

Scientific Documentation

Sorbic Acid, Powder, FCC

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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Product Specification Certificate of Analysis Safety Data Sheet (SDS) Certification of Current Good Manufacturing Practices (cGMP) Manufacturing Process Flowchart Technical Statements General Label Information – Sample Label



Specification for Sorbic Acid, Powder, FCC (S1517)

| Item Number | \$1517 |
|-------------------|--|
| Item | Sorbic Acid, Powder, FCC |
| CAS Number | 110-44-1 |
| Molecular Formula | C ₆ H ₈ O ₂ |
| Molecular Weight | 112.13 |
| MDL Number | |
| Synonyms | 2,4-Hexadienoic Acid |

| Test | Speci | fication |
|--|-------|--------------|
| | Min | Max |
| ASSAY (C ₆ H ₈ O ₂ ; ANHYDROUS BASIS) | 99.0 | 101.0 % |
| MELTING RANGE | 132° | 135°C |
| LEAD (Pb) | | 2 mg/kg |
| RESIDUE ON IGNITION | | 0.2 % |
| WATER | | 0.5 % |
| IDENTIFICATION | | TO PASS TEST |
| EXPIRATION DATE | | |
| DATE OF MANUFACTURE | | |
| APPEARANCE | | |

Spectrum Chemical Mfg Corp

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



Certificate Of Analysis

| Item Number | S1517 | Lot Number | 1LD0903 |
|-------------------|--|------------------|----------|
| Item | Sorbic Acid, Powder, FCC | CAS Number | 110-44-1 |
| Molecular Formula | C ₆ H ₈ O ₂ | Molecular Weight | 112.13 |

| тгст | SPECIFICATION | | |
|--|---------------|--------------|-----------------|
| TEST | MIN | MAX | RESULT |
| ASSAY (C ₆ H ₈ O ₂ ; ANHYDROUS BASIS) | 99.0 | 101.0 % | 99.1 % |
| MELTING RANGE | 132° | 135°C | 133.0 - 134.0°C |
| LEAD (Pb) | | 2 mg/kg | <2 mg/kg |
| RESIDUE ON IGNITION | | 0.2 % | <0.2 % |
| WATER | | 0.5 % | 0.2 % |
| IDENTIFICATION | | TO PASS TEST | PASSES TEST |
| EXPIRATION DATE | | | 17-DEC-2023 |
| DATE OF MANUFACTURE | | | 18-DEC-2021 |
| APPEARANCE | | | WHITE POWDER |
| MONOGRAPH EDITION | | | (FCC) 12 |

Certificate of Analysis Results Entered By:

HBERMUDEZ Hernan Bermudez 24-MAY-22 18:22:33

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



Certificate of Analysis Results Approved By:

STORRES Sergio Torres 25-MAY-22 14:45:13

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.

SAFETY DATA SHEET

Revision date 01-March-2022

| 1. Identification | |
|--|--------------------------|
| Product identifier | |
| Product Name | SORBIC ACID, POWDER, FCC |
| Other means of identification | |
| Product Code(s) | S1517 |
| 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

| Skin corrosion/irritation | Category 2 |
|--|-------------|
| Serious eye damage/eye irritation | Category 2A |
| Specific target organ toxicity (single exposure) | Category 3 |

Hazards not otherwise classified (HNOC)

Not applicable

Label elements

Warning

Hazard statements Causes skin irritation Causes serious eye irritation May cause respiratory irritation



Revision Number 2



Physical state Solid

Odor No information available

Precautionary Statements - Prevention

Wash face, hands and any exposed skin thoroughly after handling Avoid breathing dust/fume/gas/mist/vapors/spray Use only outdoors or in a well-ventilated area Wear protective gloves/eye protection/face protection

Precautionary Statements - Response

Specific treatment (see .? on this label) IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing If eye irritation persists: Get medical advice/attention IF ON SKIN: Wash with plenty of water and soap If skin irritation occurs: Get medical advice/attention Take off contaminated clothing and wash it before reuse IF INHALED: Remove person to fresh air and keep comfortable for breathing Call a POISON CENTER or doctor if you feel unwell

Precautionary Statements - Storage

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

Precautionary Statements - Disposal

Dispose of contents/container to an approved waste disposal plant

Other information

May be harmful if swallowed. Harmful to aquatic life with long lasting effects. Harmful to aquatic life.

