

# **Scientific Documentation**

## Syrup, 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 Syrup, NF (SY105)**

| Item Number       | SY105     |
|-------------------|-----------|
| Item              | Syrup, NF |
| CAS Number        |           |
| Molecular Formula |           |
| Molecular Weight  |           |
| MDL Number        |           |
| Synonyms          |           |

| Test                      | Specification |              |  |  |
|---------------------------|---------------|--------------|--|--|
|                           | Min           | Max          |  |  |
| SPECIFIC GRAVITY (@ 25°C) | 1.30          |              |  |  |
| ELEMENTAL IMPURITIES      | AS REPORTED   |              |  |  |
| IDENTIFICATION            | TO PASS TEST  |              |  |  |
| EXPIRATION DATE           |               |              |  |  |
| DATE OF MANUFACTURE       |               |              |  |  |
| APPEARANCE                |               |              |  |  |
| RESIDUAL SOLVENTS         |               | TO PASS TEST |  |  |

#### 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 | SY105     | Lot Number | 1MA1023 |
|-------------|-----------|------------|---------|
| Item        | Syrup, NF |            |         |

| TECT                      | SPECIFI      | CATION       | DECLUT                          |  |
|---------------------------|--------------|--------------|---------------------------------|--|
| TEST                      | MIN          | MAX          | RESULT                          |  |
| SPECIFIC GRAVITY (@ 25°C) | 1.30         |              | 1.32                            |  |
| ELEMENTAL IMPURITIES      | AS REPORTED  |              | NO ELEMENTAL IMPURITIES PRESENT |  |
| IDENTIFICATION            | TO PASS TEST |              | PASSES TEST                     |  |
| EXPIRATION DATE           |              |              | 30-NOV-2025                     |  |
| DATE OF MANUFACTURE       |              |              | 01-NOV-2022                     |  |
| APPEARANCE                |              |              | CLEAR PALE YELLOW LIQUID        |  |
| RESIDUAL SOLVENTS         |              | TO PASS TEST | NO RESIDUAL SOLVENTS USED       |  |
| MONOGRAPH EDITION         |              |              | (NF) 2022                       |  |

Certificate of Analysis Results Entered By:

HBERMUDEZ Hernan Bermudez 09-FEB-23 09:57:48

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



Certificate of Analysis Results Approved By:

TRODRIGUEZ Tatiana Rodriguez 09-FEB-23 13:00:58

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

1. IDENTIFICATION

Preparation Date: 11/26/2019 Revision date 11/26/2019 Revision Number: G1

#### Product identifier **Product code:** SY105 SYRUP, NF **Product Name:** Other means of identification Liquid sugar Synonyms: Simple syrup Mixture CAS #: RTECS# Not available Not available CI#: Recommended use of the chemical and restrictions on use Food Additive. Sweetener. Recommended use: No information available Uses advised against Spectrum Chemical Mfg. Corp Supplier: 14422 South San Pedro St. Gardena, CA 90248 (310) 516-8000 https://www.spectrumchemical.com Order Online At: Chemtrec 1-800-424-9300 Emergency telephone number Tom Tyner (USA - West Coast) **Contact Person:** Ibad Tirmiz (USA - East Coast) **Contact Person:** 2. HAZARDS IDENTIFICATION Classification This chemical is not considered hazardous by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200) Not a dangerous substance or mixture according to the Globally Harmonized System (GHS) Label elements Not classified Hazards not otherwise classified (HNOC) Not Applicable Other hazards Not available

Product code: SY105 Product name: SYRUP, NF Page 1 / 12

#### 3. COMPOSITION/INFORMATION ON INGREDIENTS

| Component              | CAS No    | Weight-% |
|------------------------|-----------|----------|
| Sucrose                | 57-50-1   | 85       |
| Water                  | 7732-18-5 | 13       |
| Methylparaben          | 99-76-3   | 1        |
| Citric Acid, Anhydrous | 77-92-9   | 1        |

#### 4. FIRST AID MEASURES

First aid measures

General Advice: National Capital Poison Center in the United States can provide assistance if you

have a poison emergency and need to talk to a poison specialist. Call

1-800-222-1222.

