

# **Scientific Documentation**

# Acetone, 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 Acetone, NF (AC115)**

Item Number	AC115
Item	Acetone, NF
CAS Number	67-64-1
Molecular Formula	C <sub>3</sub> H <sub>6</sub> O
Molecular Weight	58.08
MDL Number	
Synonyms	

Test	Specification		
	Min	Max	
APPEARANCE			
ASSAY [(CH <sub>3</sub> ) <sub>2</sub> CO]	99.0 %		
SPECIFIC GRAVITY @ 25°C		0.789	
WATER		0.5 %	
NONVOLATILE RESIDUE		0.004 %	
READILY OXIDIZABLE SUBSTANCES	THE PERMANGANATE COLOR OF THE MIXTURE DOES NOT COMPLETELY DISAPPEAR WITHIN 15 MIN.		
ELEMENTAL IMPURITIES	AS REPORTED		
IDENTIFICATION (A) FTIR	SPECTRUM MATCHES REFERENCE		
IDENTIFICATION (B)	RETENTION TIME CORRESPONDS TO STANDARD		
CERTIFIED HALAL			
EXPIRATION DATE			
DATE OF MANUFACTURE			
RESIDUAL SOLVENTS	AS REPORTED		
CLASS 1 (solvent) / BENZENE			
CLASS 2 (SOLVENT) / CUMENE			
CLASS 2 (SOLVENT) / METHANOL			
CLASS 3 (solvent) / ETHANOL			

Test	Specification	
	Min	Max
CLASS 3 (solvent) / ETHYL ACETATE		
CLASS 3 (solvent) / 1-PROPANOL		
MONOGRAPH EDITION		

## 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	AC115	Lot Number	1ML0088
Item	Acetone, NF	CAS Number	67-64-1
Molecular Formula	C <sub>3</sub> H <sub>6</sub> O	Molecular Weight	58.08

TEST	SPECIFICATION		DECLUT	
IESI	MIN	MAX	RESULT	
APPEARANCE			CLEAR,COLORLESS LIQUID	
ASSAY [(CH <sub>3</sub> ) <sub>2</sub> CO]	99.0 %		99.71%	
SPECIFIC GRAVITY @ 25°C		0.789	0.787	
WATER		0.5 %	0.26%	
NONVOLATILE RESIDUE		0.004 %	0.000%	
READILY OXIDIZABLE SUBSTANCES	THE PERMANGANATE COLOR OF THE MIXTURE DOES NOT COMPLETELY DISAPPEAR WITHIN 15 MIN.		COMPLIES	
ELEMENTAL IMPURITIES	AS REPORTED		NO ELEMENTAL IMPURITIES PRESENT	
IDENTIFICATION (A) FTIR	SPECTRUM MATCHES REFERENCE		SPECTRUM MATCHES REFERENCE	
IDENTIFICATION (B)	RETENTION TIME CORRESPONDS TO STANDARD		RETENTION TIME CORRESPONDS TO STANDARD	
CERTIFIED HALAL			CERTIFIED HALAL	
EXPIRATION DATE			04-APR-2027	
DATE OF MANUFACTURE			05-APR-2022	
RESIDUAL SOLVENTS	AS REPORTED			
CLASS 1 (solvent) / BENZENE			<2 ppm	
CLASS 2 (SOLVENT) / CUMENE			<70 ppm	

TEST	SPECIFICATION		DECLUT	
IESI	MIN	MAX	RESULT	
CLASS 2 (SOLVENT) / METHANOL			<3000 ppm	
CLASS 3 (solvent) / ETHANOL			<5000 ppm	
CLASS 3 (solvent) / ETHYL ACETATE			<5000 ppm	
CLASS 3 (solvent) / 1-PROPANOL			<5000 ppm	
MONOGRAPH EDITION			(USP- NF) 2023	

Certificate of Analysis Results Entered By:

SHANSEN Selin Hansen 18-DEC-23 11:13:30

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



Certificate of Analysis Results Approved By:

HBERMUDEZ Hernan Bermudez 18-DEC-23 14:31:50

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 29-December-2021

**Revision Number** 7

#### 1. Identification

**Product identifier** 

Product Name ACETONE, NF

Other means of identification

Product Code(s) AC115

UN/ID no UN1090

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

Serious eye damage/eye irritation	Category 2A
Reproductive toxicity	Category 2
Specific target organ toxicity (single exposure)	Category 3
Flammable liquids	Category 2