3. Composition/information on ingredients

Substance

| Chemical name | CAS No | Weight-% | Trade secret |
|---------------|----------|----------|--------------|
| Sorbic Acid | 110-44-1 | 100 | * |

*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. IF exposed or concerned: Get medical advice/attention. Get medical attention immediately if symptoms occur. |
| Eye contact | Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Keep eye wide open while rinsing. Remove contact lenses, if present and easy to do. Continue rinsing. Get medical attention if irritation develops and persists. Do not rub affected area. |
| Skin contact | Wash off immediately with soap and plenty of water for at least 15 minutes. Get medical attention if irritation develops and persists. |

| Ingestion | Do NOT induce vomiting. Clean mouth with water and drink afterwards plenty of water. Never give anything by mouth to an unconscious person. Call a physician. | |
|--|--|--|
| Self-protection of the first aider | Avoid contact with skin, eyes or clothing. Wear personal protective clothing (see section 8). | |
| Most important symptoms and effects, both acute and delayed | | |
| Symptoms | May cause redness and tearing of the eyes. Burning sensation. | |
| Indication of any immediate medical attention and special treatment needed | | |
| Note to physicians | Treat symptomatically. | |

5. Fire-fighting measures

| Suitable Extinguishing Media | Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. | |
|--|--|--|
| Large Fire | 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 | No information available. | |
| Hazardous combustion products | Carbon dioxide (CO2). | |
| Explosion data Sensitivity to mechanical impac | st none. | |
| Sensitivity to static discharge | none. | |
| Special protective equipment for fire-fighters | Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Use personal protection equipment. | |
| 6. Accidental release meas | sures | |
| Personal precautions, protective ec | uipment and emergency procedures | |
| Personal precautions | Ensure adequate ventilation. Use personal protective equipment as required. Evacuate personnel to safe areas. Avoid contact with skin, eyes or clothing. | |
| Other information | Refer to protective measures listed in Sections 7 and 8. | |
| Methods and material for containment and cleaning up | | |

| Methods for containment | Prevent further leakage or spillage if safe to do so. |
|-------------------------|---|
| Methods for cleaning up | Pick up and transfer to properly labeled containers. |

7. Handling and storage

Precautions for safe handling

Advice on safe handling Handle in accordance with good industrial hygiene and safety practice. Avoid contact with skin, eyes or clothing. Do not eat, drink or smoke when using this product. Take off contaminated clothing and wash before reuse. Ensure adequate ventilation. Avoid breathing dust/fume/gas/mist/vapors/spray.

Conditions for safe storage, including any incompatibilities

8. Exposure controls/personal protection

Control parameters

| Exposure Limits | The following ingredients are the only ingredients of the product above the cut-off level (or level that contributes to the hazard classification of the mixture) which have an exposure limit applicable in the region for which this safety data sheet is intended or other recommended limit. At this time, the other relevant constituents have no known exposure limits from the sources listed here. | |
|-------------------------------------|--|--|
| Appropriate engineering controls | | |
| Engineering controls | Showers Eyewash stations Ventilation systems. | |
| Individual protection measures, suc | ch as personal protective equipment | |
| Eye/face protection | If splashes are likely to occur, wear safety glasses with side-shields. | |
| Hand protection | Wear suitable gloves. Impervious gloves. | |
| Skin and body protection | Wear suitable protective clothing. Long sleeved clothing. | |
| 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 | Wear suitable gloves and eye/face protection. Do not eat, drink or smoke when using this product. Avoid contact with skin, eyes or clothing. | |

9. Physical and chemical properties

| Information on basic physical and chemical properties | | | | |
|---|--------------------------|------------------|--|--|
| Physical state | Solid | | | |
| Appearance | Crystalline powder | | | |
| Color | White | | | |
| Odor | No information available | | | |
| Odor threshold | No information available | | | |
| Property | Values | Remarks • Method | | |
| pH | Slightly acidic | None known | | |
| Melting point / freezing point | 134 °C / 273.2 °F | None known | | |
| Boiling point / boiling range | no data available | None known | | |
| Flash point | 127 °C / 260.6 °F | None known | | |
| Evaporation rate | no data available | None known | | |
| Flammability (solid, gas) | no data available | None known | | |
| Flammability Limit in Air | | None known | | |
| Upper flammability or explosive | No data available | | | |
| limits | | | | |
| Lower flammability or explosive | No data available | | | |
| limits | | | | |
| Vapor pressure | No data available | None known | | |
| Vapor density | no data available | None known | | |
| Relative density | 1.2 | None known | | |
| Water solubility | Soluble in water | None known | | |
| Solubility(ies) | Soluble in Methanol | None known | | |
| | Soluble in Acetic acid | | | |

