



SAFETY DATA SHEET

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Revised (year/month/day) 2015/03/30

Section 1 Identification of the Substance/mixture and of the Company/undertaking

1.1 Product Identifier

Product Name iQ® Lamina™
Part Number 800-3236
Series Name iQ® 200

1.2 Relevant identified uses of the substance or mixture and uses advised against

Product Use For In Vitro Diagnostic Use. See product literature for details.

1.3 Details of the supplier of the safety data sheet

Manufacturer

IRIS International, Inc.
9172 Eton Avenue
Chatsworth, CA 91311-5874, U.S.A.
Tel: 800-776-4747
818-527-7000

EC REP Address

mdi Europa GmbH
Langenhagener Str. 71
30855 Hannover-Langenhagen
Germany
+49-511-39089530

e-mail address contactIDD@beckman.com

1.4 Emergency telephone number

Telephone number (24H) Chemtrec Emergency Tel No. U.S.A. 800-424-9300, International (001) 703-527-3887

Distributor and Emergency Phone No.

(800) 776-4747

Section 2 Hazards Identification

2.1 Classification of substance or mixture

Product Description Mixture
Colorless; Clear; Liquid; Odorless

Classification according to EC 1272/2008 (CLP/GHS)

Not classified as hazardous per EC 1272/2008 (CLP/GHS)

Classification according to EC Directives 1999/45/EC and 67/548/EEC

Not classified as dangerous per EC Directives (1999/45/EC and 67/548 EEC)

Classification according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS

Not classified as hazardous per US-OSHA HCS 2012 and UN GHS

Section 2 Hazards Identification (Continued)

2.2 Label Elements

According to EC 1272/2008 (CLP/GHS), US-OSHA and UN GHS

Not classified as hazardous per EC 1272/2008 (CLP/GHS)

Hazardous Ingredients

N-(3-Chloroallyl)hexaminium Chloride

Pictogram

None

Signal Word

None

Hazard Statements

EUH208 May produce an allergic reaction.

Product label will display most significant precautionary statements.

2.3 Other hazards

Results of PBT and vPvB assessment

PBT: Not applicable.

vPvB: Not applicable.

See Section 11 Toxicological Information for more detailed health information.

Section 3 Composition and Information on Ingredients

3.2 Mixtures

Hazardous Ingredients:		Hazard Classification of Pure Ingredients			
Chemical Name	% by wt.	EU-67/548/EEC	EU 1272/2008 CLP/GHS	GHS	
N-(3-Chloroallyl)hexaminium Chloride CAS # 51229-78-8 EINECS # Not available Index # Not available	< 0.1	F;R11 Xn;R22	Acute Tox. Oral 4 Aquatic Longterm 2 Flam. Sol. 2 Repr. 2 Skin Irrit. 2 Skin Sens. 1 H228; H302; H315; H317; H361; H411	Acute Tox. Oral 4 Aquatic Longterm 2 Flam. Sol. 2 Repr. 2 Skin Irrit. 2 Skin Sens. 1 H228; H302; H315; H317; H361; H411	15, 8

15 - May produce an allergic reaction.

8 - Present at concentration below the cut-off limits.

See section 8 for available Occupational exposure limits

See Section 15 for additional regulatory information

See Section 16 for hazard class, hazard statements and risk phrase description

Section 4 First Aid Measures

4.1 Description of first aid measures

Inhalation

If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin artificial respiration immediately and obtain medical attention.

Eye Contact

If product enters eyes, wash eyes gently under running water for 15 minutes or longer, making sure that the eyelids are held open. If pain or irritation occur, obtain medical attention.

Section 4 First Aid Measures (Continued)

- Skin Contact** In case of skin contact, flush with copious amounts of water for at least 15 minutes. If pain or irritation occur, obtain medical attention.
- Ingestion** If ingested, wash mouth out with water. If irritation or discomfort occurs, seek medical attention.
- 4.2 Most important symptoms and effects, both acute and delayed**
This product contains a sensitizing substance below concentration limit, may produce an allergic reaction in some people. Refer Section 3.
- 4.3 Indication of any immediate medical attention and special treatment needed**
No specific medical attention or treatment required.

