

# **Scientific Documentation**

# **Diluted Hydrochloric Acid, 10 Percent (w/v), NF**

Not appropriate for regulatory submission. Please visit www.spectrumchemical.com or contact Tech Services for the most up-to-date information contained in this information package.

Spectrum Chemical Mfg Corp 769 Jersey Avenue New Brunswick, NJ 08901 Phone 732.214.1300





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# Specification for Diluted Hydrochloric Acid, 10 Percent (w/v), NF (HY105)

Item Number	HY105
Item	Diluted Hydrochloric Acid, 10 Percent (w/v), NF
CAS Number	
Molecular Formula	HCl
Molecular Weight	36.46
MDL Number	
Synonyms	Diluted Hydrochloric Acid

Test	Specification	
	Min	Max
ASSAY (HCl, w/v)	9.5	10.5 %
RESIDUE ON IGNITION		0.01 %
SULFATE	NO TURBIDITY OR PRECIPITATE	
SULFITE (SO <sub>3</sub> )	NO TURBIDITY OR DECOLORIZATION	
FREE BROMINE OR CHLORINE	NO VIOLET COLOR	
ELEMENTAL IMPURITIES:		
LEAD (Pb)	AS REPORTED	
ARSENIC (As)	AS REPORTED	
IDENTIFICATION	POSITIVE FOR CHLORIDE	
CERTIFIED HALAL		
EXPIRATION DATE		
DATE OF MANUFACTURE		
APPEARANCE		
RESIDUAL SOLVENTS	AS REPORTED	

#### Spectrum Chemical Mfg Corp

Corporate Headquarters:	West Coast Facility:
769 Jersey Ave.	14422 S. San Pedro St.
New Brunswick, NJ 08901	Gardena, CA 90248
732.214.1300	310.516.8000



# **Certificate Of Analysis**

Item Number	HY105	Lot Number	2MA0263
Item	Diluted Hydrochloric Acid, 10 Percent (w/v), NF	Molecular Formula	HCl
Molecular Weight	36.46		

тгст	SPECIFICATION		
TEST	MIN	MAX	RESULT
ASSAY (HCl, w/v)	9.5	10.5 %	10.02 %
RESIDUE ON IGNITION		0.01 %	<0.01 %
SULFATE	NO TURBIDITY OR PRECIPITATE		NO TURBIDITY OR PRECIPITATE
SULFITE (SO <sub>3</sub> )	NO TURBIDITY OR DECOLORIZATION		NO TURBIDITY OR PRECIPITATE
FREE BROMINE OR CHLORINE	NO VIOLET COLOR		NO VIOLET COLOR
ELEMENTAL IMPURITIES:			
LEAD (Pb)	AS REPORTED		<0.05 ppm
ARSENIC (As)	AS REPORTED		<0.05 ppm
IDENTIFICATION	POSITIVE FOR CHLORIDE		POSITIVE FOR CHLORIDE
CERTIFIED HALAL			CERTIFIED HALAL
EXPIRATION DATE			30-NOV-2025
DATE OF MANUFACTURE			16-JAN-2023
APPEARANCE			CLEAR,COLORLESS LIQUID
RESIDUAL SOLVENTS	AS REPORTED		NO RESIDUAL SOLVENTS USED

Certificate of Analysis Results Entered By:

SVANGOOR Swetha Vangoor 10-MAR-23 09:55:28

Spectrum Chemical Mfg Corp 755 Jersey Avenue New Brunswick 08901 NJ



All pharmaceutical ingredients are tested using current edition of applicable pharmacopeia.

Read and understand label and SDS before handling any chemicals. All Spectrum's chemicals are for manufacturing, processing, repacking or research purposes by experienced personnel only. It is the customer's responsibility to provide adequate hazardous material training and ensure that appropriate Personal Protective Equipment (PPE) is used before handling any chemical.