| | Slightly soluble in Carbon | |
|---------------------------|-----------------------------|------------|
| | Tetrachloride | |
| | Slightly soluble in Acetone | |
| | Slightly soluble in Toluene | |
| Partition coefficient | No data available | None known |
| Autoignition temperature | no data available | None known |
| Decomposition temperature | > 160 - °C 320 °F | None known |
| Kinematic viscosity | no data available | None known |
| Dynamic viscosity | No data available | None known |
| Other information | | |
| Explosive properties | No information available | |
| Oxidizing properties | No information available | |
| Softening point | No information available | |
| Molecular weight | 112.13 | |
| VOC Content (%) | No information available | |
| 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 | None known based on information supplied. |
| Incompatible materials | Strong acids. Strong bases. Strong oxidizing agents. |
| 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. Irritating to eyes. (based on components). Causes serious eye irritation. |
| Skin contact | Specific test data for the substance or mixture is not available. Causes skin irritation. (based on components). |
| Ingestion | Specific test data for the substance or mixture is not available. Ingestion may cause gastrointestinal irritation, nausea, vomiting and diarrhea. May be harmful if swallowed. |
| Symptoms related to the physical, | chemical and toxicological characteristics |
| Symptoms | Redness. May cause redness and tearing of the eyes. |
| Acute toxicity | |

Numerical measures of toxicity

Component Information

| Chemical name | Oral LD50 | Dermal LD50 | Inhalation LC50 |
|---------------|--------------------|-------------|-----------------|
| Sorbic Acid | = 3200 mg/kg (Rat) | - | - |
| 110-44-1 | | | |

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

| Skin corrosion/irritation Serious eye damage/eye irritation Respiratory or skin sensitization Germ cell mutagenicity | Classification based on data available for ingredients. Irritating to skin. Classification based on data available for ingredients. Causes serious eye irritation. No information available. No information available. |
|---|---|
| Reproductive toxicity | No information available. |
| STOT - single exposure STOT - repeated exposure Aspiration hazard | May cause respiratory irritation. No information available. No information available. |
| Other adverse effects | No information available. |
| Interactive effects | No information available. |

12. Ecological information

| Ecotoxicity | Harmful to aquatic life with long lasting effects. | | | |
|---------------|--|-----------------------|----------------|----------------------|
| Chemical name | Algae/aquatic plants | Fish | Toxicity to | Crustacea |
| | | | microorganisms | |
| Sorbic Acid | - | LC50: 1000 - 1500mg/L | - | EC50: =353.54mg/L |
| 110-44-1 | | (48h, Leuciscus idus) | | (48h, Daphnia magna) |
| | | LC50: =75mg/L (96h, | | |
| | | Oryzias latipes) | | |

Persistence and degradability Bioaccumulation

No information available. Inherently biodegradable.

Component Information

| Chemical name | Partition coefficient |
|---------------|-----------------------|
| Sorbic Acid | 1.38 |
| 110-44-1 | |

Other adverse effects

No information available.

13. Disposal considerations

Waste treatment methods

| Waste from residues/unused products | Dispose of in accordance with local regulations. Dispose of waste in accordance with environmental legislation. |
|--|---|
| Contaminated packaging | Do not reuse empty containers. |

14. Transport information

| DOT | not regulated |
|-----|---------------|
| TDG | not regulated |

| <u>MEX</u> | not regulated |
|------------|---------------|
| ICAO (air) | not regulated |
| IATA_ | not regulated |
| IMDG | not regulated |
| <u>RID</u> | not regulated |
| ADR | not regulated |
| 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 AICS | Complies All the constituents of this material are listed on the Australian Inventory of Chemical Substances (AICS). |

Legend:

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

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

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

ENCS - Japan Existing and New Chemical Substances

IECSC - China Inventory of Existing Chemical Substances

KECL - Korean Existing and Evaluated Chemical Substances

PICCS - Philippines Inventory of Chemicals and Chemical Substances

US Federal Regulations

SARA 313

Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product 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, does not contain any substances regulated as hazardous substances under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302) or the Superfund Amendments and Reauthorization Act (SARA) (40 CFR 355). There may be specific reporting requirements at the local, regional, or state level pertaining to releases of this material.

