



Scientific Documentation

CO112, Cod Liver Oil, USP

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 07.July.2022

CO112, Cod Liver Oil, USP

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spectrum®

Item Number	CO112
Item	Cod Liver Oil, USP
CAS Number	8001-69-2
Molecular Formula	
Molecular Weight	
MDL Number	
Synonyms	Oleum Jecoris Aselli ; Oleum Morrhuae

Test	Specification	
	Min	Max
VITAMIN A CONTENT	180	750 µg/g
VITAMIN D CONTENT	1.5	6.25 µg/g
COLOR	NOT MORE INTENSE THAN STANDARD	
SPECIFIC GRAVITY @ 25oC	0.918	0.927
ACID VALUE		1.0 ml
IODINE VALUE	145	180
SAPONIFICATION VALUE	180	192
ANISIDINE VALUE		30
NONDESTEARINATED COD LIVER OIL	OIL REMAINS CLEAR	
UNSAPONIFIABLE MATTER		1.30 %
ELEMENTAL IMPURITIES:		
CADMIUM (Cd)	AS REPORTED	
LEAD (Pb)	AS REPORTED	
ARSENIC (As)	AS REPORTED	
MERCURY (Hg)	AS REPORTED	
IDENTIFICATION:A	BLUE COLOR RESULTS	
IDENTIFICATION:B		
MYRISTIC ACID 14:0	2.0	6.0 %
PALMITIC ACID 16:0	7.0	14.0 %
STEARIC ACID 18:0	1.0	4.0 %
PALMITOLEIC ACID 16:1 n-7	4.5	11.5 %
cis-VACCENIC ACID 18:1 n-7	2.0	7.0 %
OLEIC ACID 18:1 n-9	12.0	21.0 %
GADOLEIC ACID 20:1 n-11	1.0	5.5 %

Test	Specification	
	Min	Max
GONDOIC ACID 20:1 n-9	5.0	17.0%
ERUCIC ACID 22:1 n-9	0	1.5 %
CETOLEIC ACID 22:1 n-11	5.0	12.0 %
LINOLEIC ACID 18:2 n-6	0.5	3.0 %
a-LINOLENIC ACID 18:3 n-3	0	2.0 %
MOROCTIC ACID 18:4 n-3	0.5	4.5 %
EICOSAPENTAENOIC ACID 20:5 n-3	7.0	16.0 %
DOCOSAHEXANENOIC ACID 22:6 n-3	6.0	18.0 %
EXPIRATION DATE		
DATE OF MANUFACTURE		
APPEARANCE		
MONOGRAPH EDITION		
RESIDUAL SOLVENTS	AS REPORTED	

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

Item Number	CO112	Lot Number	2KI0370
Item	Cod Liver Oil, USP	CAS Number	8001-69-2

TEST	SPECIFICATION		RESULT
	MIN	MAX	
VITAMIN A CONTENT	180	750 µg/g	331.8 µg/g
VITAMIN D CONTENT	1.5	6.25 µg/g	3.975 µg/g
COLOR	NOT MORE INTENSE THAN STANDARD		NOT MORE INTENSE THAN STANDARD
SPECIFIC GRAVITY @ 25°C	0.918	0.927	0.921
ACID VALUE		1.0 ml	0.13 ML
IODINE VALUE	145	180	155
SAPONIFICATION VALUE	180	192	185
ANISIDINE VALUE		30	9.9
NONDESTEARINATED COD LIVER OIL	OIL REMAINS CLEAR		OIL REMAINS CLEAR
UNSAPONIFIABLE MATTER		1.30 %	0.9
ELEMENTAL IMPURITIES:			.
CADMIUM (Cd)	AS REPORTED		<0.1 ppm
LEAD (Pb)	AS REPORTED		<0.1 ppm
ARSENIC (As)	AS REPORTED		<0.1 ppm
MERCURY (Hg)	AS REPORTED		<0.1 ppm
IDENTIFICATION:A	BLUE COLOR RESULTS		BLUE COLOR RESULTS
IDENTIFICATION:B			.
MYRISTIC ACID 14:0	2.0	6.0 %	4.2%
PALMITIC ACID 16:0	7.0	14.0 %	9.6%
STEARIC ACID 18:0	1.0	4.0 %	1.0%
PALMITOLEIC ACID 16:1 n-7	4.5	11.5 %	11.1%
cis-VACCENIC ACID 18:1 n-7	2.0	7.0 %	2.0%
OLEIC ACID 18:1 n-9	12.0	21.0 %	18.3%
GADOLEIC ACID 20:1 n-11	1.0	5.5 %	2.8%
GONDOIC ACID 20:1 n-9	5.0	17.0%	14.4%
ERUCIC ACID 22:1 n-9	0	1.5 %	1.1%
CETOLEIC ACID 22:1 n-11	5.0	12.0 %	7.9%
LINOLEIC ACID 18:2 n-6	0.5	3.0 %	0.9%
α-LINOLENIC ACID 18:3 n-3	0	2.0 %	0%

