

## 1 Identification

- **Product identifier**
- **Product Name:** Global/ICH Oral Elemental Impurities A (Big 4)
- **Part Name:** ICH-TXM2
- **Application of the substance / the mixture** For Laboratory Use Only
- **Uses advised against** Not for Human or Animal Use
- **Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**  
Spex CertiPrep, LLC.  
203 Norcross Ave, Metuchen,  
NJ 08840 USA  
732-549-7144  
USMet-CRMSales@antylia.com
- **Information department:** product safety department
- **Emergency telephone number:**  
Emergency Phone Number (24 hours)  
CHEMTREC (800-424-9300)  
Outside US: 703-527-3887

## 2 Hazard(s) identification

- **Classification of the substance or mixture**



GHS05 Corrosion

Skin Corrosion 1B H314 Causes severe skin burns and eye damage.  
Eye Damage 1 H318 Causes serious eye damage.

- **Label elements**
- **GHS label elements** The product is classified and labeled according to the Globally Harmonized System (GHS).
- **Hazard pictograms**



GHS05

- **Signal word** Danger
- **Hazard-determining components of labeling:**  
nitric acid
- **Hazard statements**  
H314 Causes severe skin burns and eye damage.
- **Precautionary statements**  
P260 Do not breathe dusts or mists.  
P264 Wash thoroughly after handling.  
P280 Wear protective gloves/protective clothing/eye protection/face protection.  
P301+P330+P331 If swallowed: Rinse mouth. Do NOT induce vomiting.  
P303+P361+P353 If on skin (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower.  
P304+P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing.  
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/doctor.  
P321 Specific treatment (see on this label).  
P363 Wash contaminated clothing before reuse.  
P405 Store locked up.  
P501 Dispose of contents/container in accordance with local/regional/national/international regulations.
- **Classification system:**
- **NFPA ratings (scale 0 - 4)**



Health = 3  
Fire = 0  
Reactivity = 0

- **HMIS-ratings (scale 0 - 4)**



Health = 3  
Fire = 0  
Reactivity = 0

Product Name: Global/ICH Oral Elemental Impurities A (Big 4)

(Contd. of page 1)

- Other hazards
- Results of PBT and vPvB assessment
- PBT: Not applicable.
- vPvB: Not applicable.

**3 Composition/information on ingredients**

- Chemical characterization: Mixtures
- Description: Mixture of the substances listed below with nonhazardous additions.

· Dangerous components:

7697-37-2	nitric acid	5.0%
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· Chemical identification of the substance/preparation

7732-18-5	water, distilled, conductivity or of similar purity	94.9954%
7440-43-9	cadmium	0.0025%
7439-97-6	mercury	0.0015%
7439-92-1	lead	0.0005%
7440-38-2	arsenic	0.0001%

**4 First-aid measures**

- Description of first aid measures
- General information: Immediately remove any clothing soiled by the product.
- After inhalation: Supply fresh air; consult doctor in case of complaints.
- After skin contact: Immediately rinse with water.
- After eye contact: Rinse opened eye for several minutes under running water. Then consult a doctor.
- After swallowing: Do not give anything to eat or drink - Do not induce vomiting
- Information for Doctor:
- Most important symptoms and effects, both acute and delayed No further relevant information available.
- Indication of any immediate medical attention and special treatment needed No further relevant information available.

**5 Fire-fighting measures**

- Extinguishing media
- Suitable extinguishing agents: Use fire fighting measures that suit the environment.
- Special hazards arising from the substance or mixture During heating or in case of fire poisonous gases are produced.
- Advice for firefighters
- Protective equipment: Mouth respiratory protective device.

**6 Accidental release measures**

- Personal precautions, protective equipment and emergency procedures
  - Mount respiratory protective device.
  - Wear protective equipment. Keep unprotected persons away.
- Environmental precautions:
  - Dilute with plenty of water.
  - Do not allow to enter sewers/ surface or ground water.
- Methods and material for containment and cleaning up:
  - Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
  - Use neutralizing agent.
  - Dispose contaminated material as waste according to section 13.
  - Ensure adequate ventilation.
- Reference to other sections
  - See Section 7 for information on safe handling.
  - See Section 8 for information on personal protection equipment.
  - See Section 13 for disposal information.
- Protective Action Criteria for Chemicals

· PAC-1:

