

SAFETY DATA SHEET

Section 1: Identification of the Substance/Mixture and of the Company/Undertaking

Product identifier: Metexchange® Hi Calibrator

Relevant identified uses of the substance or mixture and uses advised against:
 For *In Vitro* Diagnostic Use

Details of the supplier of the Safety Data Sheet:

United States:

Magellan Diagnostics, Inc.
 101 Billerica Ave., Bldg 4
 North Billerica, MA 01862 US
 Phone: (800) 275-0102
 Fax: (978) 600-1480
 Info: bloodleadtechsupport@magellandx.com

Europe:

Ichor Technologies Ltd
 1 Paper Mews
 300 High Street
 Dorking, Surrey, RH4 2TU UK
 Phone: +44 (0) 1372 377 754
 Fax: +44 (0) 1372 388 282
 Info: bloodleadtechsupport@magellandx.com

Emergency telephone number:

(800) 535-5053 (24-hour, US only)

1 (352) 323-3500 (24-hour)

Section 2: Hazards Identification

Classification of the substance or mixture:

Skin Irritant Category 2; May cause skin and eye irritation

Label elements:



Hydrochloric acid 1.31%

May cause skin and eye irritation.

May cause respiratory system irritation.

Wear protective gloves and eye protection.

Do not breathe mist or vapors.

Wash hands thoroughly after handling.

IF SWALLOWED: Rinse mouth. Do NOT induce vomiting. Immediately call a POISON CENTER or doctor.

IF ON SKIN (or hair): Wash off immediately with plenty of water for at least 15 minutes. Seek medical attention immediately if symptoms occur.

INHALED: Move to fresh air. If breathing is difficult, give oxygen. Seek medical attention immediately if symptoms occur.

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Seek medical attention.

European Classification:

Regulation (EC) No 1272/2008 Skin Irritant Category 2; H315

Irritant, Eye Irritant Category H320

R36/R37/R38: Skin, eyes and respiratory system irritation.

U.S.A.:

This material is considered hazardous by the OSHA Hazard Communication Standard (29CFR 1910.1200). All blood products must be treated as infectious and users of these products must follow 29CFR 1910.1030 regarding blood-borne pathogens.

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Section 2: Hazards Identification, continued

Canada:

This is a controlled product under WHMIS. Classification D-Other Toxic effects, D3– Biohazardous Infectious Material



Other hazards: Not applicable

Section 3: Composition/Information on Ingredients

Hazardous Substances:

Product is a mixture, an aqueous solution containing Human Blood (3–4%), non-hazardous substance calcium acetate; trace concentrations of copper and lead (0.03 – 0.3 ppm) and the following hazardous substances:

<u>Chemical Name</u>	<u>CAS No.</u>	<u>Wt. %</u>	<u>EINECS / ELINCS</u>	<u>Classification of pure substance</u>	<u>Risk/Hazard Phrases</u>
Hydrochloric acid	7647-01-0	1.31	231-595-7	Xi	R36/R37
				Skin irritant. 2B (STOT SE 3)	H315 H320
Chromium trichloride (self-classified)	10025-73-7	1.02	233-038-3	Xi	R36/38
				Skin: Irritant Eye: Irritant	H315 H320
Acetic Acid	64-19-7	0.14	200-580-7	Concentration below classification criteria	Not applicable
Hydrazine	302-01-2	0.09	206-114-9	Concentration below classification criteria	Not applicable
Ortho-phosphoric Acid	7664-38-2	0.08	231-633-2	Concentration below classification criteria	Not applicable

Note: See Section 16 for the full text of the Risk and Hazard phrases above.

Section 4: First Aid Measures

Description of first aid measures:

Inhalation: Remove source of contamination or move victim to fresh air and keep at rest in a position comfortable for breathing. If breathing is difficult, trained personnel should administer emergency oxygen. Obtain medical advice.

