 ppm Ceiling
Methanol	200 ppm TWA OSHA PEL 200 ppm TWA, 250 ppm STEL skin ACGIH TLV	200 ppm TWA skin	200 ppm TWA, 250 ppm STEL	200 ppm TWA, 800 ppm STEL

Refer to local or national authority for exposure limits not listed above.

In the United States, 29 CFR 1910.1048 is the OSHA regulation on Occupational Exposure to Formaldehyde. Assure compliance with these regulations.

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Chemical Name	Biological Limit Value
Formaldehyde	None Established
Methanol	Methanol in urine 15 mg/L, end of shift (ACGIH)

8.2 Exposure Controls:

Recommended Monitoring Procedures: Formaldehyde: Collection on ORBO 24 or coated XAD-2 with analysis by gas chromatography/nitrogen phosphorus detector. Methanol: Collect on silica gel tubes with analysis by gas chromatography.

Appropriate Engineering Controls: Use with adequate local exhaust ventilation to maintain exposure levels below the occupational exposure limits.

Personal Protective Measures

Eye/face Protection: Wear safety goggles. A faceshield should be worn where splashing is possible.

Skin Protection: Impervious clothing as needed to avoid skin contact.

Hands: Impervious gloves recommended (butyl rubber).

Respiratory Protection: None needed with adequate ventilation. If the occupational exposure limit is exceeded, use an approved respirator with organic vapor/formaldehyde cartridges (In the U.S., refer to 29 CFR1910.1048 for cartridge change schedule requirements) or a supplied air respirator appropriate for the form and concentration of the contaminants should be used. Select in accordance with OSHA 1910.134 or other applicable regulations and good Industrial Hygiene practice.

Other protection: Suitable washing facilities should be available.

SECTION 9: PHYSICAL and CHEMICAL PROPERTIES

9.1 Information on basic Physical and Chemical Properties

Appearance: Clear, colorless liquid

Odor Threshold: 0.1 ppm (formaldehyde)

Melting/Freezing Point: -133°F (-92°C)

Flash Point: : >100°C (>212°F)(Closed Cup)

Lower Flammability Limit: 6.0% (methanol)

Upper Flammability Limit: 73% (formaldehyde)

Vapor Density(Air=1): 1.11 (methanol)

Solubility: Soluble in water

Autoignition Temperature: Not available

Viscosity: Not established

Oxidizing Properties: None

Molecular Formula: Mixture

Odor: Pungent odor

pH: 7.0-7.2

Boiling Point: 100°C (212°F)

Evaporation Rate: Not determined

Vapor Pressure: Not available

Relative Density: 1.03

Octanol/Water Partition Coefficient: Not available

Decomposition Temperature: Not established

Explosive Properties: Vapors may be explosive in confined areas.

Specific Gravity (H₂O= 1): 1.03

Molecular Weight: Mixture

9.2 Other Information: None available

SECTION 10: STABILITY and REACTIVITY

10.1 Reactivity: This material is not reactive under normal conditions.

10.2 Chemical Stability: Normally stable.

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10.3 Possibility of Hazardous Reactions: None know.

10.4 Conditions to Avoid: None known.

10.5 Incompatible Materials: Oxidizing agents and bases.

10.6 Hazardous Decomposition Products: Thermal breakdown of this product during fire or very high heat conditions may evolve the following decomposition products: oxides of carbon.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on Toxicological Effects:

Potential Health Effects:

Eye Contact: May cause severe irritation or burns with redness, tearing, swelling and blurred vision. Corneal injury may occur.

Skin contact: May cause irritation. May be harmful if absorbed through the skin. May cause allergic skin reactions.

Inhalation: High vapor concentrations may cause respiratory tract irritation and central nervous system effects such as dizziness, drowsiness, nausea, vomiting, visual disturbances and unconsciousness. Based on human experience, formaldehyde may cause respiratory sensitization and asthma-like symptoms.

Ingestion: Swallowing may cause gastrointestinal irritation, nausea, vomiting and diarrhea. May cause central nervous system effects including dizziness, drowsiness, nausea, vomiting, visual disturbances and unconsciousness. May cause permanent blindness.