The Elemental Impurities standards implemented by USP and other Pharmaceutical Compendia reflect a growing understanding of the toxicology of trace levels of elemental impurities that can remain in drug substances originating from either raw materials or manufacturing processes. Identifying and quantifying impurities can be critical to predicting the best possible patient outcomes. Elemental Impurities has been a requirement of all products meeting USP/NF, EP and BP monographs since January 1, 2018. More information can be found in USP sections <232> Elemental Impurities – Limits and <233> Elemental Impurities – Procedures. Data for drug substances furnished by Spectrum Chemical Mfg. Corp can be used to ensure that patient daily exposures by oral administration to the selected elements are not exceeded in the formulation of pharmaceutical products.

Certificate of Analysis Results Approved By:

AWILLIAMS Allison Williams 13-MAR-23 08:11:32

# SAFETY DATA SHEET

Revision date 02-February-2022

1. Identification		
Product identifier		
Product Name	DILUTED HYDROCHLORIC ACID, NF	
Other means of identification		
Product Code(s)	HY105	
UN/ID no	UN1789	
Synonyms	None	
Recommended use of the chemical	and restrictions on use	
Recommended use	No information available	
Restrictions on use	No information available	
Details of the supplier of the safety	data sheet	
Supplier Address Spectrum Chemical Mfg. Corp. 14422 South San Pedro St. Gardena, CA 90248 (310) 516-8000	<u>Distributor</u> Distributed by: TekniScience 2425 Édouard Michelin Blvd. Terrebonne, Qc Canada J6Y 4P2 Telephone: 1-800-267-9799	
Emergency telephone number		
Emergency Telephone	Chemtrec 1-800-424-9300	

#### 2. Hazard(s) identification

#### **Classification**

Acute toxicity - Inhalation (Gases)	Category 4
Acute toxicity - Inhalation (Dusts/Mists)	Category 4
Skin corrosion/irritation	Category 1 Sub-category A
Serious eye damage/eye irritation	Category 1
Specific target organ toxicity (single exposure)	Category 3
Corrosive to metals	Category 1

#### Hazards not otherwise classified (HNOC)

Not applicable

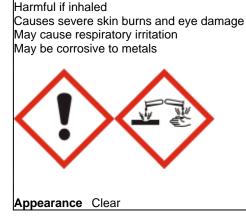
#### Label elements

Danger

Hazard statements



Revision Number 5



Physical state Liquid

Odor No information available

#### **Precautionary Statements - Prevention**

Use only outdoors or in a well-ventilated area Do not breathe dusts or mists Wash face, hands and any exposed skin thoroughly after handling Wear protective gloves/protective clothing/eye protection/face protection Keep only in original container

#### Precautionary Statements - Response

Immediately call a POISON CENTER or doctor Specific treatment (see .? on this label) IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing Immediately call a POISON CENTER or doctor IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/ shower Wash contaminated clothing before reuse IF INHALED: Remove person to fresh air and keep comfortable for breathing Immediately call a POISON CENTER or doctor IF SWALLOWED: Rinse mouth. Do NOT induce vomiting Absorb spillage to prevent material damage

#### **Precautionary Statements - Storage**

Store locked up. Store in a well-ventilated place. Keep container tightly closed Store in corrosive resistant/ .? container with a resistant inner liner

#### **Precautionary Statements - Disposal**

Dispose of contents/container to an approved waste disposal plant

#### Other information

May be harmful if swallowed.

#### 3. Composition/information on ingredients

#### Substance

Not applicable.

