 890

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October 30, 2019

Office of Food Additive Safety (HFS-200)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5001 Campus Drive
College Park, MD 20740

Subject: GRAS Notification for the Use of COZ Corn Oil as Edible Corn Oil

Dear Sir/Madam:

In accordance with 21 CFR part 170, subpart E, Corn Oil ONE, hereby provides a notice of a claim that the food ingredient described in the enclosed notification document is excluded from the premarket approval requirement of the Federal Food, Drug, and Cosmetic Act because the notifier has concluded such use to be generally recognized as safe (GRAS), based on scientific procedures.

Three paper copies of the notification are provided as required; we have also provided a copy of the notification on the enclosed CD-ROM. If you have any questions or require additional information, please do not hesitate to contact me at 202-772-4915, or ntran@exponent.com.

Sincerely,

[redacted]

Nga Tran, DrPH, MPH
Principal Scientist

1707774.000 - 1696

#890

GRAS Conclusion for COZ Corn Oil

SUBMITTED BY:

Corn Oil ONE
4400 E. University Ave
Pleasant Hill, IA 50327

SUBMITTED TO:

U.S. Food and Drug Administration
Center for Food Safety and Applied Nutrition
Office of Food Additive Safety
HFS-200
5100 Paint Branch Parkway
College Park, MD 20740-3835

CONTACT FOR TECHNICAL OR OTHER INFORMATION:

Nga Tran
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October 30, 2019

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List of Acronyms

%	Percent
°F	Degrees Fahrenheit
ADI	Acceptable Daily Intake
bw	Body weight
CAS	Chemical Abstracts Service
CASRN	Chemical Abstracts Service Registry Number
CFR	Code of Federal Regulations
cfu	Colony forming unit
CO1	Corn Oil One
COA	Certificate of Analysis
DHHS	US Department of Health and Human Services
EDI	Estimated daily intake
EPA	US Environmental Protection Agency
ERS	Economic Research Service
FA	Fatty acid
FARE	Foods and Residue Evaluation Program
FCC	Food Chemicals Codex
FCID	Food Commodity Intake Database
FDA	US Food and Drug Administration
FFA	Free fatty acid
FNDDS	Food and Nutrient Database for Dietary Studies
FPED	Food Pattern Equivalents Database
g	Gram
GRAS	Generally Recognized As Safe
ICP-MS	Inductively Coupled Plasma Mass Spectrometry
JECFA	Joint FAO/WHO Expert Committee on Food Additives
Kg	Kilogram
LOD	Limit of detection
LOQ	Limit of quantitation
mcg/µg	Microgram
Mg	Milligram
mmHg	millimeter of mercury
NCHS	National Center for Health Statistics
NFS	Not-further-specified
NHANES	National Health and Nutrition Examination Survey
NTP	National Toxicology Program
Ppb	parts per billion
Ppm	parts per million
RBD	Refining, bleaching and deodorizing

SOP	Standard Operating Procedure
TOR	Threshold of Regulation
US	United States
USDA	US Department of Agriculture
WWEIA	What We Eat in America
y	Year

Part 1: Signed Statements and Certification

Corn Oil ONE, submits to the U.S. Food and Drug Administration (FDA) this generally recognized as safe (GRAS) notice in accordance with the 21 CFR part 170, subpart E.

Name and Address of Notifier

Corn Oil ONE
4400 E. University Ave
Pleasant Hill, IA 50327

Name of GRAS Substance

The substance that is the subject of this GRAS notice is COZ corn oil.

Intended Use and Consumer Exposure

COZ corn oil that is produced from distillers corn oil using a patented CO1™ process[1] followed by conventional oil refining processes, is intended to be used as edible corn oil. Its use will be substitutional to other edible corn oil products in the US market.

Basis for Conclusion of GRAS Status

Corn Oil One's conclusion of GRAS status for the intended use of COZ corn oil as edible corn oil is based on scientific procedures in accord with 21 CFR §170.30(a) and (b).

Pre-Market Approval Exclusion Claim

Use of COZ corn oil is not subject to the pre-market approval requirements of the Federal Food, Drug, and Cosmetic Act because Corn Oil One has concluded that such use is generally recognized as safe (GRAS) through scientific procedures.

Availability of Information

The data and information that serve as the basis for this GRAS conclusion, as well as the information that has become available since the GRAS conclusion, will be sent to the FDA upon request, or are available for the FDA's review and copying during customary business hours at the office of Nga Tran at Exponent Inc., 1150 Connecticut Ave, NW, Suite 1100, Washington, DC 20036.