#### Hazards not otherwise classified (HNOC)

Not applicable

#### Label elements

#### Danger

#### Hazard statements

Causes serious eye irritation

Suspected of damaging fertility or the unborn child

May cause respiratory irritation. May cause drowsiness or dizziness

Highly flammable liquid and vapor



Appearance clear Physical state Liquid Odor No information available

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

Obtain special instructions before use

Do not handle until all safety precautions have been read and understood

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

Wash face, hands and any exposed skin thoroughly after handling

Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking

Keep container tightly closed

Ground/bond container and receiving equipment

Use explosion-proof electrical/ventilating/lighting/.?/equipment

Use only non-sparking tools

Take precautionary measures against static discharge

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

Use only outdoors or in a well-ventilated area

#### **Precautionary Statements - Response**

IF exposed or concerned: Get medical advice/attention

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

If eye irritation persists: Get medical advice/attention

IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/ shower

IF INHALED: Remove person to fresh air and keep comfortable for breathing

Call a POISON CENTER or doctor if you feel unwell

In case of fire: Use CO2, dry chemical, or foam to extinguish

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

Store locked up.

Store in a well-ventilated place. Keep cool

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

Dispose of contents/container to an approved waste disposal plant

#### Other information

Causes mild skin irritation.

#### 3. Composition/information on ingredients

#### Substance

Chemical name	CAS No	Weight-%	Trade secret
Acetone	67-64-1	100	*

<sup>\*</sup>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.

**Inhalation** Remove to fresh air.

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 medical attention if irritation develops and persists.

Skin contact Wash off immediately with soap and plenty of water while removing all contaminated

clothes and shoes.

**Ingestion** Clean mouth with water and drink afterwards plenty of water. Never give anything by mouth

to an unconscious person. Do NOT induce vomiting. Call a physician.

Self-protection of the first aider Remove all sources of ignition. Ensure that medical personnel are aware of the material(s)

involved, take precautions to protect themselves and prevent spread of contamination. Use personal protective equipment as required. See section 8 for more information. Avoid

contact with skin, eyes or clothing.

Most important symptoms and effects, both acute and delayed

**Symptoms** May cause redness and tearing of the eyes. Burning sensation. Prolonged contact may

cause redness and irritation.

Indication of any immediate medical attention and special treatment needed

#### 5. Fire-fighting measures

Suitable Extinguishing Media Large Fire Dry chemical. Carbon dioxide (CO2). water spray. Alcohol resistant foam.

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

risk of ignition. Keep product and empty container away from heat and sources of ignition. In the event of fire, cool tanks with water spray. Fire residues and contaminated fire

extinguishing water must be disposed of in accordance with local regulations.

**Hazardous combustion products** Carbon Monoxide, Carbon Dioxide.

**Explosion data** 

Sensitivity to mechanical impact none.

Sensitivity to static discharge yes

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** Evacuate personnel to safe areas. Use personal protective equipment as required. See

section 8 for more information. Avoid contact with skin, eyes or clothing. Ensure adequate ventilation. Keep people away from and upwind of spill/leak. ELIMINATE all ignition sources (no smoking, flares, sparks or flames in immediate area). Pay attention to flashback. Take precautionary measures against static discharges. All equipment used when handling the

product must be grounded. Do not touch or walk through spilled material.

Other information Ventilate the area. Refer to protective measures listed in Sections 7 and 8.

Methods and material for containment and cleaning up

Methods for containment Stop leak if you can do it without risk. Do not touch or walk through spilled material. A vapor

suppressing foam may be used to reduce vapors. Dike far ahead of spill to collect runoff

water. Keep out of drains, sewers, ditches and waterways. Absorb with earth, sand or other

Take precautionary measures against static discharges. Dam up. Soak up with inert

non-combustible material and transfer to containers for later disposal.

absorbent material. Pick up and transfer to properly labeled containers.

#### 7. Handling and storage

#### Precautions for safe handling

Methods for cleaning up

hot surfaces, sparks, open flames and other ignition sources. No smoking. Use grounding and bonding connection when transferring this material to prevent static discharge, fire or explosion. Use with local exhaust ventilation. Use spark-proof tools and explosion-proof equipment. Keep in an area equipped with sprinklers. Use according to package label instructions. Handle in accordance with good industrial hygiene and safety practice. Avoid contact with skin, eyes or clothing. Do not eat, drink or smoke when using this product.

Remove contaminated clothing and shoes.

#### Conditions for safe storage, including any incompatibilities

Storage Conditions Keep containers tightly closed in a dry, cool and well-ventilated place. Keep away from

heat, sparks, flame and other sources of ignition (i.e., pilot lights, electric motors and static electricity). Keep in properly labeled containers. Do not store near combustible materials. Keep in an area equipped with sprinklers. Store in accordance with the particular national

regulations. Store in accordance with local regulations. Store locked up.

#### 8. Exposure controls/personal protection

#### Control parameters

**Exposure Limits** 

Chemical name	ACGIH TLV	OSHA PEL	NIOSH IDLH
Acetone	No data available	1000 ppm TWA	-
67-64-1		2400 mg/m <sup>3</sup> 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.