#### <u>Mixture</u>

Chemical name	CAS No	Weight-%
Water	7732-18-5	91
Hydrochloric Acid	7647-01-0	9

#### 4. First-aid measures

**Description of first aid measures** 

General advice	Show this safety data sheet to the doctor in attendance. Immediate medical attention is required.
Inhalation	Remove to fresh air. If breathing has stopped, give artificial respiration. Get medical attention immediately. Do not use mouth-to-mouth method if victim ingested or inhaled the substance; give artificial respiration with the aid of a pocket mask equipped with a one-way valve or other proper respiratory medical device. If breathing is difficult, (trained personnel should) give oxygen. Delayed pulmonary edema may occur. Get immediate medical advice/attention.
Eye contact	Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Keep eye wide open while rinsing. Do not rub affected area. Get immediate medical advice/attention.
Skin contact	Wash off immediately with soap and plenty of water while removing all contaminated clothes and shoes. Get immediate medical advice/attention.
Ingestion	Clean mouth with water and drink afterwards plenty of water. Never give anything by mouth to an unconscious person. Do NOT induce vomiting. Get immediate medical advice/attention.
Self-protection of the first aider	Avoid contact with skin, eyes or clothing. Ensure that medical personnel are aware of the material(s) involved, take precautions to protect themselves and prevent spread of contamination. Avoid direct contact with skin. Use barrier to give mouth-to-mouth resuscitation. Avoid breathing dust/fume/gas/mist/vapors/spray. Use personal protective equipment as required. See section 8 for more information.
Most important symptoms and effe	cts, both acute and delayed
Symptoms	Burning sensation. Coughing and/ or wheezing. Difficulty in breathing.
Indication of any immediate medica	al attention and special treatment needed
Note to physicians	Product is a corrosive material. Use of gastric lavage or emesis is contraindicated. Possible perforation of stomach or esophagus should be investigated. Do not give chemical antidotes. Asphyxia from glottal edema may occur. Marked decrease in blood pressure may occur with moist rales, frothy sputum, and high pulse pressure.
5 Eiro fighting moocuroe	

	IILIIM	measures

Suitable Extinguishing Media Large Fire	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. CAUTION: Use of water spray when fighting fire may be inefficient.	
Unsuitable extinguishing media	Do not scatter spilled material with high pressure water streams.	
Specific hazards arising from the chemical	The product causes burns of eyes, skin and mucous membranes. Thermal decomposition can lead to release of irritating gases and vapors.	
Explosion data Sensitivity to mechanical impact none.		
Sensitivity to static discharge	none.	
Special protective equipment for fire-fighters	Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Use personal protection equipment.	

#### 6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

 Personal precautions
 Avoid contact with skin, eyes or clothing. Ensure adequate ventilation. Use personal protective equipment as required. Attention! Corrosive material. Evacuate personnel to safe areas. Keep people away from and upwind of spill/leak. Avoid generation of dust. Do not

	breathe dust.	
Other information	Refer to protective measures listed in Sections 7 and 8.	
Methods and material for containment and cleaning up		
Methods for containment	Prevent further leakage or spillage if safe to do so.	
Methods for cleaning up	Pick up and transfer to properly labeled containers.	

#### 7. Handling and storage

#### Precautions for safe handling

Advice on safe handling Handle in accordance with good industrial hygiene and safety practice. Avoid contact with skin, eyes or clothing. In case of insufficient ventilation, wear suitable respiratory equipment. Handle product only in closed system or provide appropriate exhaust ventilation. Do not eat, drink or smoke when using this product. Take off contaminated clothing and wash before reuse. Avoid breathing vapors or mists.

Conditions for safe storage, including any incompatibilities

Storage ConditionsKeep containers tightly closed in a dry, cool and well-ventilated place. Protect from<br/>moisture. Store locked up. Keep out of the reach of children. Store away from other<br/>materials.

#### 8. Exposure controls/personal protection

#### Control parameters

Exposure Limits

The following ingredients are the only ingredients of the product above the cut-off level (or level that contributes to the hazard classification of the mixture) which have an exposure limit applicable in the region for which this safety data sheet is intended or other recommended limit. At this time, the other relevant constituents have no known exposure limits from the sources listed here.

Chemical name	ACGIH TLV	OSHA PEL	NIOSH IDLH
Hydrochloric Acid	No data available	5 ppm Ceiling	-
7647-01-0		7 mg/m <sup>3</sup> Ceiling	

#### Appropriate engineering controls

#### Engineering controls Showers Eyewash stations Ventilation systems.

#### Individual protection measures, such as personal protective equipment

Eye/face protection	Tight sealing safety goggles. Face protection shield.
Hand protection	Wear suitable gloves. Impervious gloves.
Skin and body protection	Wear suitable protective clothing. Long sleeved clothing. Chemical resistant apron.
Respiratory protection	No protective equipment is needed under normal use conditions. If exposure limits are exceeded or irritation is experienced, ventilation and evacuation may be required.

