

Safety Data Sheet

Define MX-aq® Concentrate

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

1.1 Product Identifier

Trade Name Define MX-aq® Concentrate
Product # 3803595 3803596
SDS # 171
SDS Date August 22, 2013

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

Product Use: Histology/Cytology and General Use Reagent
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 Irritation Category 2A Skin Irritation Category 3 Skin Sensitization Category 1	Not Hazardous

EU Classification (67/548/EEC): Xi R36, R43

2.2 Label Elements:

WARNING! Contains malic acid and 5-chloro-2-methyl-4-isothiazolin-3-one and 2-methyl-2H-isothiazolin-3-one (3:1)



Hazard Phrases

H319	Causes serious eye irritation
H316	Causes mild skin irritation.
H317	May cause an allergic skin reaction.

Precautionary Phrases

P261	Avoid breathing mists.
P264	Wash thoroughly after handling.
P272	Contaminated work clothing should not be allowed out of the workplace.
P280	Wear protective gloves, protective clothing and eye 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
P337 + P313	If eye irritation persists: Get medical advice/ attention.
P302+P352	IF ON SKIN: Wash with plenty of soap and water.
P333+P313	If skin irritation or rash occurs: Get medical attention.
P363	Wash contaminated clothing before reuse.
P501	Dispose of container/contents to approved disposal site in accordance with all 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/t)	EU Classification (67/548/EEC)	CLP/GHS Classification (1272/2008)
Malic acid	6915-15-7 230-022-8	<10	Xi R36/38	Eye Irritation Category 2A (H319) Skin Irritation Category 2 (H315)
5-chloro-2-methyl- 4-isothiazolin-3- one and 2-methyl- 2H-isothiazolin-3- one (3:1)	55965-84-9 247-500-7 220-239-6	<0.01	T; R23/24/25 C; R34 R43 N; R50-53	Acute Toxicity Category 3 (H301, H311, H331) Skin Corrosion Category 1B (H314) Eye Damage Category 1 (H318) Skin Sensitization Category 1 (H317) Aquatic Acute Category 1 (H400) Aquatic Chronic Category 1 (H410)

See Section 16 for full text of GHS and EU Classifications.

SECTION 4: FIRST AID MEASURES

4.1 Description of First Aid Measures

First Aid

Eye contact: Immediately flush eyes with water for at least 15 minutes, holding the eyelids apart. Get medical attention if irritation persists.

Skin contact: Remove contaminated clothing immediately. Wash the affected areas with soap and water. Get medical attention if irritation persists.

Inhalation: Move individual to fresh air. Get medical attention if symptoms persist.

Ingestion: Never give anything by mouth to an unconscious person. Do not induce vomiting. Rinse mouth and give one glass of water. Get medical attention.

4.2 Most Important symptoms and effects, both acute and delayed: Causes eye irritation. May cause skin irritation or an allergic skin reaction.

4.3 Indication of any immediate medical attention and special treatment needed: Seek medical attention if irritation persists after flushing eyes.

SECTION 5: FIREFIGHTING MEASURES

5.1 Extinguishing Media:

Use any media that is suitable for the surrounding fire.

5.2 Special Hazards Arising from the Substance or Mixture

Unusual Fire and Explosion Hazards: None known.

Hazardous Combustion Products: Oxides of carbon, magnesium and sulfur.

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.

6.2 Environmental Precautions:

Prevent entry in storm sewers and waterways.

6.3 Methods and Material for Containment and Cleaning Up:

Stop spill at the source if it is safe to do so. Absorb with an inert material. Collect into a suitable container for disposal.

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:

Avoid contact with eyes, skin and clothing. Avoid breathing mists. Wash thoroughly after handling. Keep containers closed when not in use.

7.2 Conditions for Safe Storage, Including any Incompatibilities:

Keep containers closed. Store at room temperature.

7.3 Specific end use(s):

Industrial uses: None identified

Professional uses: Histology/Cytology and General Use Reagent

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control Parameters:

Chemical Name	US OEL	EU IOEL	UK OEL	Germany OEL
Malic acid	None Established	None Established	None Established	None Established
5-chloro-2-methyl-4-isothiazolin-3-one and 2-methyl-2H-isothiazolin-3-one (3:1)	None Established	None Established	None Established	None Established

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

Chemical Name	Biological Limit Value
Malic acid	None Established
5-chloro-2-methyl-4-isothiazolin-3-one and 2-methyl-2H-isothiazolin-3-one (3:1)	None Established

8.2 Exposure Controls:

Recommended Monitoring Procedures: None required.

Appropriate Engineering Controls: No special controls required for normal use.

Personal Protective Measures

Eye/face Protection: Wear safety glasses or goggles.

Skin Protection: Wear protective clothing if needed to avoid skin contact.

Hands: Latex or nitrile gloves recommended where needed to avoid contact.