Section 5 Fire Fighting Measures

- Flammable Properties** Nonflammable aqueous solution.
- 5.1 Extinguishing Media** In case of fire use carbon dioxide (CO₂), dry chemical, water spray or foam. For large fires use extinguishing media suitable for surrounding fire.
- 5.2 Special hazards arising from the substance or mixture**
Special Fire and Explosion Hazards
No special hazards determined.
- Hazardous Combustion Products**
No combustion products posing significant hazards are expected from this product (an aqueous solution).
- 5.3 Advice for fire fighters**
Protective Equipment Self-contained breathing apparatus is recommended for firefighters in all chemical fire situations.
- 5.4 Additional information** No further relevant information available.

Section 6 Accidental Release Measures

- 6.1 Personal precautions, protective equipment and emergency procedures**
Personal Precautions No special precautions are necessary. Use good laboratory procedures. Wear protective gloves, protective clothing and eye/face protection.
- 6.2 Environmental Precautions** Contain spill to prevent migration. Do not allow the undiluted product to enter sewers/surface or ground water.
- 6.3 Methods and material for containment and cleaning up**
Spill and Leak Procedures Absorb spilled material with an appropriate inert, non-flammable absorbent and dispose according to local regulations.
- 6.4 Reference to other sections** Refer sections 8 and 13.

Section 7 Handling and Storage

- 7.1 Precautions for safe handling** No special precautions are necessary; use good laboratory procedures.
- 7.2 Conditions for safe storage, including any incompatibilities**
 Store at 20 to 28°C, as directed on the product label.
 To maintain product quality, store according to the instructions in the product labeling.
 Store away from strong acids, strong bases, strong oxidizers and incompatible materials (section 10).
- 7.3 Specific end uses** No further relevant information available.

Section 8 Exposure Controls and Personal Protection

- 8.1 Control parameters**
- Exposure Limits**
- | | |
|----------------|------------------|
| US OSHA | None established |
| ACGIH | None established |
| DFG MAK | None established |
| Ireland | None established |
| IOELVs | None established |
| NIOSH | None established |
| Japan | None established |
- 8.2 Exposure controls**
- Engineering Controls** No special engineering controls are required. Use with good general ventilation.
- Eye Protection** Safety glasses or chemical goggles should be worn to prevent eye contact. Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.
- Skin Protection** Impervious gloves, such as Nitrile or equivalent, should be worn to prevent skin contact. Refer U.S. OSHA 29 CFR 1910.138, European Standard EN374 or appropriate government standards.
- Respiratory Protection** Under normal conditions, the use of this product should not require respiratory protection.

Section 9 Physical and Chemical Properties

- 9.1 Information on basic physical and chemical properties**
- | | | | |
|-----------------------|--------|-------------------------------------|--------------|
| Physical State | Liquid | Specific Gravity (Water=1.0) | ≈ 1.01 @20°C |
|-----------------------|--------|-------------------------------------|--------------|

Section 9 Physical and Chemical Properties (Continued)

Color	Colorless	Solubility	
Transparency	Clear	Water	Miscible
Odor	Odorless	Organic	Not determined
pH	6.5 - 7.5	Partition coefficient: n-octanol/water	Not determined
Freezing Point	Not determined	Auto-ignition Temp.	Not applicable
Boiling Point	Not determined	Decomposition Temperature	Not determined
Flash Point	Not applicable	Percent Volatiles	Not applicable
Evaporation Rate	Not determined	Vapor Pressure	Not determined
Flammability (Solid, Gas)	Not applicable	Viscosity	Not determined
Flammability Limits	Not applicable	Explosive Properties	Not applicable
Vapor Density	Not determined	Oxidizing Properties	Not applicable
Odor Threshold	Not applicable		
9.2 Other Information	No further relevant information available.		

Section 10 Stability and Reactivity

10.1 Reactivity	No further relevant information available.
10.2 Chemical Stability	The product is stable in accordance with recommended storage conditions.
10.3 Possibility of hazardous reactions	No further relevant information available.
10.4 Conditions to Avoid	To maintain product performance keep away from strong acids, strong bases, strong oxidizers. Avoid exposure to heat and direct sunlight.
10.5 Incompatible materials	No further relevant information available.
10.6 Hazardous Decomposition Products	No decomposition products posing significant hazards would be expected from this product (an aqueous solution).

