

# Scientific Documentation

## White Wax, Pastilles, NF

Not appropriate for regulatory submission.

Please visit [www.spectrumchemical.com](http://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 White Wax, Pastilles, NF (W1122)

Item Number	W1122
Item	White Wax, Pastilles, NF
CAS Number	8012-89-3
Molecular Formula	
Molecular Weight	
MDL Number	
Synonyms	

Test	Specification	
	Min	Max
MELTING RANGE	62	65°C
SAPONIFICATION CLOUD TEST	TO PASS TEST	
FATS OR FATTY ACIDS, JAPAN WAX,[nROSIN AND SOAP	TO PASS TEST	
ACID VALUE	17	24
ESTER VALUE	72	79
ELEMENTAL IMPURITIES	AS REPORTED	
IDENTIFICATION	TO PASS TEST	
EXPIRATION DATE		
DATE OF MANUFACTURE		
APPEARANCE		
RESIDUAL SOLVENTS	TO PASS TEST	

### *Spectrum Chemical Mfg Corp*

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

# Certificate Of Analysis

Item Number	W1122	Lot Number	2MC0152
Item	White Wax, Pastilles, NF	CAS Number	8012-89-3

TEST	SPECIFICATION		RESULT
	MIN	MAX	
MELTING RANGE	62	65°C	65.0°C
SAPONIFICATION CLOUD TEST	TO PASS TEST		PASSES TEST
FATS OR FATTY ACIDS, JAPAN WAX, UNROSED AND SOAP	TO PASS TEST		PASSES TEST
ACID VALUE	17	24	18.8
ESTER VALUE	72	79	75
ELEMENTAL IMPURITIES	AS REPORTED		COMPLIES WITH STANDARD
IDENTIFICATION	TO PASS TEST		PASSES TEST
EXPIRATION DATE			31-JAN-2025
DATE OF MANUFACTURE			31-JAN-2023
APPEARANCE			OFF-WHITE PASTILLES
RESIDUAL SOLVENTS	TO PASS TEST		NO RESIDUAL SOLVENTS USED

Certificate of Analysis Results Entered By:

SVANGOOR  
Swetha Vangoor  
17-APR-23 11:59:33

Spectrum Chemical Mfg Corp  
755 Jersey Avenue  
New Brunswick 08901 NJ



Certificate of Analysis Results Approved By:

AWILLIAMS  
Allison Williams  
17-APR-23 13:55:27

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

Preparation Date: 8/31/2017

Revision Date: 8/31/2017

Revision Number: G1

### 1. IDENTIFICATION

#### Product identifier

**Product code:** W1122  
**Product Name:** WHITE WAX, PASTILLES, NF

#### Other means of identification

**Synonyms:** White Wax (Bees Wax) Pastilles  
**CAS #:** 8012-89-3  
**RTECS #** Not available  
**CI#:** Not available

#### Recommended use of the chemical and restrictions on use

**Recommended use:** No information available.  
**Uses advised against** No information available

**Supplier:** Spectrum Chemical Mfg. Corp  
14422 South San Pedro St.  
Gardena, CA 90248  
(310) 516-8000.

**Order Online At:** <https://www.spectrumchemical.com>

**Emergency telephone number** Chemtrec 1-800-424-9300

**Contact Person:** Martin LaBenz (West Coast)

**Contact Person:** Ibad Tirmiz (East Coast)

### 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

### 3. COMPOSITION/INFORMATION ON INGREDIENTS

**Product code:** W1122

**Product name:** WHITE WAX,  
PASTILLES, NF

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Components	CAS-No.	Weight %
Beeswax	8012-89-3	100

#### 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** Health injuries are not known or expected under normal use.

##### 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:** Dry chemical. Carbon dioxide (CO<sub>2</sub>). Water spray, mist, or foam.

**Unsuitable Extinguishing Media:** No information available.

##### Specific hazards arising from the chemical

**Hazardous Combustion Products:** Carbon Monoxide, Carbon Dioxide.

**Specific hazards:** May be combustible at high temperatures.

##### Special Protective Actions for Firefighters

**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. Use personal protective equipment. Avoid contact with skin, eyes and clothing. Remove all sources of ignition.