TEST	SPECIFICATION		RESULT
	MIN	MAX	
MOROCTIC ACID 18:4 n-3	0.5	4.5 %	0.8%
EICOSAPENTAENOIC ACID 20:5 n-3	7.0	16.0 %	9.3%
DOCOSAHEXANOIC ACID 22:6 n-3	6.0	18.0 %	14.5%
EXPIRATION DATE			30-SEP-2023
DATE OF MANUFACTURE			01-SEP-2020
APPEARANCE			CLEAR YELLOW OIL
MONOGRAPH EDITION			USP 2021
RESIDUAL SOLVENTS	AS REPORTED		NO RESIDUAL SOLVENTS USED

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: 05/22/2015

Revision Date: 09/06/2018

Revision Number: G2

1. IDENTIFICATION

Product identifier

Product code: CO112
Product Name: COD LIVER OIL, USP

Other means of identification

Synonyms: No information available
CAS #: 8001-69-2
RTECS # GG8370700
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 according to 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: CO112

Product name: COD LIVER OIL, USP

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Components	CAS-No.	Weight %
Cod Liver Oil	8001-69-2	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** May cause eye/skin irritation
Ingestion may cause belching, bad breath, heartburn, nosebleeds. Ingestion of high doses may keep the blood from clotting and increase the chance of bleeding. Ingestion of high doses may also cause nausea and loose stools

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.

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. May be ignited by heat, sparks or flames.

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. Absorb spill with inert material (e.g. vermiculite, dry sand or earth).

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. Remove all sources of ignition. 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. Do not breathe vapors or spray mist. Handle in accordance with good industrial hygiene and safety practice.

Conditions for safe storage, including any incompatibilities

Technical Measures/Storage Conditions:

Air sensitive. Keep container tightly closed. Keep in a well-ventilated place. Store at room temperature in the original container. Store away from incompatible materials. Store under inert gas. Store under nitrogen.

Incompatible Materials:

Strong oxidizing agents

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters

National occupational exposure limits

United States

Components	CAS-No.	OSHA	NIOSH	ACGIH	AIHA WEEL
Cod Liver Oil	8001-69-2	None	None	None	None

Canada

Components	CAS-No.	Canada - Alberta	Canada - British Columbia	Canada - Ontario	Canada - Quebec
Cod Liver Oil	8001-69-2	None	None	None	None

Australia and Mexico

Components	CAS-No.	Australia	Mexico
Cod Liver Oil	8001-69-2	None	None

Appropriate engineering controls

Engineering measures to reduce exposure:

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

Eye protection: Goggles

Skin and body protection: Long sleeved clothing
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:

Clear. Oily.

Color:

Yellow.

Odor:

Fish-like.

Taste

No information available.

Formula:

No information available

Molecular/Formula weight (g/mole):

No information available

Flammability:

No information available

Flash point (°C):

215°C

Flashpoint (°C/°F):

215°C/ 419°F

Flash Point Tested according to:

Closed cup

Autoignition Temperature (°C/°F):

No information available

Lower Explosion Limit (%):

No information available

Upper Explosion Limit (%):

No information available

Melting point/range(°C/°F):

-5°C/ 23°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:

0.916-0.928

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):

Odor threshold (ppm):

Product code: CO112

Product name: COD LIVER OIL, USP

No information available

No information available

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

Viscosity:
No information available

Miscibility:
No information available

Solubility:
Insoluble in water
Slightly soluble in alcohol
Freely soluble in carbon disulfide, in
chloroform, in ether, and in ethyl
acetate

10. STABILITY AND REACTIVITY

Reactivity

Reactive with strong oxidizing agents

Chemical stability

Stability: Sensitive to air. Stable under recommended storage conditions.

Possibility of Hazardous Reactions: Hazardous polymerization does not occur

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

Incompatible Materials: Strong oxidizing agents

Hazardous decomposition products: Carbon monoxide. Carbon dioxide.

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:
Eyes. Ingestion. Skin.

Acute Toxicity

Component Information

Cod Liver Oil

CAS-No. 8001-69-2

LD50/oral/rat = No information available
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 =

Product code: CO112

Product name: COD LIVER OIL, USP

VALUE- Acute Tox Oral = No information available

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: May cause skin irritation.

Eye Contact: May cause eye irritation.

Inhalation May cause respiratory tract irritation.