**Skin Contact:** Wash off immediately with soap and plenty of water removing all contaminated clothing and

shoes. Get medical attention if irritation develops. Consult a physician if necessary.

**Eye Contact:** Flush eyes with water for 15 minutes. Get medical attention if irritation occurs. If symptoms

persist, call a physician.

**Inhalation:** Move to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give

oxygen. Get medical attention.

**Ingestion:** Do not induce vomiting without medical advice. Never give anything by mouth to an

unconscious person. Consult a physician if necessary.

Most important symptoms and effects, both acute and delayed

**Symptoms** May cause eye/skin irritation

May cause respiratory irritation

Ingestion of large amounts may cause nausea, vomiting, abdominal pain

Indication of any immediate medical attention and special treatment needed

Notes to Physician: Treat symptomatically.

**Protection of first-aiders** 

First-Aid Providers: Avoid exposure to blood or body fluids. Wear gloves and other necessary protective clothing. Dispose of contaminated clothing and equipment as bio-hazardous waste.

#### 5. FIRE-FIGHTING MEASURES

**Extinguishing Media** 

Suitable Extinguishing Media: The product is not flammable. If it is involved in a fire,

extinguish the fire using an agent suitable for the type of

surrounding fire.

Unsuitable Extinguishing Media: No information available.

Specific hazards arising from the chemical

Hazardous combustion products

No information available.

**Specific hazards** No information available.

**Special Protective Actions for Firefighters** 

Product code: SY105 Product name: SYRUP, NF Page 2 / 12

Specific Methods: No information available

Special Protective Equipment for Firefighters: As in any fire, wear self-contained breathing apparatus

pressure-demand, MSHA/NIOSH (approved or equivalent)

and full protective gear

#### 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures

Personal Precautions: Ensure adequate ventilation. Avoid contact with skin, eyes and clothing. Wear personal

protective equipment.

**Environmental precautions** Prevent further leakage or spillage if safe to do so. Prevent product from entering

drains. Prevent entry into waterways, sewers, basements or confined areas.

Methods and material for containment and cleaning up

**Methods for containment** Stop leak if you can do it without risk. Absorb spill with inert material (e.g.

vermiculite, dry sand or earth). In case of large spill, dike if needed. Dike far

ahead of liquid spill for later disposal.

Methods for cleaning up

Use appropriate tools to put the spilled material in a suitable chemical waste

disposal container. Clean contaminated surface thoroughly.

#### 7. HANDLING AND STORAGE

#### Precautions for safe handling

#### **Technical Measures/Precautions:**

Provide sufficient air exchange and/or exhaust in work rooms. Keep away from incompatible materials.

#### Safe Handling Advice:

Wear personal protective equipment. Avoid contact with skin, eyes and clothing. Do not ingest. Do not breathe vapors or spray mist. Keep away from heat and sources of ignition. Handle in accordance with good industrial hygiene and safety practice.

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

#### **Technical Measures/Storage Conditions:**

Keep container tightly closed in a dry and well-ventilated place. Store at room temperature in the original container. Store away from incompatible materials.

#### **Incompatible Materials:**

Strong oxidizing agents

#### 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

#### Control parameters

#### National occupational exposure limits

#### **United States**

| Component              | CAS No    | OSHA         | NIOSH                     | ACGIH | AIHA WEEL |
|------------------------|-----------|--------------|---------------------------|-------|-----------|
| Sucrose                | 57-50-1   | 15 mg/m³ TWA | 15 mg/m³ TWA 10 mg/m³ TWA |       | None      |
|                        |           | 5 mg/m³ TWA  | 5 mg/m³ TWA               |       |           |
| Water                  | 7732-18-5 | None         | None                      | None  | None      |
| Methylparaben          | 99-76-3   | None         | None                      | None  | None      |
| Citric Acid, Anhydrous | 77-92-9   | None         | None                      | None  | None      |