Acute toxicity:

Formaldehyde: LD50 oral rat 640 mg/kg, Inhalation rat LC50 5.9 mg/L

Methanol: LD50 oral rat 5628 mg/kg; LC50 inhalation rat 64000 ppm/4 hr; LD50 dermal rabbit 15,800 mg/kg

Skin corrosion/irritation: No data available for mixture. A 40% solution of formaldehyde is corrosive to rabbit skin.

Eye damage/ irritation: No data available for mixture. Formaldehyde has been shown to be corrosive in rabbits eyes. In human studies, 1-10 ppm produced appreciable eye irritation on initial exposure. Lacrimation occurs at 4 ppm.

Respiratory Irritation: No data available for mixture. High concentrations of vapors may be irritating to the respiratory system.

Respiratory Sensitization: No data available for mixture. Guinea pigs were exposed by the inhalation, dermal, and injection routes. Pulmonary hypersensitivity was assessed by measuring a potential increase in respiration rate. No pulmonary hypersensitivity was detected by challenge with 2 or 4 ppm formaldehyde for any of the induction routes and formaldehyde-serum albumin adducts were not observed after inhalation treatment. On the other hand, dermal sensitization was observed by all of the different induction routes. Formaldehyde led to skin sensitization in guinea pigs without causing respiratory hypersensitivity.

Skin Sensitization: No data available for mixture. Formaldehyde was shown to cause sensitization in mouse local lymphnode assay and guineas pig assays.

Germ Cell Mutagenicity: No data available for mixture. None of the components are germ cell mutagens.

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Carcinogenicity: No data available for mixture. Formaldehyde is listed by IARC as “Carcinogenic to Humans”, (Group 1), by NTP a “Known to be a Human Carcinogen”, by ACGIH as a “Suspected Human Carcinogen”(A2), by the European Union as a Carcinogen Category 3.

Reproductive Toxicity: No data available for mixture. In a reproductive study, rats were exposed to 0-40 ppm formaldehyde for 6 hr/days on days 6-20 of gestation. At 40 ppm, maternal toxicity was observed. Formaldehyde is slightly fetotoxic at 20 ppm. Neither embryo-lethal nor teratogenic effects were observed following inhalation exposure at levels up to 40 ppm.

Specific Target Organ Toxicity:

Single Exposure: Methanol has been found to cause visual and nervous system damage in studies with humans and animals. Exposure to high doses of formaldehyde (>100 ppm) showed salivation, acute dyspnea, vomiting, cramps and death in laboratory animals. Mice treated with formaldehyde on skin developed severe liver damage.

Repeat Exposure: Animal data revealed a qualitative relationship between formaldehyde absorption and hepatotoxicity. These data indicate that exposure to formaldehyde at 3 ppm or less for periods up to 6 months causes adverse effects upon the liver; higher exposure concentrations for shorter time periods produce similar effects upon the liver

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity:

Formaldehyde: LC50 Pimephales promelas (Fathead minnow) 24.1 mg/L/96 hr
Methanol: LC50 fathead minnows 29,400 mg/L/96 hr; EC50 daphnia magna >10,000 mg/L/24 hr

12.2 Persistence and degradability: Methanol and formaldehyde are readily biodegradable in screening tests

12.3 Bioaccumulative Potential: Formaldehyde has an estimated BCF of 3. Methanol an estimated BCF of <10. This suggests that the potential for bioaccumulation is low.

12.4 Mobility in Soil: Methanol and formaldehyde are expected to have very mobility in soil.

12.5 Results of PVT and vPvB assessment: Not required.

12.6 Other Adverse Effects: No data available.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste Treatment Methods:

Dispose in accordance with local, state and national regulations.

SECTION 14: TRANSPORTATION INFORMATION

	14.1 UN Number	14.2 UN Proper Shipping Name	14.3 Hazard Class(s)	14.4 Packing Group	14.5 Environmental Hazards
US DOT		Not Regulated			No
Canadian TDG		Not Regulated			No
EU ADR/RID		Not Regulated			No
IMDG		Not Regulated			No
IATA/ICAO		Not Regulated			No

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14.6 Special Precautions for User: None

14.7 Transport in Bulk According to Annex III MARPOL 73/78 and the IBC Code: Not determined.

SECTION 15: REGULATORY INFORMATION

15.1 Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

INTERNATIONAL INVENTORIES

EPA TSCA INVENTORY: All of the components are listed on the TSCA inventory.

