



SAFETY DATA SHEET

Doc. ID: 300-7651 Rev. AC
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® Calibrator
Part Number 800-3103
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
Yellow-orange; Slightly turbid; Liquid; Odorless

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

Skin Sensitization Category 1

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

Skin Sensitization Category 1
Toxic to Reproductive Category 2

Section 2 Hazards Identification (Continued)

2.2 Label Elements

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

Hazardous Ingredients

N-(3-Chloroallyl)hexaminium Chloride

Pictogram



Signal Word

WARNING

Hazard Statements

H317 May cause an allergic skin reaction.

H361 Suspected of damaging fertility or the unborn child.

Precautionary Statements

P201 Obtain special instructions before use.

P261 Avoid breathing vapours.

P272 Contaminated work clothing should not be allowed out of the workplace.

P280 Wear protective gloves, protective clothing and eye/face protection.

P302+P352 IF ON SKIN: Wash with plenty of soap and water.

P308+P313 IF exposed or concerned: Get medical advice/attention.

P333+P313 If skin irritation or rash occurs: Get medical advice/attention.

P362+P364 Take off contaminated clothing and wash it before use.

P405 Store locked up.

P501 Dispose of contents/container in accordance with local/national regulations

Product label will display most significant precautionary statements.

2.3 Other hazards

This product contains material of human origin and should be considered as potentially capable of transmitting infectious diseases.

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	

SAFETY DATA SHEET

Doc. ID: 300-7651 AC
Revised (year/month/day) 2015/03/30

Section 3 Composition and Information on Ingredients (Continued)

N-(3-Chloroallyl)hexaminium Chloride CAS # 51229-78-8 EINECS # Not available Index # Not available	0.1 - 0.5	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	
---	-----------	-----------------	--	--	--

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.
Skin Contact	In case of skin contact, flush with copious amounts of water for at least 15 minutes. Remove contaminated clothing and shoes. 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

May cause an allergic skin reaction.
Suspected of damaging fertility or the unborn child.
See Section 11 Toxicological Information for more detailed health information.

4.3 Indication of any immediate medical attention and special treatment needed

No further relevant information available.

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).

Section 5 Fire Fighting Measures (Continued)

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

This product contains material of human origin and should be handled as though capable of transmitting infectious diseases. Universal precautions should be followed during clean up 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

As a precautionary measure, treat spilled material with a 1:10 bleach/water solution. Absorb liquid and place in container suitable for disposal. Avoid generation of aerosols during clean up. Comply with applicable waste disposal regulations.

6.4 Reference to other sections

Refer sections 8 and 13.

Section 7 Handling and Storage

7.1 Precautions for safe handling This product should be handled as though capable of transmitting infectious diseases. Universal precautions should be followed when using this product.

7.2 Conditions for safe storage, including any incompatibilities

Store at 2 to 8°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

SAFETY DATA SHEET

Doc. ID: 300-7651 AC
Revised (year/month/day) 2015/03/30

Section 8 Exposure Controls and Personal Protection (Continued)

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. If overexposure should occur and ventilation is not adequate to maintain airborne concentrations at acceptable levels, the use of respiratory protection should be evaluated by a qualified professional.

Section 9 Physical and Chemical Properties

9.1 Information on basic physical and chemical properties			
Physical State	Liquid	Specific Gravity (Water=1.0)	≈ 1.0070
Color	Yellow-orange	Solubility	
Transparency	Slightly turbid	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	Avoid exposure to heat and direct sunlight. To maintain product performance keep away from strong acids, strong bases, strong oxidizers.
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	Common routes of entry include inhalation, ingestion and eye/skin contact. Specific paths of concern for potentially infectious materials are skin puncture, contact with broken skin, contact with mucous membranes and inhalation of aerosolized material.
Skin Corrosion/Irritation	No data available.
Serious eye damage/eye irritation	No data available.
Respiratory/skin sensitization	May cause an allergic skin reaction.
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	Suspected of damaging fertility or the unborn child.
Specific target organ toxicity – single exposure	No data available.
Specific target organ toxicity – repeated exposure	No data available.
Aspiration hazard	No data available.

Section 11 Toxicological Information (Continued)

Other Information

This product contains material of human origin and should be considered as potentially capable of transmitting infectious diseases.

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.

Dispose of as potentially biohazardous waste and 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 approved waste-disposal company for information.

13.2 Additional information

Suggested European waste catalogue 18 01 03* - wastes whose collection and disposal is subject to special requirements in order to prevent infection. 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

Section 15 Regulatory Information (Continued)

US Federal and State Regulations

SARA 313	Methylene chloride is subject to reporting requirements of Section 313, Title III of SARA. 0.1 % de minimis concentration
CERCLA RG's, 40 CFR 302.4	Methylene chloride is listed.
California Proposition 65	<p>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.</p> <p>WARNING: This product contains a chemical known to the State of California to cause cancer.</p> <p>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.</p> <p>WARNING: This product contains a chemical known to the State of California to cause cancer.</p>
Massachusetts MSL	<p>Methylene chloride is listed.</p> <p>Cis-1,3-dichloropropene is listed.</p>
New Jersey Dept. of Health RTK List	<p>Methylene chloride is listed.</p>
Pennsylvania RTK	<p>Methylene chloride is listed.</p> <p>Cis-1,3-dichloropropene is listed.</p>

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

Ingredients on Ingredient Disclosure List

Methylene chloride

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.

SAFETY DATA SHEET

Doc. ID: 300-7651 AC
Revised (year/month/day) 2015/03/30

Section 16 Other Information

Safety Ratings	Flammability: 0 Health: 2 Reactivity with Water: 0 Contact: 2	Code 0=None 1=Slight 2=Caution 3=Severe
-----------------------	--	--

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.

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

Section 16 Other Information (Continued)

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.

WHILE IRIS DIAGNOSTICS BELIEVES THE INFORMATION CONTAINED HEREIN IS VALID AND ACCURATE, MAKES NO WARRANTY OR REPRESENTATION AS TO ITS VALIDITY, ACCURACY, OR CURRENCY. IRIS DIAGNOSTICS SHALL NOT BE LIABLE OR OTHERWISE RESPONSIBLE IN ANY WAY FOR USE OF EITHER THIS INFORMATION OR MATERIALS TO WHICH IT APPLIES. DISPOSAL OF HAZARDOUS MATERIALS MAY BE SUBJECT TO LOCAL LAWS OR REGULATIONS.