Eye Contact: Avoid direct contact with the victim. First aid responders should wear chemical protective gloves. Immediately flush the contaminated eye(s) with lukewarm, gently flowing water for 15 minutes, while holding the eyelid(s) open. Neutral saline solution may be used as soon as it is available. Do not interrupt flushing. Take care not to rinse contaminated water into the unaffected eye or onto face. Immediately obtain medical attention.

Skin Contact: As quickly as possible, remove contaminated clothing, shoes and leather goods (e.g. watchbands, belts). Immediately flush with lukewarm, gently flowing water for 15 minutes. If irritation persists, obtain medical advice. Completely decontaminate clothing, shoes and leather goods before re-use or discard.

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Section 4: First Aid Measures, continued

Ingestion: Never give anything by mouth if victim is rapidly losing consciousness, or is unconscious or convulsing. Have victim rinse mouth thoroughly with water. **DO NOT INDUCE VOMITING.** If vomiting occurs naturally, have victim lean forward to reduce risk of aspiration. Have victim rinse mouth with water again. Call a POISON CENTER or doctor/physician if you feel unwell.

Most important symptoms and effects, both acute and delayed:

Inhalation: Symptoms of exposure may include coughing, wheezing, pain and swelling in the upper respiratory tract. Prolonged or severe exposure may lead to pulmonary edema; symptoms of pulmonary edema include chest pain and shortness of breath and can be delayed up to 24 or 48 hours after exposure.

Eye Contact: Direct contact with liquid or vapor can cause a burning sensation in the eyes, severe eye irritation or chemical burns. Serious damage may result if treatment is delayed.

Skin Contact: Direct contact with the liquid causes severe irritation. Symptoms include local discomfort or pain, redness and swelling, blister formation and possible tissue destruction. Prompt first aid may eliminate burns and irritation.

Ingestion: Swallowing can cause irritation to the lips, tongue, throat and digestive tract, abdominal and chest pain, nausea and vomiting.

Indication of any immediate medical attention and special treatment needed: Treat symptomatically.

Section 5: Fire Fighting Measures

Extinguishing media:

Product does not burn. Use extinguishing agents compatible with hydrochloric acid and appropriate for the surrounding fire.

Special hazards arising from the substance or mixture:

Contact with common metals produces flammable hydrogen gas.
When heated or in a fire, toxic and corrosive hydrogen chloride gas is released. Heat from a fire can cause a rapid build-up of pressure inside closed containers, which may cause explosive rupture and a sudden release of corrosive gas.

Advice for firefighters:

Firefighters should wear full protective gear including self-contained breathing apparatus when fighting chemical fires. Any water runoff should be minimized and contained.

Section 6: Accidental Release Measures

Personal precautions, protective equipment and emergency procedures:

Wear proper protective gloves (butyl rubber, neoprene, nitrile), goggles, boots, clothing and other protective equipment. Ventilate the area.

Environmental precautions:

Prevent releases to drains, sewers and natural waterways.

Methods and material for containment and cleaning up:

Contain and soak up spill with absorbent material which does not react with spilled chemical (e.g. cloth) or a commercial acid-neutralizing absorbent product. Place any absorbent and waste product in suitable, covered, labeled containers for proper disposal. Do not return the spilled liquid to original containers. Flush area with water.

Reference to other sections:

See Section 8 for information on selection of personal protective equipment.
See Section 13 for information on disposal of spilled product and contaminated absorbents.

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Section 7: Storage and Handling

Precautions for safe handling:

All blood products must be treated as infectious and users of these products must be properly trained in safe handling procedures. Users of this product must follow all applicable regulations regarding blood borne pathogens and practice universal precautions. Use only in a well-ventilated area in the workplace. Do not get on skin or in eyes. Avoid breathing mist/vapors/spray. Wear personal protective equipment required for the workplace. Guidelines for selection of protective equipment are described in Section 8. Wash hands thoroughly immediately after exposure to product and at the end of the work-shift. Workers whose clothing has been contaminated by product should change into clean clothing promptly. Do not eat, smoke or drink where product is handled, processed, or stored. Keep contaminated clothing in closed containers. Discard or launder before re-wearing. Inform laundry personnel of contaminant's hazards.