Respiratory Protection: None needed with adequate ventilation. If exposure levels are excessive, use an approved dust/mist respirator. Selection of respiratory protection depends on the contaminant type, form and concentration. Select in accordance with OSHA 1910.134 or other applicable regulations and good Industrial Hygiene practice.

Other protection: Eye wash facilities should be available.

SECTION 9: PHYSICAL and CHEMICAL PROPERTIES

9.1 Information on basic Physical and Chemical Properties

Appearance: Colorless liquid

Odor Threshold: Not available

Melting/Freezing Point: Not available

Flash Point: : None

Lower Flammability Limit: Not applicable

Upper Flammability Limit: Not applicable

Vapor Density(Air=1): Same as water

Solubility: Soluble in water

Autoignition Temperature: Not applicable

Odor: Slight odor

pH: 2.8 - 3.2

Boiling Point: 100°C (212°F)

Evaporation Rate: Not applicable

Vapor Pressure: Same as water

Relative Density: 1.00

Octanol/Water Partition Coefficient: Not applicable

Decomposition Temperature: Not applicable

Viscosity: Not applicable
Oxidizing Properties: None
Molecular Formula: Mixture

Explosive Properties: None
Specific Gravity (H₂O= 1): 1.00
Molecular Weight: Mixture

9.2 Other Information: None available

SECTION 10: STABILITY and REACTIVITY

10.1 Reactivity: Not applicable.

10.2 Chemical Stability: Stable under normal conditions of use.

10.3 Possibility of Hazardous Reactions: Not applicable.

10.4 Conditions to Avoid: None known.

10.5 Incompatible Materials: Slightly reactive with bases.

10.6 Hazardous Decomposition Products: Thermal decomposition will generate oxides of carbon, magnesium and sulfur.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on Toxicological Effects:

Potential Health Effects:

Eye Contact: Causes serious eye irritation with redness, tearing and pain.

Skin contact: Prolonged skin contact may cause irritation. May cause an allergic reaction in sensitized individuals.

Inhalation: Mists may cause nose, throat and upper respiratory tract irritation.

Ingestion: May cause gastrointestinal irritation with nausea and vomiting.

Acute toxicity: Malic acid: LD50 oral rat >3200 mg/kg

Skin corrosion/irritation: No data available for mixture. Components are skin irritants.

Eye damage/ irritation: No data available for mixture. Malic acid is an eye irritant.

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

Respiratory Sensitization: No data available for mixture. None of the components are respiratory sensitizers.

Skin Sensitization: No data available for mixture. Components are skin sensitizers.

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

Carcinogenicity: No data available for mixture. None of the components of this product are listed as carcinogens by OSHA, ACGIH, IARC, NTP, or the EU Dangerous Substances Directive. .

Reproductive Toxicity: No data available for mixture. Not expected to cause reproductive toxicity. Malic acid did not cause effects on reproduction or development in a one-generation study in rats and mice at doses to 350 mg/kg/day.

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Specific Target Organ Toxicity:

Single Exposure: No data available.

Repeat Exposure: No data available.

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity: Malic acid: LC50 daphnia magna 240 mg/L/48 hr.

12.2 Persistence and degradability: Malic acid is biodegradable.

12.3 Bioaccumulative Potential: Malic acid has an estimated BCF of 0.3 which suggests that the potential for bioaccumulation is low.

12.4 Mobility in Soil: No data available.

12.5 Results of PVT and vPvB assessment: Not required.

12.6 Other Adverse Effects: None known.

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			
Canadian TDG		Not regulated			
EU ADR/RID		Not regulated			
IMDG		Not regulated			
IATA/ICAO		Not regulated			

14.6 Special Precautions for User: None known.

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.

CERCLA Section 103: This product is not subject to CERCLA release reporting. Many states have more stringent release reporting requirements. Report spills required under federal, state and local regulations.

EPA SARA 302: This product does not contain chemicals regulated under SARA Section 302.

EPA SARA 311 HAZARD CLASSIFICATION: Acute Health

EPA SARA 313: This product contains the following chemicals that are regulated under SARA Title III, section 313: None

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): None known

INTERNATIONAL REGULATIONS

WHMIS CLASSIFICATION: Class D-2-B

SECTION 16: OTHER INFORMATION

Revision History: Updated Logo and website.

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

T Toxic

Xi Irritant

C Corrosive

N Dangerous for the Environment

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

R34 Causes burns.

R38 Irritating to skin.

R41 Risk of serious damage to eyes.

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R43 May cause sensitization by skin contact.

R50-53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

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

H301 Toxic if swallowed.

H311 Toxic in contact with skin.

H331 Toxic if inhaled.

H314 Causes severe skin burns and eye damage.

H315 Causes skin irritation.

H317 May cause an allergic skin reaction.

H318 Causes serious eye damage.

H400 Very toxic to aquatic life.

H410 Very toxic to aquatic life with long lasting effects.

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

HMIS Rating: Health: 2 Fire: 0 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.