Wear suitable gloves and eye/face protection. Do not eat, drink or smoke when using this product. Regular cleaning of equipment, work area and clothing is recommended. Avoid contact with skin, eyes or clothing. Remove and wash contaminated clothing and gloves, including the inside, before re-use. Contaminated work clothing should not be allowed out of the workplace. Wash hands before breaks and immediately after handling the product. Avoid breathing dust/fume/gas/mist/vapors/spray.

#### 9. Physical and chemical properties

#### Information on basic physical and chemical properties

Physical state	Liquid	
Appearance	Clear	
Color	Colorless light yellow	
Odor	No information available	
Odor threshold	No information available	
Property	Values	Remarks • Method
pH	<1	None known
Melting point / freezing point	no data available	None known
Boiling point / boiling range	no data available	None known
Flash point	no data available	None known
Evaporation rate	no data available	None known
Flammability (solid, gas)	no data available	None known
Flammability Limit in Air		None known
Upper flammability or explosive	No data available	
limits		
Lower flammability or explosive	No data available	
limits		
Vapor pressure	No data available	None known
Vapor density	no data available	None known
Relative density	1.05	None known
Water solubility	Miscible in water	None known
Solubility(ies)	Miscible with alcohol	None known
Partition coefficient	No data available	None known
Autoignition temperature	no data available	None known
Decomposition temperature		None known
Kinematic viscosity	no data available	None known
Dynamic viscosity	No data available	None known
Other information		
Explosive properties	No information available	
Oxidizing properties	No information available	
Softening point	No information available	
Molecular weight	No information available	
VOC Content (%)	No information available	
Liquid Density	No information available	
Bulk density	No information available	
Buik defisity		

#### 10. Stability and reactivity

Reactivity	No information available.
Chemical stability	Stable under normal conditions.
Possibility of hazardous reactions	None under normal processing.
Conditions to avoid	Exposure to air or moisture over prolonged periods. Excessive heat.
Incompatible materials	Oxidizing agent. Acids. Bases.

Hazardous decomposition products None known based on information supplied.

#### 11. Toxicological information

#### Information on likely routes of exposure

#### **Product Information**

Inhalation	Specific test data for the substance or mixture is not available. Corrosive by inhalation. (based on components). Inhalation of corrosive fumes/gases may cause coughing, choking, headache, dizziness, and weakness for several hours. Pulmonary edema may occur with tightness in the chest, shortness of breath, bluish skin, decreased blood pressure, and increased heart rate. Inhaled corrosive substances can lead to a toxic edema of the lungs. Pulmonary edema can be fatal. May cause irritation of respiratory tract. Harmful by inhalation.
Eye contact	Specific test data for the substance or mixture is not available. Causes serious eye damage. (based on components). Corrosive to the eyes and may cause severe damage including blindness. May cause irreversible damage to eyes.
Skin contact	Specific test data for the substance or mixture is not available. Corrosive. (based on components). Causes burns.
Ingestion	Specific test data for the substance or mixture is not available. Causes burns. (based on components). Ingestion causes burns of the upper digestive and respiratory tracts. May cause severe burning pain in the mouth and stomach with vomiting and diarrhea of dark blood. Blood pressure may decrease. Brownish or yellowish stains may be seen around the mouth. Swelling of the throat may cause shortness of breath and choking. May cause lung damage if swallowed. May be fatal if swallowed and enters airways.
Symptoms related to the physical,	chemical and toxicological characteristics
Symptoms	Redness. Burning. May cause blindness. Coughing and/ or wheezing.
Acute toxicity	
Numerical measures of toxicity	

The following values are calculated based on chapter 3.1 of the GHS document

#### **Component Information**

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Water 7732-18-5	90 mL/kg (Rat)	-	-
Hydrochloric Acid 7647-01-0	238 - 277 mg/kg (Rat)	> 5010 mg/kg (Rabbit)	= 1.68 mg/L (Rat)1 h = 3120 ppm(Rat)1 h

#### Delayed and immediate effects as well as chronic effects from short and long-term exposure

Skin corrosion/irritation	Classification based on data available for ingredients. Causes burns.
Serious eye damage/eye irritation	Classification based on data available for ingredients. Risk of serious damage to eyes. Causes burns.
Respiratory or skin sensitization	No information available.
Germ cell mutagenicity	No information available.
Carcinogenicity	No information available.