Conditions for safe storage, including any incompatibilities:

Reagents must be stored according to label directions. Store at 15 – 27°C. Protect from direct sunlight.

Specific end use(s):

For *in vitro* diagnostic tests.

Section 8: Exposure Controls / Personal Protection

Control parameters:

Consult regional/local authorities for acceptable exposure limits.

<u>Ingredient</u>	<u>Ontario TWAEV (ppm)</u>	<u>ACGIH TLV (8-hr. TWA) (ppm)</u>	<u>U.S. OSHA PEL (8-hr. TWA) (ppm)</u>	<u>U.K. WEL (8-hr. TWA) (ppm)</u>
Hydrogen chloride	2 (CEV)	2 (Ceiling)	5 (Ceiling)	1 5 STEL
Chromium trichloride	0.5 mg/m ³	0.5 mg/m ³	0.5 mg/m ³	0.5 mg/m ³ [EU - Occupational Exposure (2006/15/EC)]

Exposure controls:

Engineering Controls: Use chemical fume hood, local exhaust ventilation or other engineering controls to minimize exposure.

Personal Protection: Workers must comply with the Personal Protective Equipment requirements of the workplace in which this product is handled.

Eye/Face Protection: Wear laboratory safety goggles or other appropriate eye protection.

Skin Protection: Wear impervious gloves and protective lab coat or other appropriate skin protection.

Respiratory Protection: If respiratory protection is required, institute a complete respiratory protection program including selection, fit testing, training, maintenance and inspection. Where occupational exposure limits are exceeded, workers should wear an approved respirator. Consult with respirator manufacturer to determine respirator selection, use and limitations. Wear a positive pressure air supplied respirator for uncontrolled releases.

A respiratory protection program that meets OSHA's 29 CFR 1910.134 and ANSI Z88.2 requirements or European Standard EN 149 or Canadian Standards Association (CSA) Standard Z94.4-2002 must be followed whenever workplace conditions warrant a respirator's use.

Other: Workplaces should have a safety shower, hand-wash station and eye-wash fountain readily available in the immediate work area.

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Section 9: Physical and Chemical Properties**Information on basic physical and chemical properties:**

Appearance:	Liquid, brown. Packaged as 3.0 mL in polypropylene tubes, 10 or 70 tubes per box.
Odor:	Not available
Odor threshold:	Not available
pH:	1.5
Melting point/freezing point:	Similar to water
Initial boiling point and boiling range:	100°C
Flash point:	Not applicable, product is not flammable or combustible.
Auto-ignition temperature:	Not applicable
Upper/lower flammability or explosive limits:	Not applicable
Explosive properties:	Not applicable
Oxidising properties:	Not applicable
Sensitivity to mechanical impact:	Not applicable
Sensitivity to static discharge:	Not applicable
Vapor pressure:	Not available
Vapor density:	Not available
Relative density:	1.1
Solubility (ies):	Completely soluble in water.
Partition coefficient (n-octanol/water):	Not available
Decomposition temperature:	Not available
Viscosity:	Not available

Other information: Not available

Section 10: Stability and Reactivity**Reactivity:**

Not classified as dangerously reactive.

Chemical Stability:

Normally stable.

Possibility of Hazardous Reactions:

Hazardous polymerization does not occur.

Conditions to Avoid:

Avoid unintended contact with other chemicals specifically incompatible materials.

Incompatible Materials:

Bases (e.g. sodium hydroxide, potassium hydroxide, ammonium hydroxide, amines, 2-aminoethanol or ethyleneimine) - react violently generating heat and pressure.

