



Scientific Documentation

CO136, Corn Oil, 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

Ver4.06 25.August.2021

CO136, Corn Oil, NF

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spectrum®

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spectrum®

Item Number	CO136
Item	Corn Oil, NF
CAS Number	8001-30-7
Molecular Formula	
Molecular Weight	
MDL Number	
Synonyms	Maize Oil ; Maydis Oleum Raffinatum ; Zea Mays (Corn) Oil

Test	Specification	
	Min	Max
ACID VALUE		0.2
PEROXIDE VALUE		10.0
WATER DETERMINATION		0.1 %
ALKALINE IMPURITIES		0.1 ml
STEROL COMPOSITION		0.3 %
ELEMENTAL IMPURITIES	AS REPORTED	
UNSATURATED MATTER		1.5%
FATTY ACID COMPOSITION:		
<C14		0.1 %
C14		0.1 %
C16	8.6 - 16.5 %	
C16:1		0.5 %
C18	1.0 - 3.3 %	
C18:1	20.0 - 42.2 %	
C18:2	39.4 - 62.0 %	
C18:3	0.5 - 1.5 %	
C20		0.8 %
C20:1		0.5 %
C22		0.3 %
C22:1		0.1 %
C24		0.4 %
IDENTIFICATION (A)	MEETS REQUIREMENTS OF FATTY ACID COMPOSITION	
IDENTIFICATION (B)	Rf VALUES CORRESPONDS TO STANDARD	
EXPIRATION DATE		
DATE OF MANUFACTURE		
APPEARANCE		
RESIDUAL SOLVENTS		

Item Number	CO136	Lot Number	2KH0004
Item	Corn Oil, NF		
CAS Number	8001-30-7		
Molecular Formula		Molecular Weight	

Test	Specification		Result
	min	max	
ACID VALUE		0.2	0.09
PEROXIDE VALUE		10.0	0.6
WATER DETERMINATION		0.1 %	0.026 %
ALKALINE IMPURITIES		0.1 ml	0.00 mL
STEROL COMPOSITION		0.3 %	0.02 %
ELEMENTAL IMPURITIES	AS REPORTED		COMPLIES WITH STANDARD
UNSAPONIFIABLE MATTER		1.5%	0.48 %
FATTY ACID COMPOSITION:			.
<C14		0.1 %	NOT DETECTED
C14		0.1 %	0.03 %
C16	8.6 - 16.5 %		11.8 %
C16:1		0.5 %	0.07 %
C18	1.0 - 3.3 %		1.5 %
C18:1	20.0 - 42.2 %		29.0 %
C18:2	39.4 - 62.0 %		55.6 %
C18:3	0.5 - 1.5 %		0.9 %
C20		0.8 %	0.4 %
C20:1		0.5 %	0.3 %
C22		0.3 %	0.1 %
C22:1		0.1 %	0.05 %
C24		0.4 %	0.2 %
IDENTIFICATION (A)	MEETS REQUIREMENTS OF FATTY ACID COMPOSITION		MEETS REQUIREMENTS OF FATTY ACID COMPOSITION
IDENTIFICATION (B)	Rf VALUES CORRESPOND TO STANDARD		Rf VALUES CORRESPOND TO STANDARD
EXPIRATION DATE			31-JUL-2023
DATE OF MANUFACTURE			08-JUL-2021
APPEARANCE			CLEAR VISCOUS LIQUID

RESIDUAL SOLVENTS			.
CLASS 2 (solvent) / HEXANE			< 290 ppm
MONOGRAPH EDITION			(NF) 2021

Spectrum Chemical Mfg Corp
755 Jersey Avenue
New Brunswick 08901 NJ



Certificate of Analysis Results Certified By:

Jigisha Patel

Jigisha Patel
VP Regulatory Compliance & Technical Services,
Regulatory

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: 07/08/2015

Revision date 09/18/2019

Revision Number: G3

1. IDENTIFICATION

Product identifier

Product code: CO136
Product Name: CORN OIL, NF

Other means of identification

Synonyms: Corn extract
Extract of corn kernels
Maize oil
Oils, corn
Zea mays kernel extract
Zea mays oil
Lipomul
Maise oil
Maydol
Mazola oil
[ChemIDplus] Corn germ oil
Fats and glyceridic oils, corn
Oils, glyceridic, corn

CAS #: 8001-30-7
RTECS # GM4800000
CI#: Not available

Recommended use of the chemical and restrictions on use

Recommended use: In Foods.
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: Tom Tyner (USA - West Coast)
Contact Person: Ibad Tirmiz (USA - 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

Component	CAS No	Weight-%
Corn Oil	8001-30-7	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. Obtain 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 (CO₂). Water spray. Foam. Class K fire extinguisher. Class B fire extinguisher.