**Hand protection** Wear suitable gloves. Impervious gloves.

**Skin and body protection** Wear suitable protective clothing. Long sleeved clothing. Chemical resistant apron.

Antistatic boots.

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.

General hygiene considerations Do not eat, drink or smoke when using this product. 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.

#### 9. Physical and chemical properties

Information on basic physical and chemical properties

Physical state Liquid
Appearance clear
Color Colorless

Odor No information available Odor threshold No information available

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

pН no data available None known -95 °C / -139 °F Melting point / freezing point None known Boiling point / boiling range 56 °C / 132.8 °F None known -18 °C / -0.4 °F Flash point CC (closed cup) **Evaporation rate** no data available None known None known Flammability (solid, gas) no data available None known Flammability Limit in Air

Upper flammability or explosive 12.8%

limits

Lower flammability or explosive 2.5%

limits

Vapor pressure24None knownVapor density2None knownRelative density0.79None knownWater solubilityMiscible in waterNone knownSolubility(ies)Miscible in EtherNone known

Miscible in Chloroform Miscible in Benzene Miscible with alcohol

No data available

Partition coefficient
Autoignition temperature

Decomposition temperature

Kinematic viscosity

Dynamic viscosity

no data available
no data available
No data available

None known None known None known

None known

Other information

Explosive propertiesNo information availableOxidizing propertiesNo information availableSoftening pointNo information availableMolecular weightNo information available

**VOC Content (%)** 99+ % .?

Liquid Density No information available Bulk density No information available

#### 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** Heat, flames and sparks.

**Incompatible materials**None known based on information supplied.

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. May cause irritation of

respiratory tract.

Eye contact Specific test data for the substance or mixture is not available. Causes serious eye irritation.

(based on components). May cause redness, itching, and pain.

Specific test data for the substance or mixture is not available. May cause irritation. Skin contact

Prolonged contact may cause redness and irritation. Causes mild skin irritation.

Ingestion Specific test data for the substance or mixture is not available. Ingestion may cause

gastrointestinal irritation, nausea, vomiting and diarrhea.

#### Symptoms related to the physical, chemical and toxicological characteristics

May cause redness and tearing of the eyes. Prolonged contact may cause redness and **Symptoms** 

irritation.

**Acute toxicity** 

**Numerical measures of toxicity** 

**Component Information** 

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Acetone 67-64-1	= 5800 mg/kg (Rat)	1700mg/kg (rabbit)	18892 mg/m <sup>3</sup>

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

May cause skin irritation. Classification based on data available for ingredients. Skin corrosion/irritation

Serious eye damage/eye irritation Classification based on data available for ingredients. Causes serious eye irritation. Respiratory or skin sensitization

No information available.

Germ cell mutagenicity

No information available.

Reproductive toxicity Contains a known or suspected reproductive toxin. Classification based on data available

for ingredients. Suspected of damaging fertility or the unborn child.

STOT - single exposure STOT - repeated exposure No information available. No information available.

Target organ effects

respiratory system, Eyes, Skin, central nervous system.

**Aspiration hazard** No information available.

Other adverse effects No information available.

Interactive effects No information available.

#### 12. Ecological information

**Ecotoxicity** 

LCCIOXICITY	•			
Chemical name	Algae/aquatic plants	Fish	Toxicity to	Crustacea
			microorganisms	
Acetone	-	LC50: 4.74 - 6.33mL/L	-	EC50: 10294 -
67-64-1		(96h, Oncorhynchus		17704mg/L (48h,
		mykiss) LC50: 6210 -		Daphnia magna) EC50:
		8120mg/L (96h,		12600 - 12700mg/L (48h,
		Pimephales promelas)		Daphnia magna)
		LC50: =8300mg/L (96h,		

Lepomis macrochirus)

Persistence and degradability

No information available. **Bioaccumulation** Inherently biodegradable.

**Component Information** 

Chemical name	Partition coefficient
Acetone 67-64-1	-0.24

Other adverse effects No information available.

#### 13. Disposal considerations

#### Waste treatment methods

Waste from residues/unused

products

Should not be released into the environment. Dispose of in accordance with local

regulations. Dispose of waste in accordance with environmental legislation.

Contaminated packaging Empty containers pose a potential fire and explosion hazard. Do not cut, puncture of weld

containers.