[1] International Publication No. WO2014/078387 A1

Exemptions from Disclosure

It is our view that none of the data and information in Parts 2 through 7 of the GRAS notice are exempt from disclosure under the Freedom of Information Act (FOIA).

Certification Statement

On behalf of Feed Energy. I hereby certify that, to the best of my knowledge, this GRAS notice is a complete, representative, and balanced submission that includes unfavorable, as well as favorable information, known to me and pertinent to the evaluation of the safety and GRAS status of the use of the substance.

October 30, 2019

Name: Chris Snyder
Title: Chief Executive Officer
Company:. Corn Oil ONE

Date

Part 2. Identity, Method of Manufacture, Specifications, and Physical or Technical Effect

Identity

COZ corn oil is an edible corn oil that is produced from distillers corn oil using a patented CO1™ process[2] and followed by conventional oil refining processes. Similar to any edible corn oil, COZ corn oil is a mixture of triglycerides, of which the major fatty acid components are linoleic, oleic, and palmitic fatty acids.

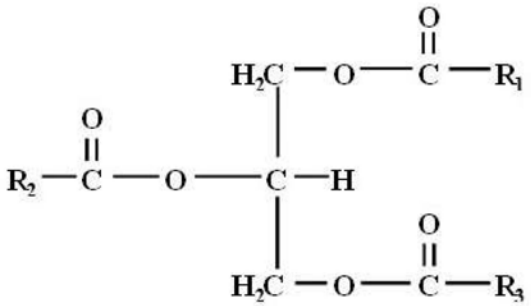
(a) Common or Usual name: Maize Oil; Corn Oil; Vegetable Oil

(b) Chemical Abstracts Service (CAS) Number: 8001-30-7

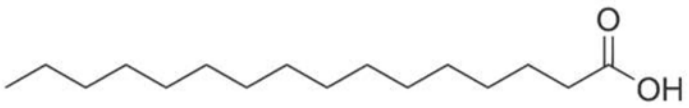
(c) Molecular Weight: Variable

(g) Molecular Structure (see Figure 1)

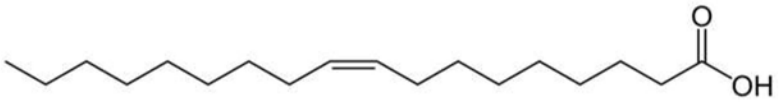
Figure 1. Typical Molecular Structure of Corn Oil



Mixed triglyceride, where R1, R2 and R3 represent key fatty acids including:

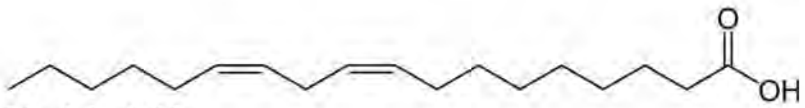


Palmitic Acid



Oleic Acid

[2] International Publication No. WO2014/078387 A1



Linoleic Acid

Manufacturing Information

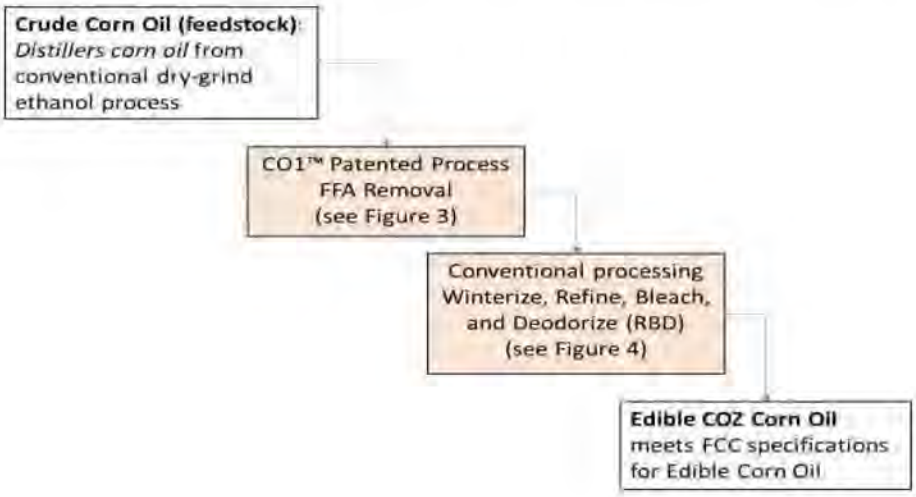
Overview

COZ corn oil is produced from distillers corn oil (DCO), a co-product from corn-ethanol production. DCO is a high value co-product that is extracted off of the mash in the production of ethanol. It is used in livestock feeds as a fat source as well as in biodiesel production. In 2017, about 3.6 billion pounds of DCO were produced by the U.S. ethanol industry, with about half of this total production being used to produce biodiesel while the other half is marketed as a high-quality metabolizable energy source for use in poultry and swine diets. In 2016, the Association of American Feed Control Officials (2017) developed and approved the official definition for DCO for use in animal feeds (AAFCO 33.10).