The table below indicates whether each agency has listed any ingredient as a carcinogen.

-					
	Chemical name	ACGIH	IARC	NTP	OSHA
	Hydrochloric Acid 7647-01-0	-	Monograph 54 [1992]	-	-

#### Legend

IARC (International Agency for Research on Cancer)

#### Group 1 - Carcinogenic to Humans

Reproductive toxicity	No information available.
STOT - single exposure	May cause respiratory irritation.
STOT - repeated exposure	No information available.
Target organ effects	respiratory system, Eyes, Skin.
Aspiration hazard	No information available.
Other adverse effects	No information available.
Interactive effects	No information available.

### 12. Ecological information

#### Ecotoxicity

Chemical name	Algae/aquatic plants	Fish	Toxicity to microorganisms	Crustacea
Hydrochloric Acid 7647-01-0	-	LC50: =282mg/L (96h, Gambusia affinis)	_	-
Persistence and degradability No information		on available.		
Bioaccumulation Inherently biodegradable.				
Other adverse effects No information available.				

13. Disposal considerations		
Waste treatment methods		
Waste from residues/unused products	Dispose of in accordance with local regulations. Dispose of waste in accordance with environmental legislation.	
Contaminated packaging	Do not reuse empty containers.	

#### 14. Transport information

DOT UN/ID no Proper shipping name Hazard class Special Provisions Special Provisions Marine Pollutant Description Emergency Response Guide Number	UN1789 Hydrochloric acid solution 8 II 386, A3, B3, B15, B133, IB2, N41, T8, TP2 Severe Marine Pollutant UN1789, Hydrochloric acid solution, 8, II 157
<u>TDG</u> UN/ID no. Proper shipping name Hazard class Packing Group	UN1789 Hydrochloric acid solution 8 II

UN1789, Hydrochloric acid solution, 8, II Description UN-No UN1789 **Proper Shipping Name** Hydrochloric acid solution Hazard class 8 Packing Group Ш Description UN1789, Hydrochloric acid solution, 8, II ICAO (air) UN/ID no. UN1789 Proper shipping name Hydrochloric acid solution Hazard class 8 Ш **Packing Group Special Provisions** A3 Description UN1789, Hydrochloric acid solution, 8, II **UN number** UN1789 Proper shipping name Hydrochloric acid solution **Hazard Class** 8 Packing group Ш Description UN1789, Hydrochloric acid solution, 8, II UN1789 **UN number** Proper shipping name Hydrochloric acid solution Hazard Class 8 Packing group Ш EmS-No F-A, S-B Marine Pollutant NP1 Description UN1789, Hydrochloric acid solution, 8, II **UN number** UN1789 Proper shipping name Hydrochloric acid solution **Hazard Class** 8 Packing group Ш Classification code C1 **Special Provisions** 520 Description UN1789, Hydrochloric acid solution, 8, II Labels 8 1789 **UN number** Proper shipping name Hydrochloric acid solution **Hazard Class** 8 Ш Packing group **Classification code** C1 **Tunnel restriction code** (E) **Special Provisions** 520 Description 1789, Hydrochloric acid solution, 8, II, (E) Labels 8 **UN/ID No** UN1789 Proper shipping name Hydrochloric acid solution **Hazard Class** 8 **Packing Group** Ш **Classification code** C1 **Special Provisions** 520 Description UN1789, Hydrochloric acid solution, 8, II Hazard label(s) 8 Limited quantity (LQ) 1 L **Equipment Requirements** PP, EP

MEX

ΙΑΤΑ

IMDG

RID

ADR

ADN

#### 15. Regulatory information

#### International Inventories

**TSCA** 

Complies

DSL/NDSL	Complies
EINECS/ELINCS	Complies
ENCS	This product complies with ENCS:
IECSC	This product complies with China:
KECL	Complies
PICCS	Complies
AICS	All the constituents of this material are listed on the Australian Inventory of Chemical Substances (AICS).

