

Scientific Documentation

Strong Ammonia Solution, 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 Strong Ammonia Solution, NF (AM180)

Item Number	AM180
Item	Strong Ammonia Solution, NF
CAS Number	1336-21-6
Molecular Formula	NH ₃ (aq)
Molecular Weight	17.03
MDL Number	
Synonyms	Ammonium Hydroxide ; Aqueous Ammonia ; Strong Ammonia Solution

Test	Specification		
	Min	Max	
APPEARANCE			
ASSAY (NH ₃ , by wt.)	27.0	31.0 %	
NONVOLATILE RESIDUE		0.05 %	
ELEMENTAL IMPURITIES	AS REPORTED		
READILY OXIDIZABLE SUBSTANCES	PINK COLOR REMAINS		
IDENTIFICATION	DENSE WHITE FUMES PRODUCED		
EXPIRATION DATE			
DATE OF MANUFACTURE			
MONOGRAPH EDITION			
RESIDUAL SOLVENTS		AS REPORTED	

Spectrum Chemical Mfg Corp

Corporate Headquarters:West Coast Facility:769 Jersey Ave.14422 S. San Pedro St.New Brunswick, NJ 08901Gardena, CA 90248732.214.1300310.516.8000



Certificate Of Analysis

Item Number	AM180	Lot Number	1NC0196
Item	Strong Ammonia Solution, NF	CAS Number	1336-21-6
Molecular Formula	NH ₃ (aq)	Molecular Weight	17.03

TECT	SPECIFICATION		DECLUT	
TEST	MIN	MAX	RESULT	
APPEARANCE			CLEAR COLORLESS LIQUID	
ASSAY (NH ₃ , by wt.)	27.0	31.0 %	28.6 %	
NONVOLATILE RESIDUE		0.05 %	<0.02 %	
ELEMENTAL IMPURITIES	AS REPORTED		NO ELEMENTAL IMPURITIES PRESENT	
READILY OXIDIZABLE SUBSTANCES	PINK COLOR REMAINS		PINK COLOR REMAINS	
IDENTIFICATION	DENSE WHITE FUMES PRODUCED		DENSE WHITE FUMES PRODUCED	
EXPIRATION DATE			07-FEB-2029	
DATE OF MANUFACTURE			09-FEB-2024	
MONOGRAPH EDITION			(USP-NF) 2023	
RESIDUAL SOLVENTS		AS REPORTED	NO RESIDUAL SOLVENTS PRESENT	

Certificate of Analysis Results Entered By:

HBERMUDEZ Hernan Bermudez 01-APR-24 11:41:57

Spectrum Chemical Mfg Corp 14422 South San Pedro Street Gardena 90248 CA



Certificate of Analysis Results Approved By:

SHANSEN Selin Hansen 05-APR-24 08:42:02

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.

SAFETY DATA SHEET SPECTRUM®



Revision date 30-September-2021 Revision Number 4

1. Identification

Product identifier

Product Name STRONG AMMONIA SOLUTION, NF

Other means of identification

Product Code(s) AM180

UN/ID no UN2672

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

Emergency telephone number

Emergency Telephone Chemtrec 1-800-424-9300

2. Hazard(s) identification

Classification

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

Hazards not otherwise classified (HNOC)

Not applicable

Label elements

Danger

Hazard statements

Harmful if swallowed

Harmful if inhaled

Causes severe skin burns and eye damage

May cause respiratory irritation



Appearance Clear Physical state Liquid Odor Strong

Precautionary Statements - Prevention

Wash face, hands and any exposed skin thoroughly after handling

Do not eat, drink or smoke when using this product

Use only outdoors or in a well-ventilated area

Do not breathe dusts or mists

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

Precautionary Statements - Response

Immediately call a POISON CENTER or doctor

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: Call a POISON CENTER or doctor if you feel unwell

Rinse mouth

Do NOT induce vomiting

Precautionary Statements - Storage

Store locked up.