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

### Methods and material for containment and cleaning up

**Methods for containment** Stop leak if you can do it without risk. Cover with plastic sheet to prevent spreading.

**Methods for cleaning up** Sweep up and shovel into suitable containers for disposal. 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. Keep away from heat and sources of ignition. Do not ingest. 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  
Strong acids

## 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

### Control parameters

#### **National occupational exposure limits**

##### **United States**

Components	CAS-No.	OSHA	NIOSH	ACGIH	AIHA WEEL
Beeswax	8012-89-3	None	None	None	None

##### **Canada**

Components	CAS-No.	Canada - Alberta	Canada - British Columbia	Canada - Ontario	Canada - Quebec
Beeswax	8012-89-3	None	None	None	None

##### **Australia and Mexico**

Components	CAS-No.	Australia	Mexico
Beeswax	8012-89-3	None	None



## Appropriate engineering controls

### Engineering measures to reduce exposure:

Ensure adequate ventilation. Use process enclosures, local exhaust ventilation, or other engineering controls to keep airborne levels below recommended exposure limits. If user operations generate dust, fume or mist, use ventilation to keep exposure to airborne contaminants below the exposure limit.

## Individual protection measures, such as personal protective equipment

### Personal Protective Equipment

<b>Eye protection:</b>	Goggles or Safety glasses with side-shields
<b>Skin and body protection:</b>	Gloves Chemical resistant apron Long sleeved clothing
<b>Respiratory protection:</b>	Respiratory protection is not necessary for normal handling. Good room ventilation or use of local exhaust (fume hood) is sufficient. Use a vapor respirator under conditions where exposure to the substance is apparent (e.g. generation of high concentrations of mist or vapor, inadequate ventilation, development of respiratory tract irritation), and engineering controls are not feasible. Be sure to use an approved/certified respirator or equivalent.
<b>Hygiene measures:</b>	Avoid contact with skin, eyes and clothing. Wash hands before breaks and immediately after handling the product. When using, do not eat, drink or smoke.

## 9. PHYSICAL AND CHEMICAL PROPERTIES

<b>Physical state:</b> Solid	<b>Appearance:</b> Waxy. Pastilles.	<b>Color:</b> White to Off-White.
<b>Odor:</b> Odorless.	<b>Taste</b> No information available.	<b>Formula:</b> No information available
<b>Molecular/Formula weight:</b> No information available	<b>Flammability:</b> No information available	<b>Flashpoint (°C/°F):</b> 265 °C (509 °F)
<b>Flash Point Tested according to:</b> Not available	<b>Autoignition Temperature (°C/°F):</b> No information available	<b>Lower Explosion Limit (%):</b> No information available
<b>Upper Explosion Limit (%):</b> No information available	<b>Melting point/range(°C/°F):</b> 62-65 °C (143.6-149 °F)	<b>Decomposition temperature(°C/°F):</b> No information available
<b>Boiling point/range(°C/°F):</b> No information available	<b>Bulk density:</b> No information available	<b>Density (g/cm3):</b> No information available
<b>Specific gravity:</b> 0.96	<b>pH:</b> No information available	<b>Vapor pressure @ 20°C (kPa):</b> No information available
<b>Evaporation rate:</b> No information available	<b>Vapor density:</b> No information available	<b>VOC content (g/L):</b> No information available
<b>Odor threshold (ppm):</b>	<b>Partition coefficient</b>	

No information available

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

**Viscosity:**  
No information available

**Miscibility:**  
No information available

**Solubility:**  
Insoluble in water

## 10. STABILITY AND REACTIVITY

### Reactivity

No information available

### Chemical stability

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

**Possibility of Hazardous Reactions:** Hazardous polymerization does not occur

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

**Incompatible Materials:** Strong oxidizing agents  
Strong acids

**Hazardous decomposition products:** Carbon oxides.

### 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:**  
Skin. Eyes. Inhalation. Ingestion.

### Acute Toxicity

### Component Information

Beeswax	
CAS-No.	8012-89-3
LD50/oral/rat = >5000 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 LC50 information = No information available	

### Product Information

LD50/oral/rat =  
VALUE- Acute Tox Oral = > 5000 mg/kg

**LD50/oral/mouse =**  
**Value - Acute Tox Oral =** No information available

**LD50/dermal/rabbit**  
**VALUE-Acute Tox Dermal =** No information available

**LD50/dermal/rat**  
**VALUE -Acute Tox Dermal =** No information available

**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:** Not likely to cause skin irritation. Although this material is not known to be an irritant, it may be mildly irritating in sensitive individuals.