CANADIAN ENVIRONMENTAL PROTECTION ACT: All of the ingredients are listed on the Canadian Domestic Substances List.

EUROPEAN UNION: All of the components of this product are listed on the European Inventory of New and Existing Chemical Substances (EINECS) inventory.

AUSTRALIA: All of the ingredients of this product are listed on the Australian Inventory of Chemical Substances (AICS).

CHINA: All of the ingredients are listed on the Chinese chemical inventory.

KOREA: All of the components of this product are listed on the Korean Existing Chemical List (KECL).

NEW ZEALAND: All of the components of this product are listed on the New Zealand Inventory of Chemicals (NzIoC).

PHILIPPINES: All of the components of this product are listed on the Philippine Inventory of Chemicals and Chemical Substances (PICCS).

JAPAN: All of the components of this product are listed on the Japanese Existing and New Chemical Substances List (ENCS).

U.S. REGULATIONS

OSHA HAZARD CLASSIFICATION: Irritant, Target Organ Effects, Carcinogen, Sensitizer

CERCLA Section 103: The RQ for the product, based on the RQ for Formaldehyde (6% maximum) of 100 lbs, is 1,666 lbs. Many states have more stringent release reporting requirements. Report spills required under federal, state and local regulations.

EPA SARA 302: This product contains the following chemicals regulated under SARA Section 302. Formaldehyde <6%

EPA SARA 311 HAZARD CLASSIFICATION: Acute Health, Chronic Health

EPA SARA 313: This product contains the following chemicals that are regulated under SARA Title III, section 313:

Methanol 67-56-1 <2%

Formaldehyde 50-00-0 <6%

CALIFORNIA PROPOSITION 65: This product contains the following chemicals which are known to the State of California to cause cancer, reproductive toxicity or birth defects (developmental toxicity): Formaldehyde <6% (cancer), Methanol <2% (Reproductive).

INTERNATIONAL REGULATIONS

WHMIS CLASSIFICATION: Class D-2-A

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SECTION 16: OTHER INFORMATION

Revision History: Updated Logo and website.

EU Classes and Risk Phrases for Reference (See Sections 2 and 3)

C Corrosive

F Highly Flammable

T Toxic

Xi Irritant

Xn Harmful

Carc. Cat 3 Carcinogen Category 3

R11 Highly Flammable

R20/21/22 Harmful by inhalation, in contact with skin and if swallowed.

R23/24/25 Toxic by inhalation, in contact with skin and if swallowed.

R34 Causes burns.

R36/37/38 Irritating to eyes, respiratory system and skin.

R39/23/24/25 Toxic: danger of very serious irreversible effects through inhalation, in contact with skin and if swallowed

R40 Possible risk of cancer.

R43 May cause sensitization by skin contact.

CLP/GHS Classification and H Phrases for Reference (See Section 3)

H225 Highly flammable liquid and vapour.

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.

H318 Causes serious eye damage.

H331 Toxic if inhaled.

H350 May cause cancer.

H370 Causes damage to nervous system and eyes.

H402 Harmful to aquatic.

NFPA Rating: Health: 2 Fire: 1 Instability: 0

HMIS Rating: Health: 2* Fire: 1 Physical Hazard: 0

This Safety Data Sheet has been prepared in accordance with the REACH regulation in the EU and the Globally Harmonized System for the Classification and Labelling of Chemicals (GHS). It complies with the requirements of the Canadian Controlled Products Regulations and US 29CFR 1910.1200. To the best of our knowledge, the information contained herein is accurate. However, neither the above named supplier nor any of its subsidiaries makes any warranty of merchantability or any other warranty, expressed or implied, which respect to such information, and we assume no liability resulting from its use. In no event shall Leica Biosystems be liable for any claims, losses, or damages of any third party or for lost profits or any special, indirect, incidental, consequential or exemplary damages resulting from use of or reliance upon this information.,