Metals (e.g. steel, copper, brass or zinc) - extremely flammable hydrogen gas is released on reaction with many common metals.

Sodium, metal - explodes on contact.

Formaldehyde - can react to form the carcinogen, bis(chloromethyl) ether.

Oxidizing agents (e.g. hydrogen peroxide, chlorates or chlorites) - may react generating heat and very toxic, corrosive chlorine gas.

Reducing agents (e.g. metal hydrides) - reaction may produce extremely flammable hydrogen gas, heat and fire.

Perchloric acid - decomposes spontaneously and violently.

Hazardous Decomposition Products:

Not applicable

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Section 11: Toxicological Information

Information on toxicological effects:

Acute Health Effects:

Relevant Route(s) of Exposure: Inhalation, Ingestion, Skin contact, Eye contact.

Inhalation: At room temperature, hydrochloric acid solutions can release vapors of hydrogen chloride. Overexposure to airborne vapors or mists can cause irritation to the respiratory tract. Symptoms of exposure may include coughing, pain and swelling in the upper respiratory tract.

Ingestion: Component substances have low oral toxicity, but swallowing large amounts can cause irritation of the digestive tract with abdominal and chest pain, nausea, vomiting and diarrhea.

Skin: Direct contact with the product can cause irritation to the skin. Hydrazine may be absorbed through the skin.

Eye: Direct contact with the product causes serious eye irritation and eye damage. Airborne vapors or mists may cause serious eye irritation. In inhalation studies, hydrogen chloride gas has caused extreme eye irritation and corneal opacity.

Acute Toxicity Data:

Acute toxicology data is not available for this mixture.

<u>Chemical</u>	<u>LD₅₀ Oral (mg/kg)</u>	<u>LD₅₀ Dermal (mg/kg)</u>	<u>LC₅₀ Inhalation (mg/m³ 4 hrs.)</u>
Hydrogen chloride	900 (rabbit)	>5 000 (rabbit)	1 400 – 1 560 ppm (rat)
Chromium trichloride	1790 (rat)	Not available	Not available

Chronic Health Effects:

No data is available for the product. In general, long-term, repeated skin contact with low concentrations of corrosive materials can cause dry, red, cracked skin (dermatitis). Occupational exposure to high airborne concentrations of acids can cause erosion of the teeth.

Sensitization:

People allergic to other chromium compounds may be more likely to develop skin allergy to Chromic chloride.

Neurological Effects:

Not available

Genetic Effects:

Not available

Reproductive Effects:

Not available

Developmental Effects:

Not available

Target Organ Effects:

Eyes, skin.

Carcinogenicity:

This product does not contain any component at a concentration of greater than 0.1% that is considered a human carcinogen by IARC (International Agency for Research on Cancer), ACGIH (American Conference of Governmental Industrial Hygienists, OSHA (Occupational Safety and Health Administration) or NTP (National Toxicology Program). IARC lists Chromium chloride in Group 3, Not classifiable. IARC lists Hydrazine in Group 2B, possibly carcinogenic to humans based on evidence of carcinogenicity in experimental animals. ACGIH lists Hydrogen chloride and Chromium chloride as A4-Not classifiable as a human carcinogen. ACGIH lists Hydrazine as A3-Confirmed animal carcinogen with unknown relevance to humans. NTP lists Hydrazine as Reasonably Anticipated to be a human carcinogen.

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Section 11: Toxicological Information, continued

Medical Conditions Aggravated by Exposure:

Repeated skin contact may aggravate an existing dermatitis. Repeated inhalation may aggravate respiratory conditions, such as asthma and bronchitis.

Interactions With Other Chemicals:

Not available

Section 12: Ecological Information

Toxicity:

Aqueous mixture has very low pH; avoid release of this product to the natural environment.