Section 11 Toxicological Information

11.1 Information on toxicological effects	
Toxicity Data for Hazardous Ingredients	Not applicable
Primary Routes of Exposure	Eye contact, ingestion, inhalation, and skin contact.

Section 11 Toxicological Information (Continued)

Skin Corrosion/Irritation	No data available.
Serious eye damage/eye irritation	No data available.
Respiratory/skin sensitization	This product contains a sensitizing substance below concentration limit, may produce an allergic reaction in some people. Refer Section 3.
Carcinogenicity	This product does not contain a reportable concentration ($\geq 0.1\%$) of any ingredient listed as carcinogen by ACGIH, IARC, NTP, OSHA or 1272/2008 EC regulation.
Germ cell mutagenicity	No data available.
Reproductive Toxicity	No data available.
Specific target organ toxicity – single exposure	No data available.
Specific target organ toxicity – repeated exposure	No data available.
Aspiration hazard	No data available.
Other Information	No further relevant information available.

Section 12 Ecological Information

12.1 Ecotoxicity	
Fresh Water Species	No information available.
Microtox	No information available.
Water Flea	No information available.
Fresh Water Algae	No information available.
12.2 Persistence and degradability	Not determined for the product.
12.3 Bioaccumulation	Not determined for the product.
12.4 Mobility in soil	Not determined for the product.
12.5 Results of PBT and vPvB assessment	Not determined for the product. PBT: Not applicable, vPvB: Not applicable.
12.6 Other Adverse Effects	This product contains environmentally hazardous substance below the cutoff level. Refer section 3 for ingredient information. Do not allow undiluted product to enter sewer/surface or ground water.

Section 13 Disposal Considerations

13.1 Waste treatment methods	
Product Waste Disposal	Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.

13.2 Additional information

Suggested European waste catalogue 18 01 07 - chemicals other than those mentioned in 18 01 06. Dispose in accordance with national, state and local waste regulations.

Section 14 Transport Information

Transportation of this product is not regulated under ICAO, IMDG, US DOT, European ADR or Canadian TDG.

Section 15 Regulatory Information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

US Federal and State Regulations

SARA 313

Formaldehyde is subject to reporting requirements of Section 313, Title III of SARA. 0.1 % de minimis concentration
Acetaldehyde is subject to reporting requirements of Section 313, Title III of SARA. 0.1 % de minimis concentration
Methylene chloride is subject to reporting requirements of Section 313, Title III of SARA. 0.1 % de minimis concentration
Ethylene Oxide is subject to reporting requirements of Section 313, Title III of SARA. 0.1 % de minimis concentration
1,4-Dioxane is subject to reporting requirements of Section 313, Title III of SARA. 0.1 % de minimis concentration

CERCLA RG's, 40 CFR 302.4

Formaldehyde is listed.
Acetaldehyde is listed.
Methylene chloride is listed.
Ethylene Oxide is listed.
1,4-Dioxane is listed.

California Proposition 65

Formaldehyde has been identified by the State of California to cause cancer. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm.

WARNING: This product contains a chemical known to the State of California to cause cancer.

Acetaldehyde has been identified by the State of California to cause cancer. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm.

WARNING: This product contains a chemical known to the State of California to cause cancer.

Methylene chloride has been identified by the State of California to cause cancer. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm.

WARNING: This product contains a chemical known to the State of California to cause cancer.

Ethylene Oxide has been identified by the State of California to cause cancer and reproductive harm. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm.

Section 15 Regulatory Information (Continued)

WARNING: This product contains a chemical known to the State of California to cause cancer and reproductive harm.

1,4-Dioxane has been identified by the State of California to cause cancer. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm.

WARNING: This product contains a chemical known to the State of California to cause cancer.

Cis-1,3-dichloropropene has been identified by the State of California to cause cancer. The State of California has adopted a regulation which requires a warning be given to individual who may be exposed to chemicals identified by the State to cause cancer or reproductive harm.