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#### Canada

| Component              | CAS No    | Canada - Alberta | Canada - British               | Canada - Ontario | Canada - Quebec |
|------------------------|-----------|------------------|--------------------------------|------------------|-----------------|
|                        |           |                  | Columbia                       |                  |                 |
| Sucrose                | 57-50-1   | 10 mg/m³ TWA     | 10 mg/m <sup>3</sup> TWA total | None             | 10 mg/m³ TWAEV  |
|                        |           |                  | dust                           |                  |                 |
|                        |           |                  | 3 mg/m³ TWA                    |                  |                 |
|                        |           |                  | respirable fraction            |                  |                 |
| Water                  | 7732-18-5 | None             | None                           | None             | None            |
| Methylparaben          | 99-76-3   | None             | None                           | None             | None            |
| Citric Acid, Anhydrous | 77-92-9   | None             | None                           | None             | None            |

#### **Australia and Mexico**

| Component              | CAS No    | Australia    | Mexico        |
|------------------------|-----------|--------------|---------------|
| Sucrose                | 57-50-1   | 10 mg/m³ TWA | 10 mg/m³ TWA  |
|                        |           | _            | 20 mg/m³ STEL |
| Water                  | 7732-18-5 | None         | None          |
| Methylparaben          | 99-76-3   | None         | None          |
| Citric Acid, Anhydrous | 77-92-9   | None         | None          |

#### Appropriate engineering controls

**Engineering measures to reduce exposure:** Ensure adequate ventilation. Provide exhaust ventilation or

other engineering controls to keep the airborne

concentrations of vapors and mist below their respective

threshold limit value.

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

#### **Personal Protective Equipment**

**Eye protection:** Goggles or Safety glasses with side-shields.

**Skin and body protection:** apron

Long sleeved clothing

Gloves

**Respiratory protection:** Vapor respirator. Be sure to use an approved/certified respirator or equivalent.

**Hygiene measures:** Avoid contact with skin, eyes and clothing. When using, do not eat, drink or

smoke. Wear suitable gloves and eye/face protection Wash hands before breaks

and immediately after handling the product

#### 9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state: Appearance: Color:

Liquid No information available. Colorless to pale yellow. Light brown.

Odor: Taste Formula

Caramel. Sweet. Sweet. No information available

Molecular/Formula weight (g/mole): Flammability (solid, gas)

No information available

Flashpoint (°C/°F):

No information available

Flash Point Tested according to: Autoignition Temperature (°C/°F): Lower Explosion Limit (%):

Not available No information available No information available

**Upper Explosion Limit (%):** 

Product code: SY105 Product name: SYRUP, NF Page 4 / 12

No information available Melting point/range(°C/°F): Decomposition temperature(°C/°F):

No information available 
No information available

Boiling point/range(°C/°F): Bulk density: Density (g/cm3):

>105°C No information available 1.3-1.4

Specific gravity: pH Vapor pressure @ 20°C (kPa):

No information available 6.0-8.5 No information available

Evaporation rate: Vapor density: VOC content (g/L):

No information available No information available No information available

Odor threshold (ppm): Partition coefficient Viscosity:

No information available (n-octanol/water): No information available

No information available

Miscibility:Solubility:No information availableSoluble in Water

Soluble in Alcohol
Soluble in Ether

#### 10. STABILITY AND REACTIVITY

Reactivity

No information available

**Chemical stability** 

**Stability:** Stable under recommended storage conditions.

<u>Possibility of Hazardous Reactions:</u> Hazardous polymerization does not occur

**Conditions to avoid:** Heat. Ignition sources. Incompatible materials.

<u>Incompatible Materials:</u> Strong oxidizing agents

products:

No information available.

Other Information

Corrosivity: No information available

Special Remarks on Corrosivity: No information available

#### 11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

**Principal Routes of Exposure:** 

**Hazardous decomposition** 

Ingestion. Eyes. Skin.