For the purpose of this GRAS notice, the DCO is referred to as crude corn oil feed stock (or crude corn oil). The manufacturing of COZ corn oil is a two-phase process (see Figure 2):

- Phase 1 - CO1™ process: the incoming raw material, crude corn oil, is subjected to the patented CO1™ process that removes more than 95% of the free fatty acids (FFA).
- Phase 2 – Conventional oil refining process: After the CO1™ process, the oil is further refined using conventional oil refining processes to produce COZ corn oil, which is an edible corn oil.

Figure 2. Overview of the Manufacturing Process for COZ Corn Oil



In the following sections, Corn Oil ONE's acceptance criteria to assure the suitability of the raw material input (i.e. crude corn oil) and the two phases in the production of COZ corn oil are further detailed.

Suitability of Crude Corn Oil As Raw Material Input

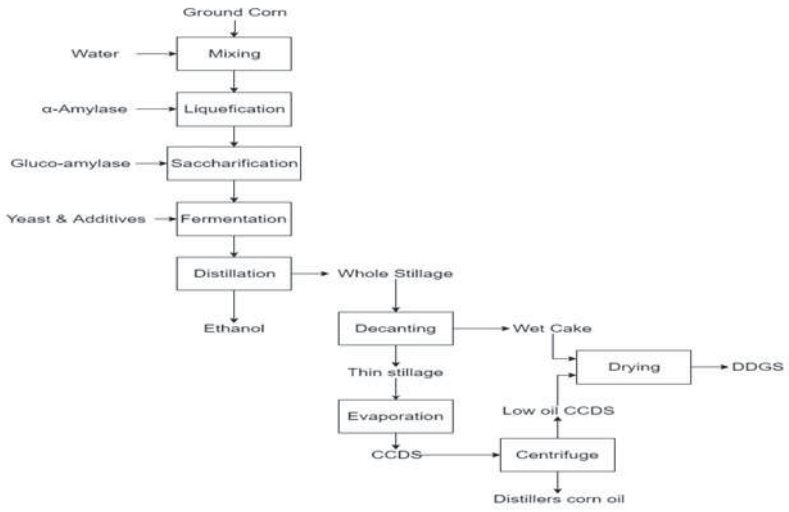
Crude corn oil that is used as the starting material in the production of COZ corn oil is distillers corn oil, which is recovered from thin stillage and wet cake by-products of the corn ethanol production process. A description of a conventional dry grind ethanol production process, from which the crude corn oil is derived, is briefly summarized in the box below.

Box 1. Conventional Dry Grind Ethanol Process

The first step in processing of the corn entails grinding the entire corn kernel into flour. This is done without separating the kernel into its subcomponents. In a liquefaction step, the flour, or meal, is mixed with water to form mash. The temperature of the mash is brought up to between 180°F and 220°F. Enzymes are added to the mash to convert the starch present in the mash to shorter-chain carbohydrates known as dextrins. Urea and lime may be added to control the pH between 6.0 and 6.5. Saccharification, the step following liquefaction in corn treatment, breaks the dextrins into glucose through the addition of enzymes, and pH is controlled by the addition of sulfuric acid to maximize enzyme effectiveness. In saccharification, the mash is cooled down to between 80°F and 90°F.

Dry yeast is added to the mash in the fermentation vessels to convert the glucose into ethanol and carbon dioxide. After fermentation is complete, the broth or beer contains between 8 and 13 percent ethanol by weight. The beer should also contain no residual glucose.

The fermented beer is then heated to remove a majority of the ethanol through a beer column that operates between 172°F and 212°F. Ethanol-rich vapors are separated from the beer to create stillage. The stillage, now absent of ethanol and slightly dehydrated, is centrifuged to separate bulk liquid from solids. The two separated streams are known as thin stillage and wet cake. Crude corn oil is recovered from the wet cake and syrup, dehydrated thin stillage, through centrifugation or extraction. Surface-active agents (oil recovery chemicals) are added to increase crude corn oil recovery. A flow diagram of a conventional dry grind ethanol plant is shown below.