7697-37-2	nitric acid	0.16 ppm
7440-43-9	cadmium	0.10 mg/m <sup>3</sup>
7439-97-6	mercury	0.15 mg/m <sup>3</sup>
7439-92-1	lead	0.15 mg/m <sup>3</sup>
7440-38-2	arsenic	1.5 mg/m <sup>3</sup>

· PAC-2:

7697-37-2	nitric acid	24 ppm
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(Contd. on page 3)

Product Name: Global/ICH Oral Elemental Impurities A (Big 4)

(Contd. of page 2)

7440-43-9	cadmium	0.76 mg/m <sup>3</sup>
7439-97-6	mercury	1.7 mg/m <sup>3</sup>
7439-92-1	lead	120 mg/m <sup>3</sup>
7440-38-2	arsenic	17 mg/m <sup>3</sup>
<b>· PAC-3:</b>		
7697-37-2	nitric acid	92 ppm
7440-43-9	cadmium	4.7 mg/m <sup>3</sup>
7439-97-6	mercury	8.9 mg/m <sup>3</sup>
7439-92-1	lead	700 mg/m <sup>3</sup>
7440-38-2	arsenic	100 mg/m <sup>3</sup>

## 7 Handling and storage

- **Handling:**
- **Precautions for safe handling**  
Ensure good ventilation/exhaustion at the workplace.  
Prevent formation of aerosols.
- **Information about protection against explosions and fires:** Keep respiratory protective device available.
- **Conditions for safe storage, including any incompatibilities**
- **Storage:**
- **Requirements to be met by storerooms and receptacles:** No special requirements.
- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:** Keep receptacle tightly sealed.
- **Specific end use(s)** No further relevant information available.

## 8 Exposure controls/personal protection

- **Additional information about design of technical systems:** No further data; see section 7.
- **Control parameters**
- **Components with limit values that require monitoring at the workplace:**  
The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.
- **Additional information:** The lists that were valid during the creation were used as basis.
- **Exposure controls**
- **Personal protective equipment:**
- **General protective and hygienic measures:**  
Keep away from foodstuffs, beverages and feed.  
Immediately remove all soiled and contaminated clothing.  
Wash hands before breaks and at the end of work.  
Avoid contact with the eyes.  
Avoid contact with the eyes and skin.
- **Respiratory protection:**  
In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use respiratory protective device that is independent of circulating air.
- **Protection of hands:**



Protective gloves

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.  
Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.  
Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

- **Material of gloves**  
The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.
- **Penetration time of glove material** The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

(Contd. on page 4)

Product Name: Global/ICH Oral Elemental Impurities A (Big 4)

(Contd. of page 3)

· Eye protection:



Tightly sealed goggles

## 9 Physical and chemical properties

· Information on basic physical and chemical properties	
· General Information	
· Appearance:	
Form:	Liquid
Color:	According to product specification
· Odor:	Characteristic
· Odour Threshold:	Not applicable.
· pH-value:	Not applicable.
· Change in condition	
Melting point/Melting range:	Undetermined.
Boiling point/Boiling range:	83 °C (181.4 °F)
· Flash point:	Not applicable.
· Flammability (solid, gaseous):	Not applicable.
· Decomposition temperature:	Not applicable.
· Ignition temperature:	Product is not selfigniting.
· Danger of explosion:	Product does not present an explosion hazard.
· Explosion limits:	
Lower:	Not applicable.
Upper:	Not applicable.
· Vapor pressure at 20 °C (68 °F):	23 hPa (17.3 mm Hg)
· Density at 20 °C (68 °F)	1.02558 g/cm <sup>3</sup> (8.55847 lbs/gal)
· Relative density	Not applicable.
· Vapor density	Not applicable.
· Evaporation rate	Not applicable.
· Solubility in / Miscibility with	
Water:	Fully miscible.
· Partition coefficient (n-octanol/water): Not applicable.	
· Viscosity:	
Dynamic:	Not applicable.
Kinematic:	Not applicable.
· Solvent content:	
Water:	95.0 %
VOC content:	0.00 %
Solids content:	0.0 %
· Other information	No further relevant information available.

## 10 Stability and reactivity

- Reactivity No further relevant information available.
- Chemical stability
- Thermal decomposition / conditions to be avoided: No decomposition if used according to specifications.
- Possibility of hazardous reactions No dangerous reactions known.
- Conditions to avoid No further relevant information available.
- Incompatible materials: No further relevant information available.
- Hazardous decomposition products: No dangerous decomposition products known.