Legend:

**TSCA** - United States Toxic Substances Control Act Section 8(b) Inventory

DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List

EINECS/ELINCS - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances

**ENCS** - Japan Existing and New Chemical Substances

**IECSC** - China Inventory of Existing Chemical Substances

KECL - Korean Existing and Evaluated Chemical Substances

**PICCS** - Philippines Inventory of Chemicals and Chemical Substances

#### US Federal Regulations

#### SARA 313

Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product contains a chemical or chemicals which are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372.

Chemical name	SARA 313 - Threshold Values %
Hydrochloric Acid - 7647-01-0	1.0

#### SARA 311/312 Hazard Categories

Should this product meet EPCRA 311/312 Tier reporting criteria at 40 CFR 370, refer to Section 2 of this SDS for appropriate classifications.

#### CWA (Clean Water Act)

This product does not contain any substances regulated as pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42).

#### **CERCLA**

This material, as supplied, contains one or more substances regulated as a hazardous substance under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302).

Chemical name	Hazardous Substances RQs	Extremely Hazardous Substances RQs
Hydrochloric Acid	5000 lb final RQ	-
7647-01-0	2270 kg final RQ	

#### US State Regulations

#### **California Proposition 65**

This product does not contain any Proposition 65 chemicals.

#### U.S. State Right-to-Know Regulations

Chemical name	New Jersey	Massachusetts	Pennsylvania
Hydrochloric Acid	1012	Present	Environmental hazard

7647-01-0		

#### U.S. EPA Label Information

EPA Pesticide Registration Number Not applicable

#### 16. Other information

#### NFPA Health hazards 3 Flammability 0 Instability 0 Physical and chemical properties -HMIS Health hazards 3\* Flammability 0 Physical hazards 0 Personal protection X Chronic Hazard Star Legend \* = Chronic Health Hazard Key or legend to abbreviations and acronyms used in the safety data sheet Legend Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION TWA TWA (time-weighted average) STEL STEL (Short Term Exposure Limit) Ceiling Maximum limit value Key literature references and sources for data used to compile the SDS Agency for Toxic Substances and Disease Registry (ATSDR) U.S. Environmental Protection Agency ChemView Database European Food Safety Authority (EFSA) EPA (Environmental Protection Agency) Acute Exposure Guideline Level(s) (AEGL(s)) U.S. Environmental Protection Agency Federal Insecticide, Fungicide, and Rodenticide Act U.S. Environmental Protection Agency High Production Volume Chemicals Food Research Journal Hazardous Substance Database International Uniform Chemical Information Database (IUCLID) Japan GHS Classification Australia National Industrial Chemicals Notification and Assessment Scheme (NICNAS) NIOSH (National Institute for Occupational Safety and Health) National Library of Medicine's ChemID Plus (NLM CIP) National Library of Medicine's PubMed database (NLM PUBMED) National Toxicology Program (NTP) New Zealand's Chemical Classification and Information Database (CCID) Organization for Economic Co-operation and Development Environment, Health, and Safety Publications Organization for Economic Co-operation and Development High Production Volume Chemicals Program Organization for Economic Co-operation and Development Screening Information Data Set World Health Organization Revision date 02-February-2022 No information available. **Revision Note** Disclaimer

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

End of Safety Data Sheet

# spectrum

#### Certification of Compliance with current Good Manufacturing Practices

Dear Valued Customer:

Spectrum Chemical Mfg Corp certifies that the following product(s) is produced, processed, packaged and held in compliance with current Good Manufacturing Practices (cGMP) in accordance with the applicable parts of 21 CFR, parts 210 and 211 of the Code of Federal Regulations.