**Acute Toxicity** 

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

ATEmix (oral) 75000 mg/kg

**Component Information** 

Sucrose

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CAS No 57-50-1

LD50/oral/rat = 29700 mg/kg Oral LD50 Rat

**LD50/oral/mouse** = No information available

**LD50/dermal/rabbit** = No information available

**LD50/dermal/rat** = No information available

LC50/inhalation/rat = No information available

LC50/inhalation/mouse = No information available

Other LD50 or LC50information = No information available

Water

CAS No 7732-18-5

LD50/oral/rat = > 90 mL/kg Oral LD50 Rat

**LD50/oral/mouse** = No information available

**LD50/dermal/rabbit** = No information available

**LD50/dermal/rat** = No information available

**LC50/inhalation/rat** = No information available

LC50/inhalation/mouse = No information available

Other LD50 or LC50information = No information available

Methylparaben

CAS No 99-76-3

LD50/oral/rat = 2100 mg/kg (RTECS)

>5600 mg/kg (Hazardous Substance Data Bank)

**LD50/oral/mouse** = >8000 mg/kg (RTECS)

**LD50/dermal/rabbit** = No information available

**LD50/dermal/rat** = No information available

**LC50/inhalation/rat** = No information available

**LC50/inhalation/mouse** = No information available

Other LD50 or LC50information = 6000 mg/kg Oral LD50 Rabbit

3000 mg/kg Oral LD50 Guinea pig

Citric Acid, Anhydrous

CAS No 77-92-9

LD50/oral/rat = 3 g/kg Oral LD50 Rat; 3000 mg/kg Oral LD50 Rat

LD50/oral/mouse = 5040 mg/kg Oral LD50 Mouse

**LD50/dermal/rabbit** = No information available

**LD50/dermal/rat** = No information available

**LC50/inhalation/rat** = No information available

**LC50/inhalation/mouse** = No information available

Other LD50 or LC50information = 903 mg/kg, intraperitoneal, mouse;

290 mg/kg, intraperitoneal, rat;

42 mg/kg, intravenous, mouse;

330 mg/kg, intravenous, rabbit;

2700 mg/kg, subcutaneous, mouse;

5500 mg/kg, subcutaneous, rat

#### **Product Information**

LD50/oral/rat =

Value - Acute Toxicity = No information available

LD50/oral/mouse =

Value - Acute Tox = No information available

LD50/dermal/rabbit

Value - Acute Toxicity = No information available

LD50/dermal/rat

**VALUE - Acute Tox =** No information available

Product code: SY105 Product name: SYRUP, NF Page 6 / 12

LC50/inhalation/rat

**VALUE-Vapor** = No information available

**VALUE-Gas** = No information available

**VALUE-Dust/Mist** = No information available

LC50/Inhalation/mouse

**VALUE-Vapor** = No information available **VALUE - Gas** = No information available

**VALUE - Dust/Mist =** No information available

**Symptoms** 

**Skin Contact:** May cause skin irritation.

**Eye Contact:** May cause eye irritation.

**Inhalation** May cause respiratory tract irritation.

**Ingestion** Health injuries are not known or expected under normal use. Ingestion of large

amounts may cause nausea, vomiting and abdominal pain. Ingestion of very large

quantities may cause gastrointestinal upset or indigestion.

**Aspiration hazard** No information available.

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

**Chronic Toxicity** No information available.

**Sensitization:** No information available.

Mutagenic Effects: No information available

Carcinogenic effects: Not considered carcinogenic.

| Component              | CAS No    | IARC       | ACGIH -<br>Carcinogens                             | NTP        | OSHA HCS -<br>Carcinogens | Australia -<br>Notifiable<br>Carcinogenic<br>Substances | Australia -<br>Prohibited<br>Carcinogenic<br>Substances |
|------------------------|-----------|------------|--|------------|---------------------------|---|---|
| Sucrose                | 57-50-1   | Not listed | A4 Not<br>Classifiable as<br>a Human<br>Carcinogen | Not listed | Not listed                | Not listed  | Not listed  |
| Water                  | 7732-18-5 | Not listed | Not listed   | Not listed | Not listed                | Not listed  | Not listed  |
| Methylparaben          | 99-76-3   | Not listed | Not listed   | Not listed | Not listed                | Not listed  | Not listed  |
| Citric Acid, Anhydrous | 77-92-9   | Not listed | Not listed   | Not listed | Not listed                | Not listed  | Not listed  |