WARNING: This product contains a chemical known to the State of California to cause cancer.

Massachusetts MSL

Formaldehyde is listed.
Acetaldehyde is listed.
Methylene chloride is listed.
Ethylene Oxide is listed.
1,4-Dioxane is listed.
Cis-1,3-dichloropropene is listed.

New Jersey Dept. of Health RTK List

Formaldehyde is listed.
Acetaldehyde is listed.
Methylene chloride is listed.
Ethylene Oxide is listed.
1,4-Dioxane is listed.

Pennsylvania RTK

Formaldehyde is listed.
Acetaldehyde is listed.
Methylene chloride is listed.
Ethylene Oxide is listed.
1,4-Dioxane is listed.
Cis-1,3-dichloropropene is listed.

EU Regulations

This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.

Water Hazard Class (Germany) WGK 1, low water endangering

REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization.

No ingredients listed.

According to EC Directives (1999/45/EC and 67/548 EEC)

Not classified as dangerous per EC Directives (1999/45/EC and 67/548 EEC)

Canada

This product is exempt from WHMIS label and SDS requirements.

PIN Not applicable

Section 15 Regulatory Information (Continued)

Ingredients on Ingredient Disclosure List

Formaldehyde
 Acetaldehyde
 Methylene chloride
 Ethylene Oxide
 2-Phenoxyethanol
 1,4-Dioxane
 Ethoxylated lauryl alcohol

Ingredients with unknown toxicological properties

Product is exempt

15.2 Chemical Safety Assessment A Chemical Safety Assessment has not been carried out.

Some hazardous ingredients listed in Section 15 are below OSHAs and WHMIS' 1.0% w/w (0.1% for carcinogens) or EU's ingredient specific concentrations required for reporting in Section 3.

Section 16 Other Information

Safety Ratings	Flammability: 0 Health: 1 Reactivity with Water: 0 Contact: 1	Code 0=None 1=Slight 2=Caution 3=Severe
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Revision Changes Updated to GHS.

Hazard Class, hazard statements and risk phrase description from section 3

F - Highly flammable
 Xn - Harmful
 R11 Highly flammable.
 R22 Harmful if swallowed.
 Acute Tox. Oral 4 - Acute Toxicity Oral, Category 4
 Flam. Sol. 2 - Flammable Solids, Category 2
 Aquatic Longterm 2 - Aquatic Hazard Long term, Category 2
 Skin Irrit. 2 - Skin Irritation Category 2
 Skin Sens. 1 - Skin Sensitization Category 1
 Repr. 2 - Toxic to Reproductive Category 2
 H228 - Flammable solid.
 H302 - Harmful if swallowed.
 H315 - Causes skin irritation.
 H317 - May cause an allergic skin reaction.
 H361 - Suspected of damaging fertility or the unborn child.
 H411 - Toxic to aquatic life with long lasting effects.

Section 16 Other Information (Continued)

Abbreviations and Acronyms

ACGIH - American Conference of Governmental Industrial Hygienists
ADR - European Agreement Concerning The International Carriage Of Dangerous Goods By Road
CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act
CLP - Classification, Labeling and Packaging
DFGMAK - Republic Germany's maximum exposure limit
GHS - Globally Harmonized System
HCS - Hazard Communication Standard
IARC - International Agency for Research on Cancer
IATA - International Air Transport Association
ICAO - International Civil Aviation Organization
IMDG - International Maritime Dangerous Goods
IOELVs - European Unions' Indicative Occupational Exposure Limit Values
NIOSH - National Institute for Occupational Safety and Health
NTP - National Toxicology Program
OSHA - Occupational Safety and Health Administration
PBT - Persistent bioaccumulative and toxic substances
SARA - Superfund Amendments and Reauthorization Act
TDG - Canadian Transportation Of Dangerous Goods Regulations.
UN GHS - United Nations Globally Harmonized System
US DOT - United States Department of Transportation
WHMIS - Workplace Hazardous Material Information System
vPvB - Very persistent and very bioaccumulative substances

For further information, please contact your local Iris Diagnostics representative.

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