**Eye Contact:** Not likely to cause eye irritation.

**Inhalation** Not expected to be an inhalation hazard. It is a waxy solid in the form of pastilles and it not expected to cause irritation of the respiratory tract. Vapors emitted from molten wax are expected to have a low degree of irritation by inhalation.

**Ingestion** Health injuries are not known or expected under normal use. It is not absorbed following ingestion. May cause constipation. Although it is generally considered nonirritating, ingestion of large amounts may cause gastrointestinal (digestive) tract irritation and may cause intestinal obstruction. May cause abdominal pain. Ingestion may cause nausea, vomiting.

**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.

Components	CAS-No.	IARC	ACGIH - Carcinogens	NTP	OSHA HCS - Carcinogens	Australia - Notifiable Carcinogenic Substances	Australia - Prohibited Carcinogenic Substances
Beeswax	8012-89-3	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**

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

### **12. ECOLOGICAL INFORMATION**

#### **Ecotoxicity**

**Ecotoxicity effects:** No data available.

**Persistence and degradability:** No information available

**Bioaccumulative potential:** No information available.

**Mobility:** No 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

Components	CAS-No.	RCRA - F Series Wastes	RCRA - K Series Wastes	RCRA - P Series Wastes	RCRA - U Series Wastes
Beeswax	8012-89-3	None	None	None	None

### **14. TRANSPORT INFORMATION**

#### **DOT**

**UN-No:** Not Regulated  
**Proper Shipping Name:** No information available  
**Hazard Class:** No information available  
**Subsidiary Class** No information available  
**Packing group:** No information available  
**Emergency Response Guide Number** No information available  
**Marine Pollutant** No data available  
**DOT RQ (lbs):** No information available  
**Special Provisions** No Information available  
**Symbol(s):** No information available  
**Description:** No information available

**TDG (Canada)**

**UN-No:** Not Regulated  
**Proper Shipping Name:** No information available  
**Hazard Class:** No information available  
**Subsidiary Risk:** No information available  
**Packing Group:** No information available  
**Marine Pollutant Description:** No information available

**ADR**

**UN-No:** Not Regulated  
**Proper Shipping Name:** No information available  
**Hazard Class:** No information available  
**Packing Group:** No information available  
**Subsidiary Risk:** No information available

**IMO / IMDG**

**UN-No:** Not Regulated  
**Proper Shipping Name:** No information available  
**Hazard Class:** No information available  
**Subsidiary Risk:** No information available  
**Packing Group:** No information available  
**Marine Pollutant** No information available

**RID**

**UN-No:** Not Regulated  
**Proper Shipping Name:** No information available  
**Hazard Class:** No information available  
**Subsidiary Risk:** No information available  
**Packing Group:** No information available

**ICAO**

**UN-No:** Not Regulated  
**Proper Shipping Name:** No information available  
**Hazard Class:** No information available  
**Subsidiary Risk:** No information available  
**Packing Group:** No information available

**IATA**

**UN-No:** Not Regulated  
**Proper Shipping Name:** No information available  
**Hazard Class:** No information available  
**Subsidiary Risk:** No information available  
**Packing Group:** No information available  
**ERG Code:** No information available  
**Special Provisions** No information available

<b>15. REGULATORY INFORMATION</b>
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**International Inventories**

Components	CAS-No.	U.S. TSCA	KOREA KECL	Philippines (PICCS)	Japan ENCS	CHINA	Australia (AICS)	EINECS-No.
Beeswax	8012-89-3	Present	Present KE-02113	Present	Present (8)-429	Present	Present	Present 232-383-7

**U.S. Regulations****Product code:** W1122**Product name:** WHITE WAX,  
PASTILLES, NF**8 / 10**

#### Beeswax

FDA - Food Additives Generally Recognized as Safe (GRAS): 21 CFR 184.1973

FDA - 21 CFR - Total Food Additives 101.4 184.1973

#### 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)

Components	CAS-No.	Carcinogen	Developmental Toxicity	Male Reproductive Toxicity	Female Reproductive Toxicity:
Beeswax	8012-89-3	Not Listed	Not Listed	Not Listed	Not Listed

#### CERCLA/SARA

Components	CAS-No.	CERCLA - Hazardous Substances and their Reportable Quantities	Section 302 Extremely Hazardous Substances and TPQs	Section 302 Extremely Hazardous Substances and RQs	Section 313 - Chemical Category	Section 313 - Reporting de minimis
Beeswax	8012-89-3	None	None	None	None	None

#### U.S. TSCA

Components	CAS-No.	TSCA Section 5(a)2 - Chemicals With Significant New Use Rules (SNURS)	TSCA 8(d) -Health and Safety Reporting
Beeswax	8012-89-3	Not Applicable	Not Applicable

#### Canada

##### WHMIS 2015 - GHS Classifications

WHMIS 2015 Hazard Classification Information:

Not a dangerous product according to HPR classification criteria.