ACGIH (American Conference of Governmental Industrial Hygienists)

IARC (International Agency for Research on Cancer)

NTP (National Toxicology Program)

OSHA (Occupational Safety and Health Administration of the US Department of Labor)

Reproductive toxicity No data is available

Reproductive Effects: No information available
Developmental Effects: No information available
Teratogenic Effects: No information available

Specific Target Organ Toxicity

Product code: SY105 Product name: SYRUP, NF Page 7 / 12

STOT - single exposure STOT - repeated exposure Target Organs: No information available. No information available. No information available.

#### 12. ECOLOGICAL INFORMATION

#### **Ecotoxicity**

**Ecotoxicity effects:** Aquatic environment.

Citric Acid, Anhydrous - 77-92-9

Fish 1516 mg/L LC50 Lepomis macrochirus 96 h static 1

Crustacea 120 mg/L EC50 Daphnia magna 72 h

Persistence and degradability: No information available

**Bioaccumulative potential:** No information available.

Mobility in soilNo information availableOther adverse effectsNo information available.

#### 13. DISPOSAL CONSIDERATIONS

#### **Disposal Methods**

#### Waste from residues / unused products:

Waste must be disposed of in accordance with Federal, State and Local regulation.

#### Contaminated packaging:

Empty containers should be taken for local recycling, recovery or waste disposal. Do not re-use empty containers Dispose of as unused product. Dispose of in accordance with federal, state and local regulations

| Component              | CAS No    | RCRA - F Series | RCRA - K Series | RCRA - P Series | RCRA - U Series |
|------------------------|-----------|-----------------|-----------------|-----------------|-----------------|
|                        |           | Wastes          | Wastes          | Wastes          | Wastes          |
| Sucrose                | 57-50-1   | None            | None            | None            | None            |
| Water                  | 7732-18-5 | None            | None            | None            | None            |
| Methylparaben          | 99-76-3   | None            | None            | None            | None            |
| Citric Acid, Anhydrous | 77-92-9   | None            | None            | None            | None            |

#### 14. TRANSPORT INFORMATION

#### DOT

UN-No: Not Regulated

Proper Shipping Name:
Hazard Class
Subsidiary Class
Packing group:
No information available

Number

Marine Pollutant
DOT RQ (lbs):
Special Provisions
Symbol(s):
No data available
No information available
No information available
No information available
No information available

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TDG (Canada)

UN-No: Not Regulated

Proper Shipping Name:
Hazard Class
Subsidiary Risk:
Packing Group:
Marine Pollutant
Description:
No information available

**ADR** 

UN Number Not regulated

Proper Shipping Name:
Transport hazard class(es)
Packing group
Subsidiary Risk:

No information available
No information available
No information available

**IMDG** 

UN-No: Not Regulated

Proper Shipping Name:
Hazard Class:
Subsidiary Risk:
Packing Group:
Marine Pollutant

No information available
No information available
No information available
No information available

**RID** 

UN Number Not Regulated

Proper Shipping Name:
Transport hazard class(es)
Subsidiary Risk:
Packing group

No information available
No information available
No information available

ICAO (air)

UN-No: Not Regulated

Proper Shipping Name:
Hazard Class
Subsidiary Risk:
Packing Group:

No information available
No information available
No information available

IATA

UN Number Not Regulated

Proper Shipping Name:
Transport hazard class(es)
Subsidiary Risk:
Packing group
No information available