Catalog Number	Product Name	
HY105	Diluted Hydrochloric Acid, 10 Percent (w/v), NF	

Spectrum is an FDA registered and inspected Drug Establishment. Our United States Food and Drug Administration (USFDA) Registration numbers are as follows:

Spectrum-Gardena, CA: Spectrum-New Brunswick, NJ: 2020632 2246824

Thank you for your interest in Spectrum products. If we may be of further assistance, please feel free to contact the Quality Assurance department at 310-516-8000 or via email at <u>qualityassurance@spectrumchemical.com</u>

Sincerely,

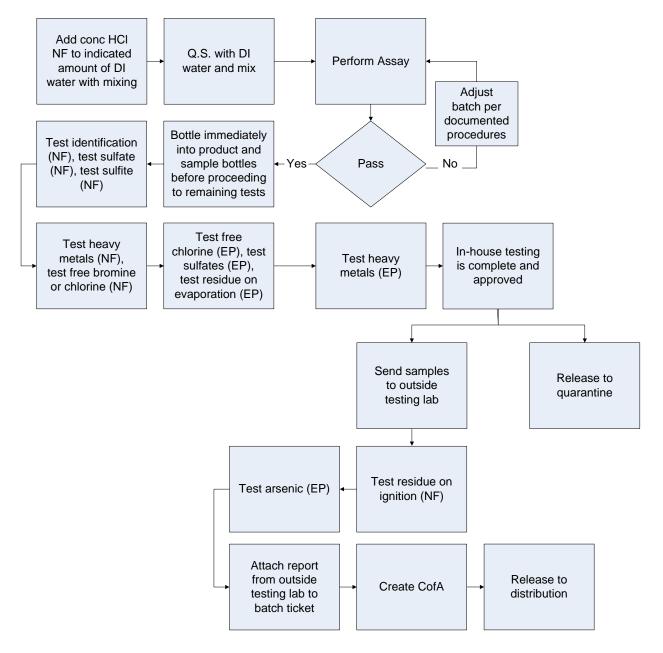
Oulu Clamy

Oralia Chavez Quality Assurance Specialist



# **Manufacturing Process Flowchart**

## Diluted Hydrochloric Acid, 10 Percent (w/v), NF - HY105



#### Spectrum Chemical Mfg Corp

#### Corporate Headquarters:

769 Jersey Ave. New Brunswick, NJ 08901 732.214.1300 *West Coast Facility:* 14422 S. San Pedro St. Gardena, CA 90248 310.516.8000

# HY105, Diluted Hydrochloric Acid, 10 Percent (w/v), NF

#### **Source Statement**

The above mentioned catalog item is blended from concentrated hydrochloric acid and purified water. No animal or plant derived products are used in the manufacturing process.

#### **BSE/TSE Statement**

The above mentioned catalog item does not contain nor is manufactured using any animal derived products and is therefore, BSE/TSE free.

#### **Allergen Statement**

The above mentioned catalog item does not contain any of the following:

- Milk
- Egg
- Fish
- Shellfish
- Tree Nuts
- Wheat
- Peanuts
- Soy

Cereals containing Gluten

spectrum

- Celery
- Mustard
- Sesame Seed
- Corn
- Latex
- Sulfites > 10 ppm

#### **EU Fragrance Allergen Statement**

The above mentioned catalog item does not contain any of the 26 EU fragrance allergens listed in Annex III lines 67-92. These substances are not intentionally added to the following chemical and therefore are not expected to be present.

#### **GMO Statement**

The above mentioned catalog item is manufactured without the use of genetically modified organisms and is therefore GMO free.

#### **Melamine Statement**

The above mentioned catalog does not use or add melamine to the manufacturing process and is considered melamine-free.



#### **Nitrosamine Statement**

Based on knowledge of the manufacturing process, nitrosamine impurities are not known or suspected to be present in this material.

#### **Animal Testing Statement**

The above mentioned catalog item has not been tested on animals.