Unsuitable Extinguishing Media: Do not use a solid (straight) water stream as it may scatter and spread fire.

Specific hazards arising from the chemical

Hazardous combustion products

Carbon Monoxide, Carbon Dioxide.

Specific hazards

May be combustible at high temperatures. May be ignited by heat, sparks or flames. Container explosion may occur under fire conditions or when heated.

Special Protective Actions for Firefighters

Specific Methods:

Water mist may be used to cool closed containers For larger fires, use water spray or fog. Cool containers with flooding quantities of water until well after fire is out

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. Prevent entry into waterways, sewers.

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), then place in a suitable chemical waste container. 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. Remove all sources of ignition.

Safe Handling Advice:

Wear personal protective equipment. Avoid contact with skin, eyes and clothing. Do not breathe vapors or spray mist. Do not ingest. Do not smoke. 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. Sensitive to light. Store in light-resistant containers. Flushed with nitrogen. Store at room temperature in the original container.

Incompatible Materials:

Oxidizing agents

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters

National occupational exposure limits

United States

Component	CAS No	OSHA	NIOSH	ACGIH	AIHA WEEL
Corn Oil	8001-30-7	None	None	None	None

Canada

Component	CAS No	Canada - Alberta	Canada - British Columbia	Canada - Ontario	Canada - Quebec
Corn Oil	8001-30-7	None	None	None	None

Australia and Mexico

Component	CAS No	Australia	Mexico
Corn Oil	8001-30-7	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: Long sleeved clothing
Chemical resistant apron
Gloves

Respiratory protection: 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.

Hygiene measures: Avoid contact with skin, eyes and clothing. When using, do not eat, drink or smoke. Wash hands before breaks and immediately after handling the product

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state:
Liquid

Appearance:
Oily.

Color:
Yellow. Light yellow.

Odor:
Characteristic.

Taste
No information available.

Formula
No information available

Molecular/Formula weight (g/mole):

No information available	Flammability (solid, gas) no data available	Flashpoint (°C/°F): 254°C/ 489.2°F 321°C/ 609.8°F
Flash Point Tested according to: Closed cup Open cup	Autoignition Temperature (°C/°F): 392°C/ 737.6°F	Lower Explosion Limit (%): No information available
Upper Explosion Limit (%): No information available	Melting point/range(°C/°F): -14°C/ 6.8°F	Decomposition temperature(°C/°F): No information available
Boiling point/range(°C/°F): No information available	Bulk density: No information available	Density (g/cm3): No information available
Specific gravity: 0.918	pH No information available	Vapor pressure @ 20°C (kPa): No information available
Evaporation rate: No information available	Vapor density: No information available	VOC content (g/L): No information available
Odor threshold (ppm): No information available	Partition coefficient (n-octanol/water): No information available	Viscosity: No information available
Miscibility: No information available	Solubility: Insoluble in water	

10. STABILITY AND REACTIVITY

Reactivity

Reactive with oxidizing agents

Chemical stability

Stability: Sensitive to light. Exposure to light accelerates decomposition. Stable under recommended storage conditions.

Possibility of Hazardous Reactions: Hazardous polymerization does not occur

Conditions to avoid: Heat. Ignition sources. Incompatible materials. Exposure to light.

Incompatible Materials: Oxidizing agents

Hazardous decomposition products: Carbon oxides.

Other Information

Corrosivity: Non-corrosive in the presence of glass

Special Remarks on Corrosivity: No information available

11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

Principal Routes of Exposure:
Skin. Eyes.

Acute Toxicity

Component Information

Corn Oil	
CAS No	8001-30-7

LD50/oral/rat = > 100 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 LC50 information = No information available

Product Information

LD50/oral/rat =
Value - Acute Toxicity = > 100 ml/kg

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

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 transient eye irritation.

Inhalation May cause irritation of respiratory tract. Low hazard for usual industrial handling.

Ingestion Health injuries are not known or expected under normal use. Low hazard for usual industrial handling.

Aspiration hazard No information available.

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

Chronic Toxicity Repeated or prolonged skin contact may cause allergic reactions with susceptible persons.

Sensitization: No information available.

Mutagenic Effects: No information available

Carcinogenic effects: Not considered carcinogenic.