Response

Special Provisions No information available

#### 15. REGULATORY INFORMATION

#### International Inventories

| Component     | CAS No    | U.S. TSCA    | KOREA KECL | Philippines (PICCS) | Japan ENCS  | China IECSC | Australia<br>(AICS) | EINECS-No. |
|---------------|-----------|--------------|------------|---------------------|-------------|-------------|---------------------|------------|
| Sucrose       | 57-50-1   | PresentACTIV | Present    | Present             | Not present | Present     | Present             | Present    |
|               |           | E            | KE-17258   |                     |             |             |                     | 200-334-9  |
| Water         | 7732-18-5 | PresentACTIV | Present    | Present             | Not present | Present     | Present             | Present    |
|               |           | E            | KE-35400   |                     |             |             |                     | 231-791-2  |
| Methylparaben | 99-76-3   | PresentACTIV | Present    | Present             | Present     | Present     | Present             | Present    |

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|                        |         | Е            | KE-20379 |         | (3)-1585 |               |         | 202-785-7 |
|------------------------|---------|--------------|----------|---------|----------|---------------|---------|-----------|
| Citric Acid, Anhydrous | 77-92-9 | PresentACTIV |          | Present |          | Present[25349 | Present | Present   |
|                        |         |              | KE-20831 |         | (2)-1318 |               |         | 201-069-1 |

#### **U.S. Regulations**

Sucrose

Massachusetts RTK: Present Pennsylvania RTK: Present

Minnesota - Hazardous Substance List: Present

FDA - Food Additives Generally Recognized as Safe (GRAS): 21 CFR 184.1854

FDA - Direct Food Additives 21 CFR 172.869 (free)

**FDA - 21 CFR - Total Food Additives** 100.130, 101.4, 101.80, 101.9, 131.112, 131.170, 131.200, 131.203, 131.206, 133.124, **- List Sourced from EAFUS** 133.178, 133.179, 145.134, 145.180, 145.3, 146.140, 146.141, 146.145, 146.146, 146.3, 150.160, 155.170, 155.200, 169.175, 169.179, 172.810, 172.816, 172.859, 172.861,

172.880, 172.884, 173.145, 184.1854, 73.85 (includes liquid)

Methylparaben

FDA - Food Additives Generally Recognized as Safe (GRAS): 21 CFR 184.1490

FDA - Direct Food Additives 21 CFR 172.515

FDA - 21 CFR - Total Food Additives 150.141, 150.161, 172.515, 181.23, 184.1490

- List Sourced from EAFUS

Citric Acid, Anhydrous

FDA - Food Additives Generally Recognized as Safe (GRAS): 21 CFR 184.1033

**FDA - 21 CFR - Total Food Additives** 131.111, 131.112, 133.123, 133.124, 133.129, 133.169, 133.173, 133.178, 133.179, **- List Sourced from EAFUS** 145.134, 145.145, 146.187, 150.141, 150.161, 155.130, 161.190, 163.11, 163.110, 163.112, 169.115, 169.140, 169.150, 172.755, 172.861, 173.160, 173.165, 173.280

163.112, 169.115, 169.140, 169.150, 172.755, 172.861, 173.160, 173.165, 173.280,

178.1010, 184.1033, 73.85

#### California Prop. 65: Safe Drinking Water and Toxic Enforcement Act of 1986.

#### Chemicals Known to the State of California to Cause Cancer:

This product does not contain a chemical requiring a warning under California Prop. 65. (See table below)

#### Chemicals Known to the State of California to Cause Reproductive Toxicity:

This product does not contain a chemical requiring a warning under California Prop. 65. (See table below)

| Component              | CAS No    | Carcinogen | Developmental Toxicity | Male         | Female       |
|------------------------|-----------|------------|------------------------|--------------|--------------|
|                        |           |            |                        | Reproductive | Reproductive |
|                        |           |            |                        | Toxicity     | Toxicity:    |
| Sucrose                | 57-50-1   | Not Listed | Not Listed             | Not Listed   | Not Listed   |
| Water                  | 7732-18-5 | Not Listed | Not Listed             | Not Listed   | Not Listed   |
| Methylparaben          | 99-76-3   | Not Listed | Not Listed             | Not Listed   | Not Listed   |
| Citric Acid, Anhydrous | 77-92-9   | Not Listed | Not Listed             | Not Listed   | Not Listed   |