#### **Organic Compliance Statement**

The above mentioned catalog item has not been produced using GMOs, irradiation, ethylene oxide (EtO) or sewage sludge.

#### **Shelf Life Statement**

The above mentioned catalog item is typically assigned a shelf life of 36 months from the date of manufacture. The actual assigned shelf life for any specific lot should be referenced on the Certificate of Analysis.

#### **Other Chemicals Statement**

Spectrum does not have any reason to suspect the above mentioned catalog item contains any of the following chemicals. This product does not come into contact with these chemicals during packaging or storage:

- Aflatoxins
- Antibiotics
- Bisphenol A (BPA)
- CMR Substances

- Parabens
- Pesticides
- Phthalates
- Preservatives

# spectrum®

# RE: Elemental Impurities - Diluted Hydrochloric Acid, 10 Percent (w/v), NF (Cat # HY105)

To Whom It May Concern:

Thank you for your interest in Spectrum high quality chemicals.

The above material complies with the USP<232>, <233> Elemental Impurities and the ICH Q3D Elemental Impurities Guideline. The following elemental impurities are likely to be present:

<b>Elemental Impurity</b>		Class	Expected Concentration
Lead	Pb	1	< 5 ppm
Arsenic	As	1	< 0.5 ppm

Other elemental impurities considered by USP <232>, <233> and ICH Q3D which are not addressed in the above mentioned table are not likely to be present. These substances are not used in the production process, are not intentionally added or known to be present in the above mentioned material.

This information is subject to change and is intended for risk assessment only. It is responsibility of the end user to evaluate suitability of any chemical for the intended use as well as to assess compound-specific limits of daily intake of metal impurities. For lot-specific information, please refer to the respective Certificate of Analysis.

If you have any further questions, please contact us by telephone at 1(800)772-8786 Option 2, or by email at <u>TechServices@spectrumchemical.com</u>.

Sincerely,

Technical Services Spectrum Chemical Mfg. Corp.

This document has been produced electronically and is valid without a signature.

#### CORPORATE HEADQUARTERS

769 Jersey Avenue New Brunswick, NJ 08901 PHONE 732.214.1300 FAX 732.246.7132

#### WEST COAST FACILITY

14422 South San Pedro Street Gardena, California 90248 PHONE 310.516.8000 FAX 310.516.9843

AN ISO 9001:2015 REGISTERED COMPANY



RE: Residual Solvents - Diluted Hydrochloric Acid, 10 Percent (w/v), NF (Cat # HY105)

To Whom It May Concern:

Thank you for your interest in Spectrum high quality chemicals.

The above mentioned catalog item complies with the requirements of the USP <467> Residual Solvents and the ICH Q3C Residual Solvents Guideline. No Class 1, Class 2, Class 3 or other solvents are used or produced in the manufacture of this product.

For lot-specific information, please refer to the respective Certificate of Analysis.

If you have any further questions, please contact us by telephone at 1(800)772-8786 Option 2, or by email at <u>TechServices@spectrumchemical.com</u>.

Sincerely,

Technical Services Spectrum Chemical Mfg. Corp.

This document has been produced electronically and is valid without a signature.

#### CORPORATE HEADQUARTERS

769 Jersey Avenue New Brunswick, NJ 08901 PHONE 732.214.1300 FAX 732.246.7132

#### WEST COAST FACILITY

14422 South San Pedro Street Gardena, California 90248 PHONE 310.516.8000 FAX 310.516.9843

AN ISO 9001:2015 REGISTERED COMPANY

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# spectrum®

### **Label Information**

The Spectrum label presents technical and safety information in an easily understood format. Our technical specialists stay abreast of the latest requirements of the Globally Harmonized System for Classification and Labelling of Chemicals (GHS), as well as the Occupational Safety and Health Administration (OSHA), the Food and Drug Administration (FDA) and other government regulatory agencies in order to ensure compliance, accuracy and concise hazard communication. Below you will find a typical label example for this catalog item.



#### Spectrum Chemical Mfg Corp

#### Corporate Headquarters:

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