Ingestion Ingestion may cause belching, bad breath, heartburn, nosebleeds. Ingestion of high doses may keep the blood from clotting and increase the chance of bleeding. Ingestion of high doses may also cause nausea and loose stools.

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
Cod Liver Oil	8001-69-2	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

Product code: CO112

Product name: COD LIVER OIL, USP

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
Cod Liver Oil	8001-69-2	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
 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

15. REGULATORY INFORMATION

International Inventories

Components	CAS-No.	U.S. TSCA	KOREA KECL	Philippines (PICCS)	Japan ENCS	CHINA	Australia (AICS)	EINECS-No.
<i>Cod Liver Oil</i>	8001-69-2	PresentACTIVE	Not present	Present	Not present	Present	Present	Present 232-289-6

U.S. Regulations

Cod Liver Oil

Pennsylvania RTK: Present

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:
Cod Liver Oil	8001-69-2	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
<i>Cod Liver Oil</i>	8001-69-2	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
Cod Liver Oil	8001-69-2	Not Applicable	Not Applicable

Canada**WHMIS 2015 - GHS Classifications**

WHMIS 2015 Hazard Classification Information:

Component
Cod Liver Oil
8001-69-2 (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

Inventory

Components	CAS-No.	Canada (DSL)	Canada (NDSL)
Cod Liver Oil	8001-69-2	Present	Not Listed

Components	CAS-No.	CEPA Schedule I - Toxic Substances
Cod Liver Oil	8001-69-2	Not listed
Components	CAS-No.	CEPA - 2010 Greenhouse Gases Subject to Mandatory Reporting
Cod Liver Oil	8001-69-2	Not listed

EU Classification**EU GHS - SV - CLP 1272/2008**

Components	CAS-No.	EU GHS - SV - CLP (1272/2008)
Cod Liver Oil	8001-69-2	No information

EU - CLP (1272/2008)**R-phrases(s)**

not determined (not applicable)

Product code: CO112

Product name: COD LIVER OIL, USP

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S -phrase(s)

none

Components	CAS-No.	Classification	Concentration Limits:	Safety Phrases
Cod Liver Oil	8001-69-2		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: 05/22/2015
Revision Date: 09/06/2018
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
CO112	Cod Liver Oil, USP

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

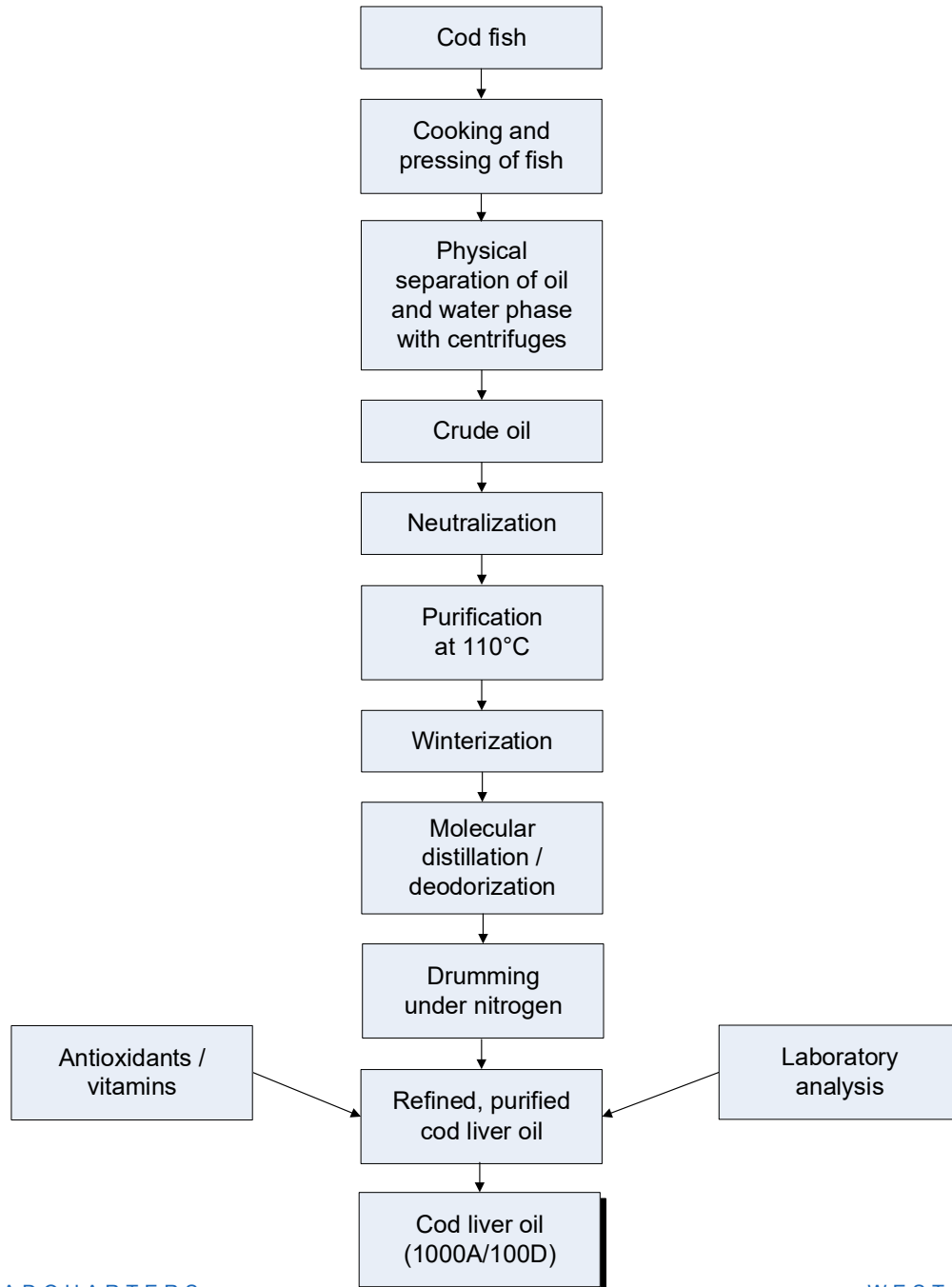
Thank you for your interest in Spectrum products. If we may be of further assistance, please feel free to contact the Quality Assurance department at 310-516-8000 or via email at qualityassurance@spectrumchemical.com