Crude corn oil obtained from conventional dry grind ethanol plant contains non-oil impurities such as free fatty acids, color pigments, trace metals, sterols, tocopherols, squalene and oxidation products that can adversely affect appearance, stability and flavor of the oil. These impurities are removed by conventional refining, bleaching and deodorization processes practiced in producing food-grade edible vegetable oils.

Fermentation byproducts could also be present in crude corn oil, including glycerol (21 CFR §182.1320), lactic acid (21 CFR §184.1061), acetic acid (21 CFR §184.1005), iso-butyl alcohol (21 CFR §172.515), iso-amyl alcohol (21 CFR §172.515), and amyl alcohol (21 CFR §172.515)

Potential sources of unintended constituents in crude corn oil could include mycotoxins and pesticide residues in the raw corn input. Other chemicals that could be used in the corn-ethanol production process (e.g., urea, caustic soda, antibiotics, enzymes, oil recovery chemicals, pH control, etc.), or could be present in the corn-ethanol plant (e.g.boiler water additives, sanitation chemicals) present other potential sources of unintended impurities in the crude corn oil.

To ensure that the incoming crude corn oil material is suitable for further processing into edible corn oil, Corn Oil ONE has established acceptance criteria and a compliance assessment strategy for the incoming crude corn oil.

Crude Corn Oil Acceptance Criteria

Corn Oil ONE has established acceptance criteria for the following characteristics of incoming crude corn oil: free fatty acids (FFA), unsaponifiables, insolubles, iodine values, and moisture (see Table 1). The FFA acceptance limit is higher than in crude corn oil from conventional corn refineries, but the CO1™ process is able to remove the FFA (sees sections below on CO1™ and RBD process). The acceptance for other criteria (unsaponifiables, insolubles, iodine value, and moisture) are consistent with characteristics of crude corn oil derived from conventional corn refineries (see Table 1).

Table 1. Crude Corn Oil Acceptance Criteria

Criteria	Crude corn oil from conventional corn refineries [1]	Corn Oil ONE's acceptance criteria for crude corn oil [2]
Free fatty acids (as Oleic)	3 – 5%	Max 20%*
Unsaponifiables	Max 2%	Max 2.5%
Insolubles	--	Max 0.5%
Iodine Value	120 -132	Min 115
Moisture	0.5 – 1%	Max 1%

* FFA acceptance limit is higher than in crude corn oil from conventional corn refineries, but the CO1™ process is able to remove >95% of the FFA

1. USDA Commodity Requirements, BOT1, Bulk Oil and Tallow for Use in Export Programs, Effective Date 09/01/05; USDA, Announcement B08, Purchase of Crude Degummed Soybean Oil, Crude Corn Oil and Crude Sunflower Seed Oil For Use in Export Programs, Effective 1/20/99.
2. AFOA Rule 6E :Trading rules for Distiller's Corn Oil recovered from the alcohol manufacturing process

To ensure the crude corn oil (the starting material in the production of COZ corn oil) is suitable for further processing into edible corn oil, Corn Oil ONE has also established acceptance limits for antibiotics, mycotoxins, metals, pesticides, and other potential chemical impurities (see Table

2). The rationale for these limits are detailed in **Appendix A**. The five antibiotics (Virginiamycin, Erythromycin, Penicillin G, Tetracycline and Tylosin) that may be used in ethanol production according to a report by the US Grains Council are included in the crude corn oil acceptance limits.[3]

Table 2. Crude Corn Oil - Contaminant Acceptance Limit

Criteria	Acceptance Limit	Method
Antibiotic residues		
Virginiamycin	Not detected (LOD = 0.05 ppm)	FDA LIB (4438)
Erythromycin	Not detected (LOD = 0.05 ppm)	
Penicillin G	Not detected (LOD = 0.05 ppm)	
Tetracycline	Not detected (LOD = 0.05 ppm)	
Tylosin	Not detected (LOD = 0.05 ppm)	
Mycotoxins		
Aflatoxin (total)	< 20 ppb	AOAC 2008.2
Fumonisin (total)	< 2 ppm	AOAC 2008.2
Deoxynivalenol (DON)	< 1ppm	AOAC 2008.2
Metals Arsenic Cadmium Lead Mercury	<0.1 ppm	ICP-MS
Pesticides	40 CFR§180: Tolerances and exemptions for pesticide and chemical residues in food.	USDA FSIS method CLG_HEC1
Other chemical impurities	0.025 ppm (25 ppb)	Mass balance calculation

LOD = limit of detection

Compliance Assessment

In order to ensure supplier's compliance, with its acceptance criteria for the input crude corn oil, Corn Oil ONE has established a standard operating procedure (SOP) that lay out the acceptance criteria for incoming crude corn oil (Tables 1 and 2 above) and specifies compliance steps concerning sampling and testing procedures for crude corn oil, as well as assessment procedures to ensure compliance with its acceptance limit for chemical impurities (**see Appendix B**).