Component	CAS No	IARC	ACGIH - Carcinogens	NTP	OSHA HCS - Carcinogens	Australia - Notifiable Carcinogenic Substances	Australia - Prohibited Carcinogenic Substances
Corn Oil	8001-30-7	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 on adverse reproductive effects on humans found. Corn oil is used a vehicle in many toxicology studies, and is thereby assumed not to exert important effects in its own right. In fact, the majority of reproductive and developmental toxicology studies using corn oil controls do not note adverse effects; however, there have been only a few studies that directly assess this issue, as follows: Adverse reproductive effects (biochemical and metabolic effects and developmental abnormalities on new born) were found when pregnant rats were fed extremely high amounts of corn oil (36,000 mg/kg and 12,500 mg/kg)

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 in soil No information available

Other adverse effects 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

Component	CAS No	RCRA - F Series Wastes	RCRA - K Series Wastes	RCRA - P Series Wastes	RCRA - U Series Wastes
Corn Oil	8001-30-7	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 No Information available
Description: No information available

ADR

UN Number Not regulated
Proper Shipping Name: No information available
Transport hazard class(es) No information available
Packing group No information available
Subsidiary Risk: No information available

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 Number Not Regulated
Proper Shipping Name: No information available
Transport hazard class(es) No information available
Subsidiary Risk: No information available
Packing group No information available

ICAO (air)

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 Number Not Regulated
Proper Shipping Name: No information available
Transport hazard class(es) No information available
Subsidiary Risk: No information available
Packing group No information available
Precautionary Statements - Response No information available
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 (AICS)	EINECS-No.
<i>Corn Oil</i>	8001-30-7	PresentACTIVE	Present KE-08973	Present	Not present	Present	Present	Present 232-281-2

U.S. Regulations

Corn Oil

Pennsylvania RTK: Present
Pennsylvania RTK - Special Hazardous Substances Corn oil

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 Reproductive Toxicity	Female Reproductive Toxicity:
<i>Corn Oil</i>	8001-30-7	Not Listed	Not Listed	Not Listed	Not Listed

CERCLA/SARA

Component	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
<i>Corn Oil</i>	8001-30-7	None	None	None	None	None

U.S. TSCA

Component	CAS No	TSCA Section 5(a)2 - Chemicals With Significant New Use Rules (SNURS)	TSCA 8(d) -Health and Safety Reporting
<i>Corn Oil</i>	8001-30-7	Not Applicable	Not Applicable

Canada

WHMIS 2015 - GHS Classifications

WHMIS 2015 Hazard Classification

Information:

Component
Corn Oil
8001-30-7 (100)

WHMIS 2015 Hazard Classification
Self-heating substances and mixtures - Undefined: (hazard class was established from consulted scientific literature but did not allow to specify hazard category)

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)
Corn Oil	8001-30-7	Present	Not Listed

Component	CAS No	CEPA Schedule I - Toxic Substances
Corn Oil	8001-30-7	Not listed

Component	CAS No	CEPA - 2010 Greenhouse Gases Subject to Mandatory Reporting
Corn Oil	8001-30-7	Not listed

EU Classification

EU GHS - SV - CLP 1272/2008

Component	CAS No	EU GHS - SV - CLP (1272/2008)
Corn Oil	8001-30-7	No information

EU - CLP (1272/2008)

R-phrase(s)

not determined (not applicable)

S -phrase(s)

none

Component	CAS No	Classification	Concentration Limits:	Safety Phrases
Corn Oil	8001-30-7		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: 07/08/2015
Revision date 09/18/2019
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



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
CO136	Corn Oil, NF

Spectrum is an FDA registered and inspected Drug Establishment. Our United States Food and Drug Administration (USFDA) Registration numbers are as follows:

Spectrum-Gardena, CA: 2020632
Spectrum-New Brunswick, NJ: 2246824

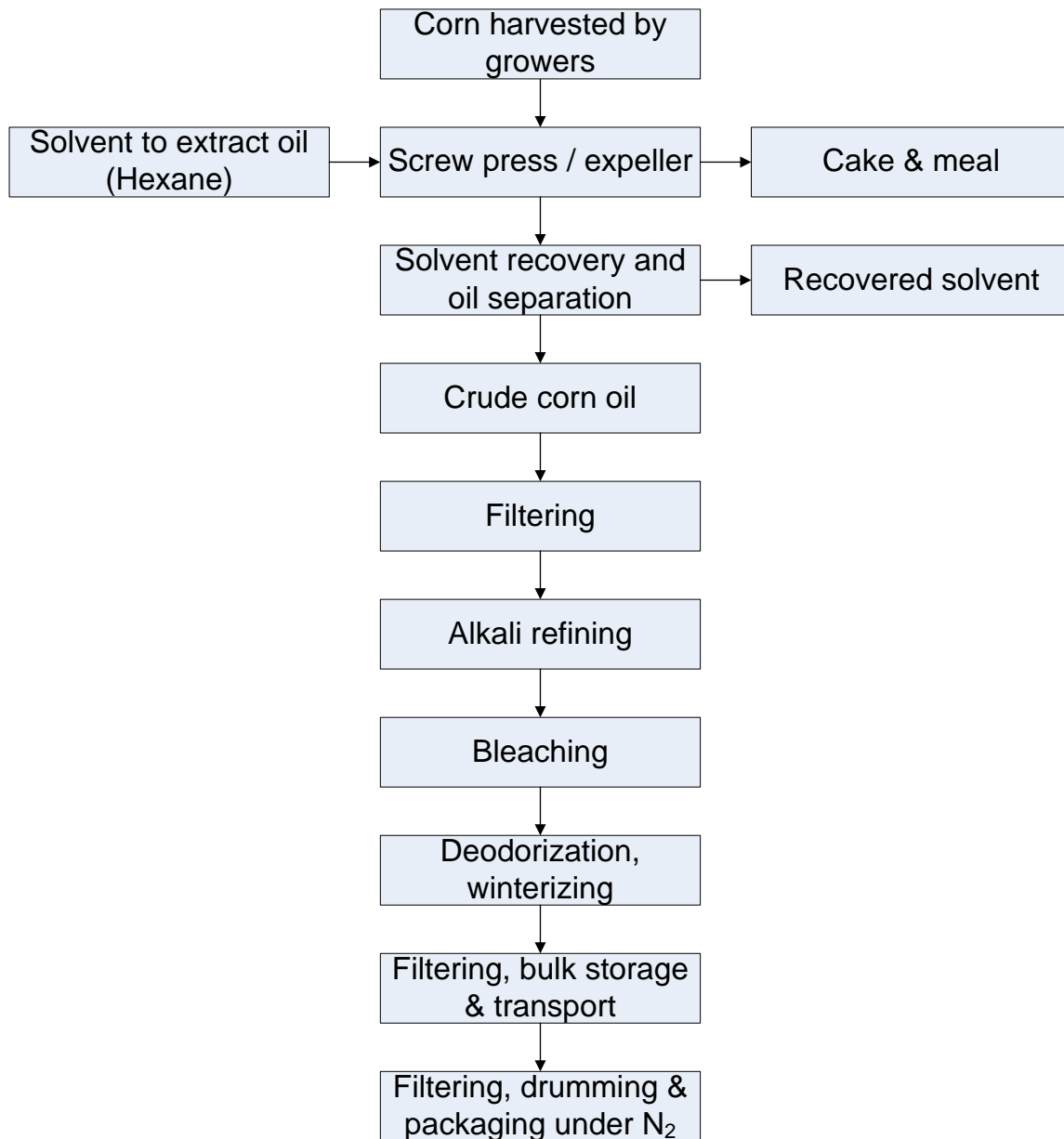
Thank you for your interest in Spectrum products. If we may be of further assistance, please feel free to contact the Quality Assurance department at 310-516-8000 or via email at qualityassurance@spectrumchemical.com

Sincerely,

Oralia Chavez
Quality Assurance Specialist

Manufacturing Process Flowchart

Corn Oil, NF - CO136



Spectrum Chemical Mfg Corp

Corporate Headquarters:

769 Jersey Ave.
New Brunswick, NJ 08901
732.214.1300

West Coast Facility:

14422 S. San Pedro St.
Gardena, CA 90248
310.516.8000

CO136, Corn Oil, NF

Source Statement

The above mentioned catalog item is manufactured from plant derived material (corn). 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
- 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 with the use of genetically modified organisms and is therefore GMO free. Although the above mentioned catalog item is derived from GMO plants, it should not contain genetic material and hence should not contain genetically modified DNA or protein due to the manufacturing process it undergoes.

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 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



RE: Elemental Impurities - Corn Oil, NF (Cat# CO136)

To Whom It May Concern:

Thank you for your interest in Spectrum high quality chemicals.

The above mentioned material complies with the USP<232>, <233> Elemental Impurities and the ICH Q3D Elemental Impurities Guideline. No Class 1, Class 2A, Class 2B or Class 3 elemental impurities are likely to be present. These substances are not used in the production process, are not intentionally added or known to be present in the above mentioned material.