(Contd. on page 5)

Product Name: Global/ICH Oral Elemental Impurities A (Big 4)

(Contd. of page 4)

**11 Toxicological information**

· **Information on toxicological effects**

· **Acute toxicity:**

· **LD/LC50 values that are relevant for classification:**

7697-37-2 nitric acid

Inhalative	LC50/4 h	2.65 mg/l (ATE)
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· **Primary irritant effect:**

· **on the skin:** Caustic effect on skin and mucous membranes.

· **on the eye:**

Strong caustic effect.

Strong irritant with the danger of severe eye injury.

· **Sensitization:** No sensitizing effects known.

· **Additional toxicological information:**

The product shows the following dangers according to internally approved calculation methods for preparations:

Corrosive

Irritant

· **Carcinogenic categories**

· **IARC (International Agency for Research on Cancer)**

7440-43-9	cadmium	I
7439-97-6	mercury	3
7439-92-1	lead	2B
7440-38-2	arsenic	I

· **NTP (National Toxicology Program)**

7440-43-9	cadmium	K
7439-92-1	lead	R
7440-38-2	arsenic	K

· **OSHA-Ca (Occupational Safety & Health Administration)**

7440-43-9	cadmium
7440-38-2	arsenic

**12 Ecological information**

· **Toxicity**

· **Aquatic toxicity:** No further relevant information available.

· **Persistence and degradability:** No further relevant information available.

· **Behavior in environmental systems:**

· **Bioaccumulative potential:** No further relevant information available.

· **Mobility in soil:** No further relevant information available.

· **Additional ecological information:**

· **General notes:**

Water hazard class 2 (Self-assessment): hazardous for water

Do not allow product to reach ground water, water course or sewage system.

Must not reach bodies of water or drainage ditch undiluted or unneutralized.

Danger to drinking water if even small quantities leak into the ground.

· **Results of PBT and vPvB assessment**

· **PBT:** Not applicable.

· **vPvB:** Not applicable.

· **Other adverse effects:** No further relevant information available.

**13 Disposal considerations**

· **Waste treatment methods**

· **Recommendation:** Must not be disposed of together with household garbage. Do not allow product to reach sewage system.

· **Uncleaned packagings:**

· **Recommendation:** Disposal must be made according to official regulations.

· **Recommended cleansing agent:** Water, if necessary with cleansing agents.

**14 Transport information**

· **UN-Number**

· **DOT, ADR, IMDG, IATA**

UN3264

(Contd. on page 6)

Product Name: Global/ICH Oral Elemental Impurities A (Big 4)

(Contd. of page 5)

<ul style="list-style-type: none"> <li>· UN proper shipping name</li> <li>· DOT</li> <li>· ADR</li> <li>· IMDG, IATA</li> </ul>	<p>Corrosive liquid, acidic, inorganic, n.o.s. (Nitric acid) 3264 CORROSIVE LIQUID, ACIDIC, INORGANIC, N.O.S. (NITRIC ACID) CORROSIVE LIQUID, ACIDIC, INORGANIC, N.O.S. (NITRIC ACID)</p>
<ul style="list-style-type: none"> <li>· Transport hazard class(es)</li> <li>· DOT</li> </ul>	
<ul style="list-style-type: none"> <li>· Class</li> <li>· Label</li> </ul>	<p>8 Corrosive substances 8</p>
<ul style="list-style-type: none"> <li>· ADR, IMDG, IATA</li> </ul>	
<ul style="list-style-type: none"> <li>· Class</li> <li>· Label</li> </ul>	<p>8 Corrosive substances 8</p>
<ul style="list-style-type: none"> <li>· Packing group</li> <li>· DOT, ADR, IMDG, IATA</li> </ul>	<p>III</p>
<ul style="list-style-type: none"> <li>· Environmental hazards:</li> </ul>	<p>Not applicable.</p>
<ul style="list-style-type: none"> <li>· Special precautions for user</li> <li>· Hazard identification number (Kemler code):</li> <li>· EMS Number:</li> <li>· Segregation groups</li> <li>· Stowage Category</li> <li>· Stowage Code</li> <li>· Segregation Code</li> </ul>	<p>Warning: Corrosive substances 80 F-A,S-B (SGG1) Acids A SW2 Clear of living quarters. SG36 Stow "separated from" SGG18-alkalis. SG49 Stow "separated from" SGG6-cyanides</p>
<ul style="list-style-type: none"> <li>· Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code</li> </ul>	<p>Not applicable.</p>
<ul style="list-style-type: none"> <li>· Transport/Additional information:</li> </ul>	
<ul style="list-style-type: none"> <li>· ADR</li> <li>· Excepted quantities (EQ)</li> </ul>	<p>Code: E1 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 1000 ml</p>
<ul style="list-style-type: none"> <li>· IMDG</li> <li>· Limited quantities (LQ)</li> <li>· Excepted quantities (EQ)</li> </ul>	<p>5L Code: E1 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 1000 ml</p>
<ul style="list-style-type: none"> <li>· UN "Model Regulation":</li> </ul>	<p>UN 3264 CORROSIVE LIQUID, ACIDIC, INORGANIC, N.O.S. (NITRIC ACID), 8, III</p>