Store in a well-ventilated place. Keep container tightly closed

Precautionary Statements - Disposal

Dispose of contents/container to an approved waste disposal plant

Unknown acute toxicity

- 0 % of the mixture consists of ingredient(s) of unknown acute oral toxicity
- 0 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (gas)
- 0 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (dust/mist)

Other information

No information available.

3. Composition/information on ingredients

Substance

Not applicable.

Mixture

Chemical name	CAS No	Weight-%	Trade secret
Water	7732-18-5	69 - 73	*
Ammonia	7664-41-7	27 - 31	*

^{*}The exact percentage (concentration) of composition has been withheld as a trade secret.

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. Keep

eye wide open while rinsing. Do not rub affected area. Remove contact lenses, if present

and easy to do. Continue rinsing. 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 Do NOT induce vomiting. Clean mouth with water and drink afterwards plenty of water.

Never give anything by mouth to an unconscious person. Get immediate medical

advice/attention.

Self-protection of the first aider Ensure that medical personnel are aware of the material(s) involved, take precautions to

protect themselves and prevent spread of contamination. Avoid contact with skin, eyes or clothing. 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 effects, both acute and delayed

Symptoms Burning sensation. Coughing and/ or wheezing. Difficulty in breathing.

Indication of any immediate medical 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. Fire-fighting measures

surrounding environment.

Large Fire CAUTION: Use of water spray when fighting fire may be inefficient.

Unsuitable extinguishing mediaDo 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.

Hazardous combustion products Ammonia. Nitrogen oxides (NOx).

Explosion data

Sensitivity to mechanical impact none.

Sensitivity to static discharge none.

Special protective equipment for Firefighters should wear self-contained breathing apparatus and full firefighting turnout

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

Personal precautions Attention! Corrosive material. Avoid contact with skin, eyes or clothing. Ensure adequate

ventilation. Use personal protective equipment as required. 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 Conditions Keep containers tightly closed in a dry, cool and well-ventilated place. Keep at a

temperature not exceeding 25 °C. Excursions between 30 °C / 86 °F and 40 °C / 104 °F during shipping are allowed. Keep out of the reach of children. Protect from moisture. Store

locked up. Store away from other 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
Ammonia	No data available	50 ppm TWA	300 ppm IDLH
7664-41-7		35 mg/m³ TWA	

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 protectionNo protective equipment is needed under normal use conditions. If exposure limits are

exceeded or irritation is experienced, ventilation and evacuation may be required.

General hygiene considerations Avoid contact with skin, eyes or clothing. Wear suitable gloves and eye/face protection. Do

not eat, drink or smoke when using this product. Remove and wash contaminated clothing and gloves, including the inside, before re-use. Contaminated work clothing should not be allowed out of the workplace. Regular cleaning of equipment, work area and clothing is recommended. Wash hands before breaks and immediately after handling the product.

None known

Avoid breathing dust/fume/gas/mist/vapors/spray.

9. Physical and chemical properties

Information on basic physical and chemical properties

Physical stateLiquidAppearanceClearColorColorlessOdorStrong

Odor threshold No information available

<u>Property</u> <u>Values</u> <u>Remarks • Method</u>

pH 11.6 - this is the actual pH in a 1 N None known

solution

Melting point / freezing point-69.2°C / -92.6°FNone knownBoiling point / boiling range31 - 38 °C / 87.8 - 100.4°FNone knownFlash pointno data availableNone knownEvaporation rateno data availableNone knownFlammability (solid, gas)no data availableNone known

Flammability Limit in Air

Upper flammability or explosive No data available

limits

Lower flammability or explosive No data available

limits

Vapor pressure 287.9 @ 25 °C None known Vapor density no data available None known Relative density 0.898 None known Water solubility Soluble in water None known Solubility(ies) no data available None known **Partition coefficient** No data available None known **Autoignition temperature** no data available None known **Decomposition temperature** None known

Kinematic viscosityno data availableNone knownDynamic viscosityNo data availableNone known

Other information

Explosive propertiesNo information availableOxidizing propertiesNo information availableSoftening pointNo information available

Molecular weight 35.05

VOC Content (%)

Liquid Density

Bulk density

No information available
No information available

10. Stability and reactivity

Reactivity No information available.