Persistence and degradability:

Not available

Bioaccumulative potential:

Not available

Mobility in soil:

Not available

Results of PBT and vPvB assessment:

Not available

Other adverse effects:

Not available

Section 13: Disposal Considerations

Waste treatment methods:

Do NOT discard into any sewers, on the ground or into any body of water. Store material for disposal in covered, labeled containers. RCRA Corrosive waste: D002

Product contains Chromium compounds and human blood. Follow applicable laboratory practices for disposing of hazardous waste. Dispose of contents/container in accordance with local/regional/national/ international regulations. Follow all applicable regulations regarding disposal of blood borne pathogens.

Section 14: Transport Information

Shipped in EXCEPTED QUANTITIES.

Packaged as 3 mL in polypropylene tubes, 10 or 70 tubes per box.

UN Number:

UN1789

UN proper shipping name:

Hydrochloric acid, solution

Transport hazard class(es):

8

Packing group:

III

Environmental hazards:

Not applicable

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Section 15: Regulatory Information

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

USA

Toxic Substances Control Act 8(b) Inventory: Substances are listed on the TSCA inventory.

SARA Title III:

Sec. 302/304: Chromic chloride 1 lb EPCRA RQ

Sec: 311/312: Immediate health effects; Delayed health effects

Sec. 313: Chromic chloride/Chromium compounds

CERCLA RQ: Chromium compounds (Hydrogen chloride: 5000 lb or 2270 kg)

Canada

This product has been classified in accordance with the hazard criteria of the *Controlled Products Regulations* and the MSDS contains all the information required by the *Controlled Products Regulations*.

WHMIS Classification D-other toxic effects D2B; D3; based on human blood content.

New Substance Notification Regulations: All substances in this preparation are listed on the Domestic Substances List (DSL).

National Pollutant Release Inventory: Chromium compounds are NRPI reportable substances.

EU

EINECS Inventory: All chemical substances in this mixture are listed in EINECS.

Other National Inventories

Australia: All substances are present on the Inventory of Chemical Substances (AICS).

China: All substances are present on the Inventory.

Japan: All substances are present on ENCS.

Korea: All substances are present on the Inventory of Existing and Evaluated Chemical Substances.

New Zealand: All substances are present on the Inventory.

Philippines: All substances are present on the Inventory of Chemicals and Chemical Substances (PICCS).

Chemical safety assessment:

Not applicable

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Section 16: Other Information

References and sources for data:

HSDDB – Hazardous Substances Data Bank; US National Library of Medicine
 Cheminfo – Canadian Centre for Occupational Health and Safety
 Supplier MSDSs for component substances.

Methods for classification of mixtures:

Classification of this solution was determined from Regulation EC No 1272/2008
 Annex I Section 3.3.3.3.4.2.

Full text of risk/hazard statements under Section 3:

R36/37/38: May cause eye, skin and respiratory system irritation.
 H315: Causes skin irritation
 H320: Causes eye irritation

Legend to abbreviations:

WHMIS – Workplace Hazardous Materials Information System.
 SARA - Title III of the Superfund Amendments and Reauthorization Act of 1986
 CERCLA RQ - Comprehensive Environmental Response, Compensation, and Liability Act of 1980
 PBT Persistent, Bioaccumulative and Toxic substances
 vPvB Very Persistent, very Bioaccumulative substances
 TWAEV – Time weighted average exposure value
 TWA – Time weighted average
 TLV - Threshold Limit Value
 WEL – Workplace exposure limit
 PEL – Permissible exposure limit
 ACGIH – American Conference of Governmental Industrial Hygienists
 OSHA - Occupational Safety and Health Administration

Supplier Note:

Product is intended for use by qualified professionals experienced in handling potentially hazardous chemicals and trained in good laboratory practices. The above information is believed to be correct but does not purport to be all inclusive. All materials may present unknown hazards and should be used with caution. Magellan Diagnostics, Inc. shall not be held liable for any damage resulting from handling or contact with above product.

Prepared by:

Magellan Diagnostics, Inc.