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

Disclaimer

NFPA Health hazards 2 Flammability 1 Instability 0 Physical and chemical properties -HMIS Health hazards 2 Flammability 1 Physical hazards 0 Personal protection X Key or legend to abbreviations and acronyms used in the safety data sheet Legend Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION TWA TWA (time-weighted average) STEL STEL (Short Term Exposure Limit) Ceiling Maximum limit value Key literature references and sources for data used to compile the SDS Agency for Toxic Substances and Disease Registry (ATSDR) U.S. Environmental Protection Agency ChemView Database European Food Safety Authority (EFSA) EPA (Environmental Protection Agency) Acute Exposure Guideline Level(s) (AEGL(s)) U.S. Environmental Protection Agency Federal Insecticide, Fungicide, and Rodenticide Act U.S. Environmental Protection Agency High Production Volume Chemicals Food Research Journal Hazardous Substance Database International Uniform Chemical Information Database (IUCLID) Japan GHS Classification Australia National Industrial Chemicals Notification and Assessment Scheme (NICNAS) NIOSH (National Institute for Occupational Safety and Health) National Library of Medicine's ChemID Plus (NLM CIP) National Library of Medicine's PubMed database (NLM PUBMED) National Toxicology Program (NTP) New Zealand's Chemical Classification and Information Database (CCID) Organization for Economic Co-operation and Development Environment, Health, and Safety Publications Organization for Economic Co-operation and Development High Production Volume Chemicals Program Organization for Economic Co-operation and Development Screening Information Data Set World Health Organization Revision date 01-March-2022 No information available. **Revision Note**

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

End of Safety Data Sheet

spectrum

Certification of Compliance with current Good Manufacturing Practices

Dear Valued Customer:

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

| Catalog Number | Product Name |
|-------------------|--------------------------|
| S1517 | Sorbic Acid, Powder, FCC |

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 <u>gualityassurance@spectrumchemical.com</u>

Sincerely,

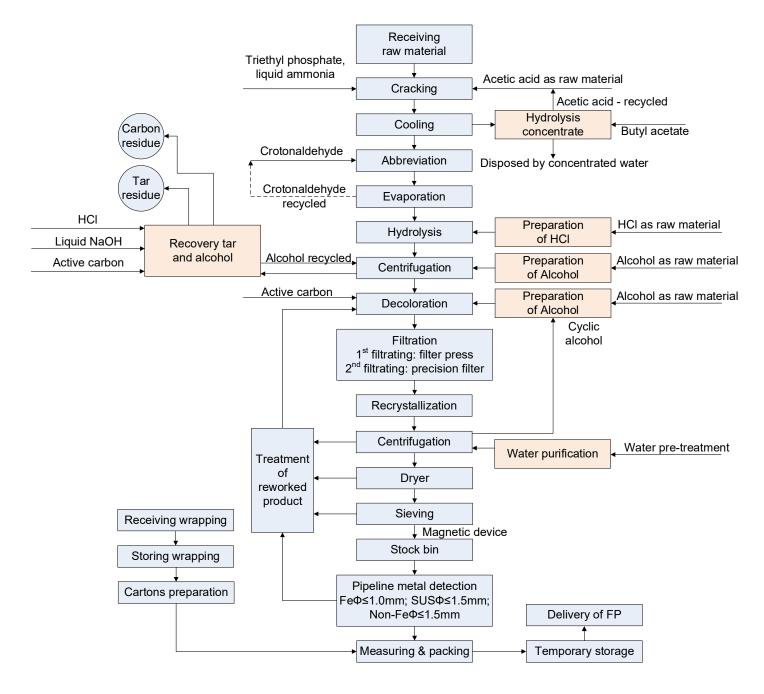
Oulu Clamy

Oralia Chavez Quality Assurance Specialist



Manufacturing Process Flowchart

Sorbic Acid, Powder, FCC (Cat# S1517)



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

spectrum

S1517, Sorbic Acid, Powder, FCC

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 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
- Antibiotics
- Bisphenol A (BPA)
- CMR Substances
- Parabens
- Pesticides
- Phthalates
- Preservatives

spectrum®

Label Information

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

Spectrum Chemical Mfg Corp

Corporate Headquarters:

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

732.214.1300