15 Regulatory information

- Safety, health and environmental regulations/legislation specific for the substance or mixture No further relevant information available.
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<ul style="list-style-type: none"> <li>· Section 313 (Specific toxic chemical listings):</li> </ul>	
7697-37-2	nitric acid
7440-43-9	cadmium
7439-97-6	mercury
7439-92-1	lead
7440-38-2	arsenic
<ul style="list-style-type: none"> <li>· TSCA (Toxic Substances Control Act):</li> </ul>	<p>All components have the value ACTIVE.</p>
<ul style="list-style-type: none"> <li>· Hazardous Air Pollutants</li> </ul>	
7439-92-1	lead

(Contd. on page 7)

Product Name: Global/ICH Oral Elemental Impurities A (Big 4)

(Contd. of page 6)

· **Proposition 65**

· <b>Chemicals known to cause cancer:</b>	
7440-43-9	cadmium
7439-92-1	lead
7440-38-2	arsenic
· <b>Chemicals known to cause reproductive toxicity for females:</b>	
None of the ingredients is listed.	
· <b>Chemicals known to cause reproductive toxicity for males:</b>	
7440-43-9	cadmium
· <b>Chemicals known to cause developmental toxicity:</b>	
7440-43-9	cadmium
7439-97-6	mercury

· **Carcinogenic categories**

· <b>EPA (Environmental Protection Agency)</b>		
7440-43-9	cadmium	B1
7439-97-6	mercury	D
7439-92-1	lead	B2
7440-38-2	arsenic	A

· **TLV (Threshold Limit Value)**

7440-43-9	cadmium	A2
7439-97-6	mercury	A4
7439-92-1	lead	A3
7440-38-2	arsenic	A1

· **NIOSH-Ca (National Institute for Occupational Safety and Health)**

7440-43-9	cadmium
7440-38-2	arsenic

· **GHS label elements** The product is classified and labeled according to the Globally Harmonized System (GHS).

· **Hazard pictograms**



GHS05

· **Signal word** Danger

· **Hazard-determining components of labeling:**

nitric acid

· **Hazard statements**

H314 Causes severe skin burns and eye damage.

· **Precautionary statements**

P260 Do not breathe dusts or mists.

P264 Wash thoroughly after handling.

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

P301+P330+P331 If swallowed: Rinse mouth. Do NOT induce vomiting.

P303+P361+P353 If on skin (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower.

P304+P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing.

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/doctor.

P321 Specific treatment (see on this label).

P363 Wash contaminated clothing before reuse.

P405 Store locked up.

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

· **Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

**16 Other information**

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

· **Department issuing SDS:** product safety department

· **Contact:**

Spex CertiPrep, LLC.

1-732-549-7144

(Contd. on page 8)

Printing date 10/05/2023

Reviewed on 10/05/2023

**Product Name: Global/ICH Oral Elemental Impurities A (Big 4)**

(Contd. of page 7)

· **Date of preparation / last revision** 10/05/2023

· **Abbreviations and acronyms:**

ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

DOT: US Department of Transportation

IATA: International Air Transport Association

EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society)

NFPA: National Fire Protection Association (USA)

HMIS: Hazardous Materials Identification System (USA)

VOC: Volatile Organic Compounds (USA, EU)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

NIOSH: National Institute for Occupational Safety

OSHA: Occupational Safety & Health

TLV: Threshold Limit Value

PEL: Permissible Exposure Limit

REL: Recommended Exposure Limit

Skin Corrosion 1B: Skin corrosion/irritation – Category 1B

Eye Damage 1: Serious eye damage/eye irritation – Category 1