#### 14. Transport information

DOT

UN/ID no UN1090 **Proper Shipping Name:** Acetone **Hazard class** Packing group:

**Description:** UN1090, Acetone , 3,, PG II

**TDG** 

UN1090 UN-No: **Proper Shipping Name:** Acetone Hazard class 3 Packing Group: Ш

Description: ACETONE,3,UN1090,PG II

MEX not regulated

ICAO (air)

UN-No: UN1090 **Proper Shipping Name:** Acetone **Hazard class** 3 **Packing Group:** 

**Description:** Acetone,3,UN1090,PG II

IATA

**UN** number UN1090 **Proper Shipping Name:** Acetone Transport hazard class(es) Packing group

Description: UN1090, Acetone, 3, PG II

**IMDG** not regulated

RID

UN1090 **UN** number **Proper Shipping Name:** Acetone Transport hazard class(es) 3 Ш Packing group

**Description:** UN1090 Acetone,3,II,RID

**ADR** 

UN number UN1090
Proper Shipping Name: Acetone
Transport hazard class(es) 3
Packing group II

**Description:** UN1090 Acetone,3,II

ADN not regulated

#### 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

**NECL** - 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 does not contain any chemicals which are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372.

#### 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
Acetone	5000 lb final RQ	-
67-64-1	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**

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 2 Flammability 3 Instability 0

Physical and chemical properties -

**HMIS** 

Health hazards 2 \* Flammability 3 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 29-December-2021 Revision Note 29-December-2021 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
AC115	Acetone, 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 <a href="mailto:qualityassurance@spectrumchemical.com">qualityassurance@spectrumchemical.com</a>

Sincerely,

Oralia Chavez

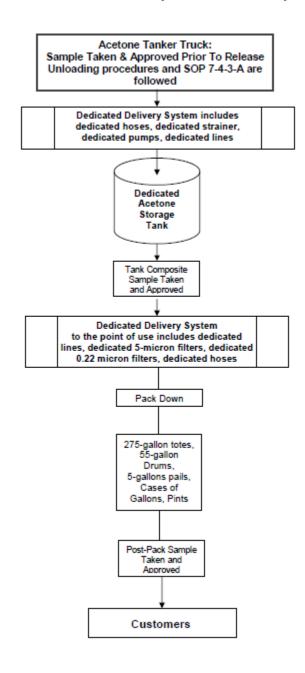
**Quality Assurance Specialist** 

Order Clony



# **Manufacturing Process Flowchart**

Acetone, NF (Cat# AC115)



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



# AC115, Acetone, 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 - Acetone, NF (Cat# AC115)

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 - Acetone, NF (Cat# AC115)

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 USP <467> Residual Solvents and ICH Q3C Residual Solvents Guideline. The following solvents are likely to be present:

Residual Solvent	Class	Expected Concentration
Benzene	1	< 2 ppm
Cumene	2	< 70 ppm
Methanol	2	< 3000 ppm
Ethanol	3	< 5000 ppm
Ethyl Acetate	3	< 5000 ppm
1-Propanol	3	< 5000 ppm

No other solvents are used or produced in the manufacturing process of this material.

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 <a href="mailto:TechServices@spectrumchemical.com">TechServices@spectrumchemical.com</a>.

Sincerely,

Technical Services Spectrum Chemical Mfg. Corp.

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

CORPORATE HEADQUARTERS

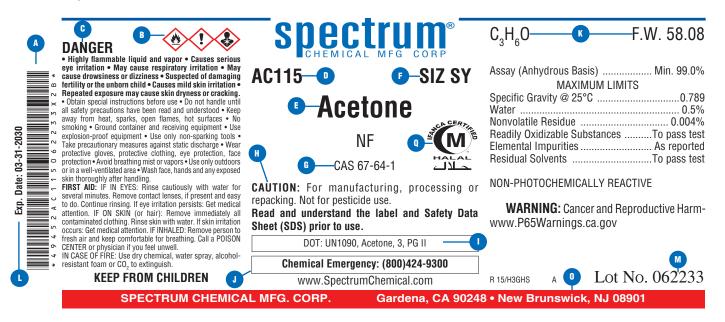
769 Jersey Avenue New Brunswick, NJ 08901 PHONE 732.214.1300 FAX 732.246.7132 WEST COAST FACILITY

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



#### **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.



- A Bar Code
- GHS Hazard Pictograms
- Warning, Safety Data and Precautionary Information
- Product Catalog Number
- Item Name, Form, Grade
- Size/Quantity

- Chemical Abstracts Service (CAS) Registry Number
- Caution Information
- DOT Shipping Information
- Toll-Free 24-Hour Chemical Emergency Telephone Number
- Empirical Formula, Formula Weight and Technical Specifications Panel
- Expiration Information
- Lot Number
- Nosher Certified by Kosher Supervision of America (KSA).
- Storage Color Band
- Halal Certified by IFANCA
- bioCertified

This color-coded band indicates the hazard most likely to be posed by that material under storage conditions. The criteria used to assign band colors have been established by the Storage Code working group of the Society for Chemical Hazard Communication (SCHC). It is recommended that like colors be stored together, unless otherwise stated, based on the color codes indicated to the right. However, it is the responsibility of the customer to check with their local fire department for possible conflicts with our recommendations when storing hazardous chemicals.

#### Spectrum Chemical Mfg Corp

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