Chemical stability Stable under recommended storage conditions.

Possibility of hazardous reactions None under normal processing.

Conditions to avoid Exposure to air or moisture over prolonged periods. Excessive heat.

Incompatible materials Acids. Bases. Oxidizing agent.

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 .

ATEmix (oral) 1,296.30 mg/kg
ATEmix (inhalation-gas) 2,592.60 ppm
ATEmix (inhalation-dust/mist) 1.86 mg/l

Unknown acute toxicity

0 % of the mixture consists of ingredient(s) of unknown acute oral toxicity

- 0 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (gas)
- 0 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (dust/mist)

Component Information

	Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
	Water 7732-18-5	90 mL/kg(Rat)	-	-
Ammonia = 350 mg/kg (Rat) 7664-41-7		-	= 2000 ppm (Rat) 4 h	

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

Germ cell mutagenicity

No information available. No information available.

Reproductive toxicityNo information available.

STOT - single exposure STOT - repeated exposure Target organ effects May cause respiratory irritation.

No information available. 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	Crustacea
		10-2 2 2 2 2 2	microorganisms	1000
Ammonia	-	LC50: 0.26 - 4.6mg/L	-	LC50: =25.4mg/L (48h,
7664-41-7		(96h, Lepomis		Daphnia magna)
		macrochirus) LC50: 0.73		
		- 2.35mg/L (96h,		
		Pimephales promelas)		
		LC50: =0.44mg/L (96h,		
		Cyprinus carpio) LC50:		
		=1.17mg/L (96h, Lepomis		
		macrochirus) LC50:		
		=1.19mg/L (96h, Poecilia		
		reticulata) LC50:		
		=5.9mg/L (96h,		
		Pimephales promelas)		
		LC50: >1.5mg/L (96h,		
		Poecilia reticulata)		

Persistence and degradability Bioaccumulation

No information available. Inherently biodegradable.

Component Information

Chemical name	Partition coefficient
Ammonia	-1.14
7664-41-7	

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 UN2672

Proper Shipping Name: Ammonia solution

Hazard class 8
Packing group: |||

Special Provisions 336, IB3, IP8, T7, TP2

Marine Pollutant Severe Marine Pollutant

Description: UN2672, Ammonia solution, 8, III

Emergency Response Guide 154

Number

TDG

UN-No: UN2672

Proper Shipping Name: Ammonia solution

Hazard class 8
Packing Group:

Description: UN2672, Ammonia solution, 8, III

MEX

UN-No UN2672

Proper Shipping Name Ammonia solution

Hazard class 8
Packing Group III

Description UN2672, Ammonia solution, 8, III

ICAO (air)

UN-No: UN2672

Proper Shipping Name: Ammonia solution

Hazard class 8
Packing Group: III
Special Provisions A64

Description: UN2672, Ammonia solution, 8, III

<u>IATA</u>

UN number UN2672

Proper Shipping Name: Ammonia solution

Transport hazard class(es) 8
Packing group III

Description: UN2672, Ammonia solution, 8, III

IMDG

UN number UN2672

Proper shipping name Ammonia solution

Transport hazard class(es) 8
Packing group III
EmS-No F-A, S-B
Marine pollutant P

Description UN2672, Ammonia solution, 8, III, Marine pollutant

RID

UN number UN2672

Proper Shipping Name: Ammonia solution

Transport hazard class(es) 8
Packing group III
Classification code C5
Special Provisions 543