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

If you have any further questions, please contact us by telephone at 1(800)772-8786 Option 2, or by email at TechServices@spectrumchemical.com.

Sincerely,

Technical Services
Spectrum Chemical Mfg. Corp.

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

CORPORATE HEADQUARTERS

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

WEST COAST FACILITY

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



RE: Residual Solvents - Corn Oil, NF (Cat# CO136)

To Whom It May Concern:

Thank you for your interest in Spectrum high quality chemicals.

The above mentioned catalog item complies with the requirements of USP <467> Residual Solvents and ICH Q3C Residual Solvents Guideline. The following solvents are likely to be present:

Residual Solvent	Class	Expected Concentration
Hexane	2	< 290 ppm

No Class 1, Class 3 or other solvents are used or produced in the manufacturing process of this material.

For lot-specific information, please refer to the respective Certificate of Analysis.

If you have any further questions, please contact us by telephone at 1(800)772-8786 Option 2, or by email at TechServices@spectrumchemical.com.

Sincerely,

Technical Services
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FAX 310.516.9843

Label Information

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

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

CAUTION: For manufacturing, processing or repacking. Not for use in preparing injectable dosage forms. **Read and understand the label and Safety Data Sheet (SDS) prior to use.**

Chemical Emergency: (800)424-9300
www.SpectrumChemical.com

WARNING: Cancer and Reproductive Harm
www.P65Warnings.ca.gov

FLUSHED WITH NITROGEN

MAXIMUM LIMITS

Fatty Acid Composition	To pass test
Acid Value	0.2
Peroxide Value	10.0
Water Determination	0.1%
Alkaline Impurities	To pass test
Sterol Composition	To pass test
Elemental Impurities	As reported
Unsaponifiable Matter	1.5%
Residual Solvents	To pass test

Lot No. 062233

SPECTRUM CHEMICAL MFG. CORP. Gardena, CA 90248 • New Brunswick, NJ 08901

- A** Bar Code
- B** GHS Hazard Pictograms
- C** Warning, Safety Data and Precautionary Information
- D** Product Catalog Number
- E** Item Name, Form, Grade
- O** Storage Color Band
- F** Size/Quantity
- G** Chemical Abstracts Service (CAS) Registry Number
- H** Caution Information
- I** DOT Shipping Information
- J** Toll-Free 24-Hour Chemical Emergency Telephone Number
- K** Empirical Formula, Formula Weight and Technical Specifications Panel
- L** Expiration Information
- M** Lot Number
- N** Kosher Certified by Kosher Supervision of America (KSA).

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

- **YELLOW:** Oxidizer
- **RED:** Flammable
- **GREEN:** General Storage
- **BLUE:** Health Hazard
- **WHITE:** Corrosive

Spectrum Chemical Mfg Corp

Corporate Headquarters:

769 Jersey Ave.
New Brunswick, NJ 08901

732.214.1300

West Coast Facility:

14422 S. San Pedro St.
Gardena, CA 90248

310.516.8000



RE: Lot Numbering System

Dear Valued Customer:

This letter is to inform you of Spectrum Chemicals and Laboratory Products' Lot Numbering System. The system is based on an alpha-numerical sequence which provides the month, year and location of production.

The lot numbering system utilized until 2010 is a sequence of **six characters**, two letters followed by four numbers. The first letter represents the year, for example, Y denotes 2009 and Z denotes 2010. The second letter represents the month and site, for example, A-L denotes January through December at Spectrum's Gardena, CA facility, while M-X denotes January through December at the New Brunswick, NJ facility. The following four numbers are sequentially assigned.

Example: ZI0928 = The 928th material produced in California in September 2010

The lot numbering system utilized for 2011 and forward, is a sequence of **seven characters**. The first character, a number, represents the production facility:

- 1 = Gardena, CA Facility
- 2 = New Brunswick, NJ Facility
- 3 = China Facility
- 4 = Pharmacy, NJ Facility

The second character, a letter, represents the year. For example, A denotes 2011 and B denotes 2012. The third character, a letter, represents the month, with A denoting January and L denoting December. The following four numbers are sequentially assigned.

Example: 2AA0706 = The 706th material produced in New Jersey in January 2011

Thank you for your interest with Spectrum products. Please feel free to contact us at 310-516-8000 or via email at quality_assurance@spectrumchemical.com if we may be of further assistance.

Sincerely,

Oralia Chavez,
Quality Assurance Specialist

CORPORATE HEADQUARTERS

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

WEST COAST FACILITY

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