**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

##### WHMIS 1988 Hazard Class

Non-controlled

##### Canada Controlled Products Regulation:

This product has been classified according to the hazard criteria of the CPR (Controlled Products Regulation) and the MSDS contains all of the information required by the CPR.

#### Inventory

Components	CAS-No.	Canada (DSL)	Canada (NDSL)
Beeswax	8012-89-3	Present	Not Listed

Components	CAS-No.	CEPA Schedule I - Toxic Substances
Beeswax	8012-89-3	Not listed
Components	CAS-No.	CEPA - 2010 Greenhouse Gases Subject to Mandatory Reporting
Beeswax	8012-89-3	Not listed

Product code: W1122

Product name: WHITE WAX,  
PASTILLES, NF

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**EU Classification**

EU GHS - SV - CLP 1272/2008

Components	CAS-No.	EU GHS - SV - CLP (1272/2008)
Beeswax	8012-89-3	

EU - CLP (1272/2008)

**R-phrases(s)**

not determined (not applicable)

**S -phrase(s)**

none

Components	CAS-No.	Classification	Concentration Limits:	Safety Phrases
Beeswax	8012-89-3		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:** 8/31/2017  
**Revision Date:** 8/31/2017  
**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**



**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
W1122	White Wax, Pastilles, 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](mailto:qualityassurance@spectrumchemical.com)