#### **CERCLA/SARA**

| Component                 | CAS No    | CERCLA -<br>Hazardous<br>Substances and<br>their Reportable<br>Quantities | Section 302 Extremely Hazardous Substances and TPQs | Section 302 Extremely Hazardous Substances and RQs | Section 313 -<br>Chemical Category | Section 313 -<br>Reporting<br>de minimis |
|---------------------------|-----------|---|---|--|------------------------------------|--|
| Sucrose                   | 57-50-1   | None  | None  | None   | None                               | None                                     |
| Water                     | 7732-18-5 | None  | None  | None   | None                               | None                                     |
| Methylparaben             | 99-76-3   | None  | None  | None   | None                               | None                                     |
| Citric Acid,<br>Anhydrous | 77-92-9   | None  | None  | None   | None                               | None                                     |

#### **U.S. TSCA**

| Component     | CAS No    | TSCA Section 5(a)2 - Chemicals<br>With Significant New Use Rules<br>(SNURS) | 1 ',           |
|---------------|-----------|---|----------------|
| Sucrose       | 57-50-1   | Not Applicable  | Not Applicable |
| Water         | 7732-18-5 | Not Applicable  | Not Applicable |
| Methylparaben | 99-76-3   | Not Applicable  | Not Applicable |

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| Citric Acid. Anhydrous | 77-92-9 | Not Applicable | Not Applicable |
|------------------------|---------|----------------|----------------|
|                        |         |                |                |

#### Canada

#### WHIMIS 2015 - GHS Classifications

WHMIS 2015 Hazard Classification Information:

Component Sucrose 57-50-1 (85)

Water 7732-18-5 (13) Citric Acid, Anhydrous 77-92-9 (1) WHMIS 2015 Hazard Classification

Combustible Dust - Category 1: May form combustible dust concentrations in air (factors such as combustibility and explosiveness of dusts including composition and shape and size of particles could cause substance to belong to 'Combustible dust' hazard class)

Not a dangerous product according to HPR classification criteria

Serious Eye Damage/Eye Irritation - Category 2: H319 Causes serious eye irritation.; Combustible Dust - Category 1: May form combustible dust concentrations in air (factors such as combustibility and explosiveness of dusts including composition and shape and size of particles could cause substance to belong to 'Combustible dust' hazard class)

Canada Hazardous Products Regulation This product has been classified according to the hazard criteria of the HPR (Hazardous Products Regulation) and the SDS contains all of the information required by the HPR

#### **DSL/NDSL**

| Component              | CAS No    | Canada (DSL) | Canada (NDSL) |
|------------------------|-----------|--------------|---------------|
| Sucrose                | 57-50-1   | Present      | Not Listed    |
| Water                  | 7732-18-5 | Present      | Not Listed    |
| Methylparaben          | 99-76-3   | Present      | Not Listed    |
| Citric Acid, Anhydrous | 77-92-9   | Present      | Not Listed    |

| Component              | CAS No CEPA Schedule I - Toxic Sub |                                      |  |
|------------------------|------------------------------------|--------------------------------------|--|
| Sucrose                | 57-50-1                            | Not listed                           |  |
| Water                  | 7732-18-5                          | Not listed                           |  |
| Methylparaben          | 99-76-3                            | Not listed                           |  |
| Citric Acid, Anhydrous | 77-92-9                            | Not listed                           |  |
| Component              | CAS No                             | CEPA - 2010 Greenhouse Gases Subject |  |
| _                      |                                    | to Mandatory Reporting               |  |
| Sucrose                | 57-50-1                            | Not listed                           |  |
| Water                  | 7732-18-5                          | Not listed                           |  |
| Methylparaben          | 99-76-3                            | Not listed                           |  |
| Citric Acid. Anhydrous | 77-92-9                            | Not listed                           |  |