Sincerely,

Oralia Chavez
Quality Assurance Specialist

Manufacturing Process Flowchart

Cod Liver Oil, USP – CO112



CORPORATE HEADQUARTERS

769 Jersey Avenue

New Brunswick, NJ 08901

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FAX 732.246.7132

WEST COAST FACILITY

14422 South San Pedro Street

Gardena, California 90248

PHONE 310.516.8000

FAX 310.516.9843

CO112, Cod Liver Oil, USP

Source Statement

The above mentioned catalog item is manufactured by using animal derived material (oil from fish liver). No 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
- 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.

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
- Parabens
- Phthalates



RE: Elemental Impurities - Cod Liver Oil, USP (Cat# CO112)

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	< 0.1 ppm
Lead	Pb	1	< 0.1 ppm
Arsenic	As	1	< 0.1 ppm
Mercury	Hg	1	< 0.1 ppm

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.

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 - Cod Liver Oil, USP (Cat# CO112)

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.

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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.

<p>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.</p> <p>KEEP FROM CHILDREN</p>	<p>C0112 SIZ SY</p> <p>Cod Liver Oil</p> <p>USP</p> <p>CAS 8001-69-2</p>	<table border="0"> <tr><td>Vitamin A Content</td><td>180-750 µg/g</td></tr> <tr><td>Vitamin D Content</td><td>1.5-6.25 µg/g</td></tr> <tr><td>Color</td><td>To pass test</td></tr> <tr><td>Specific Gravity @ 25°C</td><td>0.918-0.927</td></tr> <tr><td>Acid Value</td><td>To pass test</td></tr> <tr><td>Iodine Value</td><td>145-180</td></tr> <tr><td>Saponification Value</td><td>180-192</td></tr> <tr><td colspan="2" style="text-align: center;">MAXIMUM LIMITS</td></tr> <tr><td>Anisidine Value</td><td>30</td></tr> <tr><td>Nondestearinated Cod Liver Oil</td><td>To pass test</td></tr> <tr><td>Unsaponifiable Matter</td><td>1.30%</td></tr> <tr><td>Elemental Impurities</td><td>As reported</td></tr> <tr><td>Residual Solvents</td><td>To pass test</td></tr> </table> <p>AIR SENSITIVE: Keep tightly closed.</p> <p>FLUSHED WITH NITROGEN</p>	Vitamin A Content	180-750 µg/g	Vitamin D Content	1.5-6.25 µg/g	Color	To pass test	Specific Gravity @ 25°C	0.918-0.927	Acid Value	To pass test	Iodine Value	145-180	Saponification Value	180-192	MAXIMUM LIMITS		Anisidine Value	30	Nondestearinated Cod Liver Oil	To pass test	Unsaponifiable Matter	1.30%	Elemental Impurities	As reported	Residual Solvents	To pass test
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<p>Exp. Date: 00-00-0000</p> 	<div style="border: 1px solid black; padding: 5px; width: fit-content; margin: 0 auto;"> Chemical Emergency: (800)424-9300 </div> <p>www.SpectrumChemical.com</p>	<p>G 10/H11GHS ? Lot No. XQ#####</p>																										

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

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