Description: UN2672, Ammonia solution, 8, III, ENVIRONMENTALLY HAZARDOUS

Labels 8

ADR

UN number 2672

Proper Shipping Name: Ammonia solution

Transport hazard class(es) 8
Packing group | | |

Classification code C5 Tunnel restriction code (E) Special Provisions 543

Description: 2672, Ammonia solution, 8, III, (E), ENVIRONMENTALLY HAZARDOUS

Labels 8

<u>ADN</u>

UN/ID No UN2672

Proper shipping name Ammonia solution

Transport hazard class(es) 8
Packing Group III
Classification code C5
Special Provisions 543

Description UN2672, Ammonia solution, 8, III, ENVIRONMENTALLY HAZARDOUS

Hazard label(s) 8
Limited quantity (LQ) 5 L
Equipment Requirements PP, EP

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 %	
Ammonia - 7664-41-7	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 contains the following substances which are regulated pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42).

Chemical name	CWA - Reportable	CWA - Toxic Pollutants	CWA - Priority Pollutants	CWA - Hazardous
	Quantities			Substances
Ammonia	-	-	-	Present

7664-41-7		

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
Ammonia	100 lb final RQ	-
7664-41-7	45.4 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

This product does not contain any substances regulated under applicable state right-to-know regulations

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

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 30-September-2021
Revision Note No information available.

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



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
AM180	Strong Ammonia Solution, 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: 2020632 Spectrum-New Brunswick, NJ: 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 qualityassurance@spectrumchemical.com

Sincerely,

Oralia Chavez

Quality Assurance Specialist

Order Clony



AM180, Strong Ammonia Solution, NF

Source Statement

The above mentioned catalog item is manufactured by chemical synthesis. 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
- 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 60 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



RE: Elemental Impurities - Strong Ammonia Solution, NF (Cat# AM180)

To Whom It May Concern:

Thank you for your interest in Spectrum high quality chemicals.

The above mentioned material complies with the USP<232>, <233> Elemental Impurities and the ICH Q3D Elemental Impurities Guideline. No Class 1, Class 2A, Class 2B or Class 3 elemental impurities are 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 TechServices@spectrumchemical.com.

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



RE: Residual Solvents - Strong Ammonia Solution, NF (Cat# AM180)

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 TechServices@spectrumchemical.com.

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
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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.



DANGER

0000-00-00

Causes severe skin burns and eye damage
 Harmful if swallowed or if inhaled
 May cause respiratory irritation.

- Do not eat, drink or smoke when using this product
 Wear protective gloves, protective clothing, eye
 protection, face protection Do not breathe mist or
 vapors Use only outdoors or in a well-ventilated area

 Weah feet heade and any expected with the resulting
- vapors Use only outdoors or in a well-ventiliated area
 • Wash face, hands and any exposed skin thoroughly
 after handling.
 ▼ FIRST AID: Immediately call a POISON CENTER or
 physician. IF IN EYES: Rinse cautiously with water for
- physician. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. IF ON SKIN (or hair):

 Take off immediately all contaminated clothing. Rinse skin with water. Wash contaminated clothing before reuse. IF INHALED: Remove person to fresh air and keep comfortable for breathing. IF SWALLOWED: Rinse mouth. DO NOT induce vomiting. If conscious, give water or milk. Never give anything by mouth to an unconscious person.

KEEP FROM CHILDREN

AM180 SIZ SY Strong Ammonia Solution

(Aqueous Ammonia; Ammonium Hydroxide) N.F.

CAS 1336-21-6

CAUTION: For manufacturing, processing or repacking.
Read and understand the label and Safety Data Sheet (SDS)

DOT: UN2672, Ammonia, solution, 8, PG III

Chemical Emergency: (800)424-9300

www.SpectrumChemical.com

 $NH_3(aq)$

F.W. 17.03

Assay (NH₃; by Wt.)27.0-31.0% MAXIMUM LIMITS

Store below 26°C.

WARNING: Cancer and Reproductive Harmwww.P65Warnings.ca.gov

W 11/G11GHS ? Lot No. XQ####

Spectrum Chemical Mfg Corp

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