#### **EU Classification**

#### EU GHS - SV - CLP 1272/2008

| Component              | CAS No    | EU GHS - SV - CLP (1272/2008) |
|------------------------|-----------|-------------------------------|
| Sucrose                | 57-50-1   |                               |
| Water                  | 7732-18-5 |                               |
| Methylparaben          | 99-76-3   | No information                |
| Citric Acid, Anhydrous | 77-92-9   | No information                |

#### EU - CLP (1272/2008)

#### R-phrase(s)

not determined (not applicable)

Product code: SY105 Product name: SYRUP, NF Page 11 / 12

#### S -phrase(s)

none

| Component              | CAS No    | Classification |                | Safety Phrases |
|------------------------|-----------|----------------|----------------|----------------|
|                        |           |                | Limits:        |                |
| Sucrose                | 57-50-1   |                | No information |                |
| Water                  | 7732-18-5 |                | No information |                |
| Methylparaben          | 99-76-3   |                | No information |                |
| Citric Acid, Anhydrous | 77-92-9   |                | No information |                |

The product is classified in accordance with Annex VI to Directive 67/548/EEC

#### Indication of danger:

None

#### **16. OTHER INFORMATION**

Preparation Date: 11/26/2019
Revision date 11/26/2019
Prepared by: Sonia Owen

**Disclaimer:** All chemicals may pose unknown hazards and should be used with caution. This

Safety Data Sheet (SDS) applies only to the material as packaged. If this product is combined with other materials, deteriorates, or becomes contaminated, it may pose hazards not mentioned in this SDS. The physical properties reported in this SDS are obtained from the literature and do not constitute product specifications. Information contained herein does not constitute a warranty, whether expressed or implied, as to the safety, merchantability or fitness of the goods for a particular purpose. Spectrum Chemicals & Laboratory Products, Inc. assumes no responsibility for results obtained or for incidental or consequential damages, including lost profits, arising from the use of these data. No warranty against infringement of any patent, copyright or trademark is made or implied. It shall be the user's responsibility to develop proper methods of handling and personal protection based on the actual conditions of use. While this SDS is based on technical data judged to be reliable, Spectrum assumes no responsibility for the

completeness or accuracy of the information contained herein.

#### **End of Safety Data Sheet**

Product code: SY105 Product name: SYRUP, NF Page 12 / 12



# 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 |
|----------------|--------------|
| SY105          | Syrup, 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,
Quality Assurance
Spectrum Chemical Mfg. Corp.

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



## SY105, Syrup, NF

#### Source Statement

The above-mentioned catalog item is manufactured from Sucrose, Citric Acid and Methyl Paraben. No animal 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 the above-mentioned 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
- Pesticides
- Phthalates



#### **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.

USE CARE: This material has been evaluated per GHS/OSHA criteria and is not classified as hazardous. All chemicals may pose unknown hazards and must be used with caution. Use personal protection and safe handling methods consistent with proper workplace safety practices. Consult SDS for additional properties and precautions. If adverse reaction occurs seek medical attention.

**KEEP FROM CHILDREN** 

SY105

Siz sy **Syrup** 

NF

**CAUTION:** For manufacturing, processing or repacking.

Read and understand the label and Safety Data Sheet (SDS) prior to use.

Chemical Emergency: (800)424-9300

www.SpectrumChemical.com

Components:

Water ......CAS 7732-18-5 Sucrose .....CAS 57-50-1

Specific Gravity @ 25°C ......Min. 1.30 MAXIMUM LIMITS

Elemental Impurities ......As reported Residual Solvents ......To pass test

G 8/H1GHS ? Lot No. XQ####

#### Spectrum Chemical Mfg Corp

Corporate Headquarters: 769 Jersey Ave.

732.214.1300

New Brunswick, NJ 08901

West Coast Facility: 14422 S. San Pedro St. Gardena, CA 90248

310.516.8000