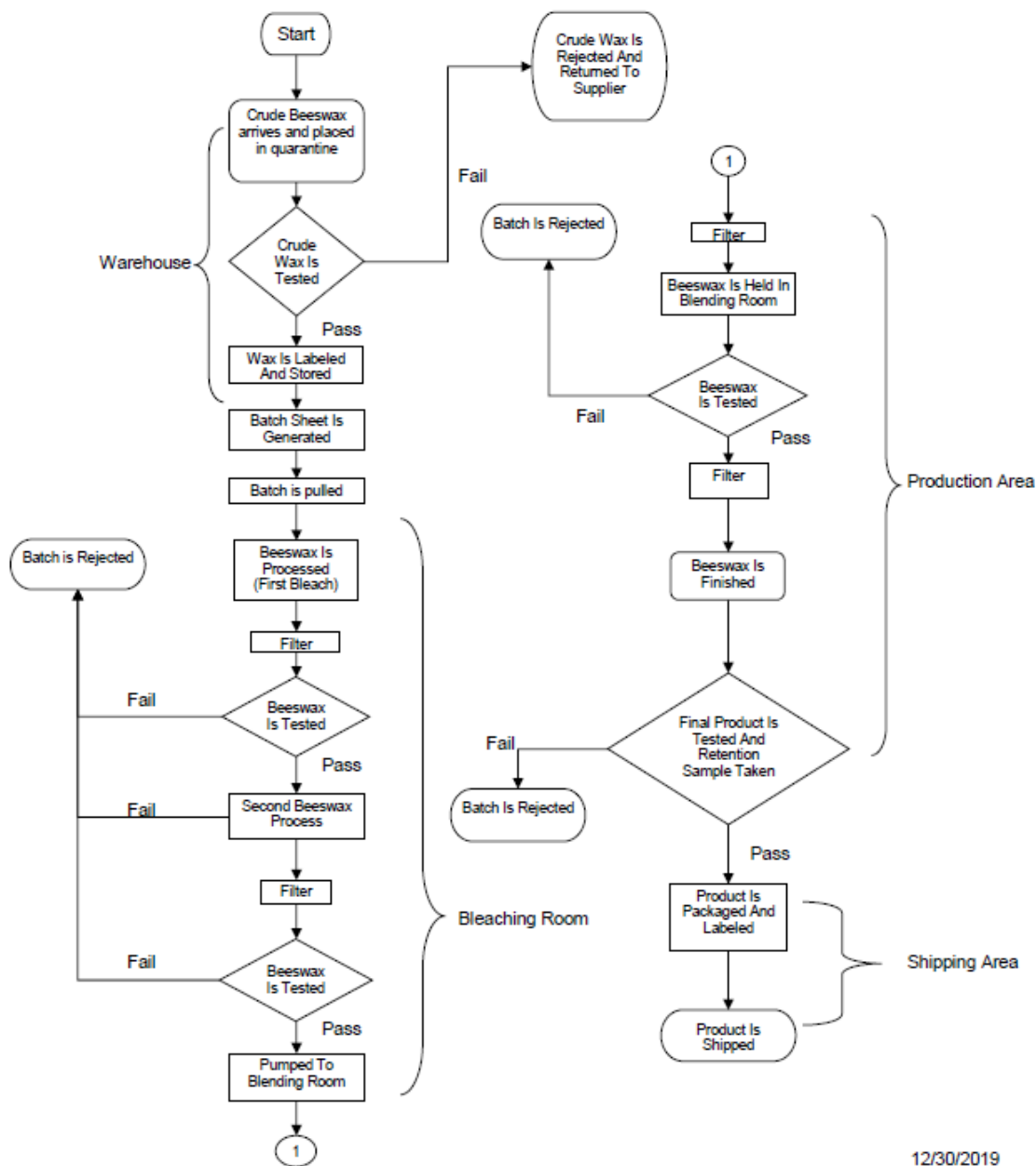
Sincerely,

A handwritten signature in black ink, appearing to read "Oralia Chavez", written in a cursive style.

Oralia Chavez  
Quality Assurance Specialist



## Manufacturing Process Flowchart White Wax, Pastilles, NF (Cat# W1122)



12/30/2019

### 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

## **W1122, White Wax, Pastilles, NF**

### **Source Statement**

The above mentioned catalog item is manufactured from Honeybees excretions.

### **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, or sewage sludge.

## **Shelf Life Statement**

The above mentioned catalog item is typically assigned a shelf life of 24 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
- CMR Substances
- Phthalates
- Preservatives



**RE: Elemental Impurities - White Wax, Pastilles, NF (Cat# W1122)**

To Whom It May Concern:

Thank you for your interest in Spectrum high quality chemicals.

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

Elemental Impurity		Class	Expected Concentration
Cadmium	Cd	1	< 0.10
Lead	Pb	1	< 0.1
Arsenic	As	1	< 0.1
Mercury	Hg	1	< 0.05
Cobalt	Co	2A	< 0.10
Vanadium	V	2A	< 0.20
Nickel	Ni	2A	< .040
Thallium	Tl	2B	< 0.10
Gold	Au	2B	< 0.75
Palladium	Pd	2B	< 0.42
Iridium	Ir	2B	< 0.42
Osmium	Os	2B	< 0.38
Rhodium	Rh	2B	< 0.42
Ruthenium	Ru	2B	< 0.42
Selenium	Se	2B	< 0.10
Silver	Ag	2B	< 0.10
Platinum	Pt	2B	< 0.42
Lithium	Li	3	< 2.30
Antimony	Sb	3	< 0.10
Barium	Ba	3	< 5.8
Molybdenum	Mo	3	< 0.10
Copper	Cu	3	0.13
Tin	Sn	3	< 0.20
Chromium	Cr	3	0.53

Elements indicated as "Not tested" are not intentionally added to the manufacturing process.

\* Lead is present below the limit of 10 ppm under the specification Lead as required by the USP monograph.

**CORPORATE HEADQUARTERS**

769 Jersey Avenue

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**WEST COAST FACILITY**

14422 South San Pedro Street

Gardena, California 90248

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

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

If you have any further questions, please contact us by telephone at 1(800)772-8786 Option 2, or by email at [TechServices@spectrumchemical.com](mailto: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 - White Wax, Pastilles, NF (Cat# W1122)**

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](mailto:TechServices@spectrumchemical.com).

Sincerely,

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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.



**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**

**W1122                      SIZ SY**

**White Wax**

Pastilles

NF

CAS 8012-89-3

**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](http://www.SpectrumChemical.com)

The bleached and purified wax from the honeycomb of the bee [*Apis mellifera* Linné (Fam. Apidae)].

Melting Range..... 62°-66°C  
Ceresin, Paraffins, and Certain Other Waxes.....  
.....To pass test  
Fats or Fatty Acids, Japan Wax, Rosin and Soap ..  
.....To pass test  
Acid Value..... 17-24  
Ester Value..... 68-80

**MAXIMUM LIMITS**  
Elemental Impurities ..... As reported  
Residual Solvents .....To pass test

G 5/L8GHS      ?      Lot No. XQ####

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