Corn Oil ONE's testing of incoming crude corn oil demonstrates that the incoming crude oil used to manufacture COZ corn oil complies with the contaminant limits for antibiotics, mycotoxins, metals and pesticides as specified in its SOP. The COAs for three batches of incoming crude corn

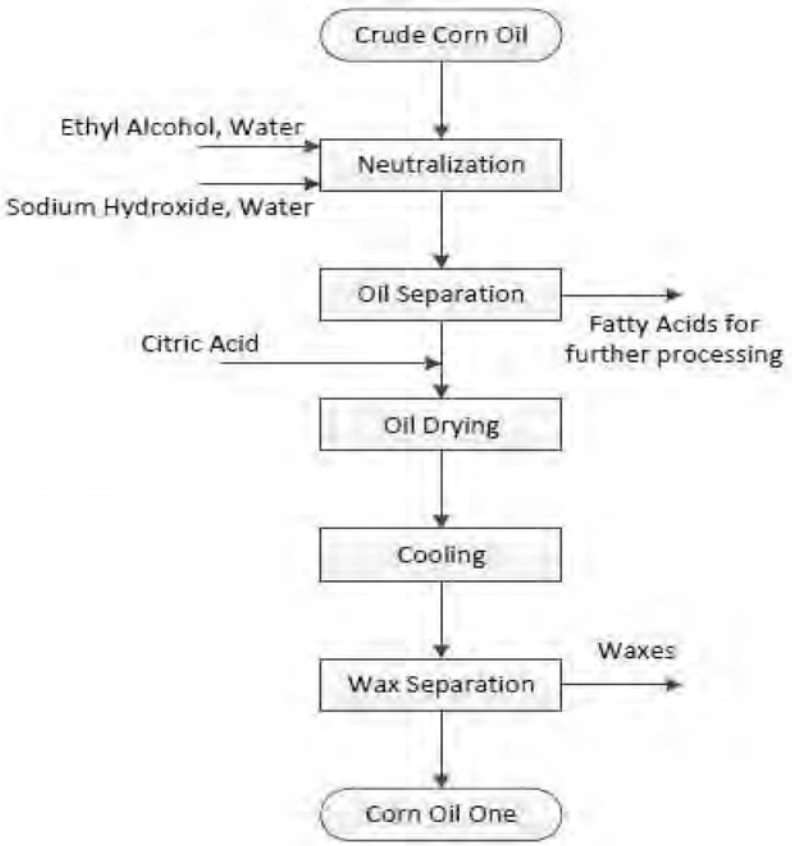
[3] https://grains.org/wp-content/uploads/2018/01/Complete-2012-DDGS-Handbook.pdf

oil are included in **Appendix C**. The compliance evaluation for "other chemical" impurities from a supplier of Corn Oil ONE is located in **Appendix D.**

Phase 1 - CO1™ Process

The first phase in the production of COZ corn oil is the CO1™ process, see Figure 3. The incoming raw material, crude corn oil, is subjected to the patented CO1™ process that removes more than 95% of the free fatty acids (FFA).

Figure 3. Phase 1 - CO1™ Process



All processing aids used in the CO1™ processing steps have regulatory approvals for use in food (see Table 3).

Table 3. Processing Aids Used in CO1™ Processing Step

Chemicals	Function	Regulatory Approvals
Sodium Hydroxide	pH Control Agent	21 CFR § 184.1763
Citric Acid	pH Control Agent	21 CFR § 184.1033
Ethyl Alcohol	Processing Aid	21 CFR § 184.1293

Phase 2 – Conventional oil Refining Process

After the CO1™ process, the corn oil is further refined using conventional oil refining processes to produce COZ corn oil, which is an edible corn oil, see Figure 4.

All processing aids used in conventional oil refining, bleaching and deodorizing (RBD) steps have regulatory approvals for use in food (see Table 4).

Figure 4. Phase 2 - Conventional Oil Refining Steps to Produce COZ Corn Oil

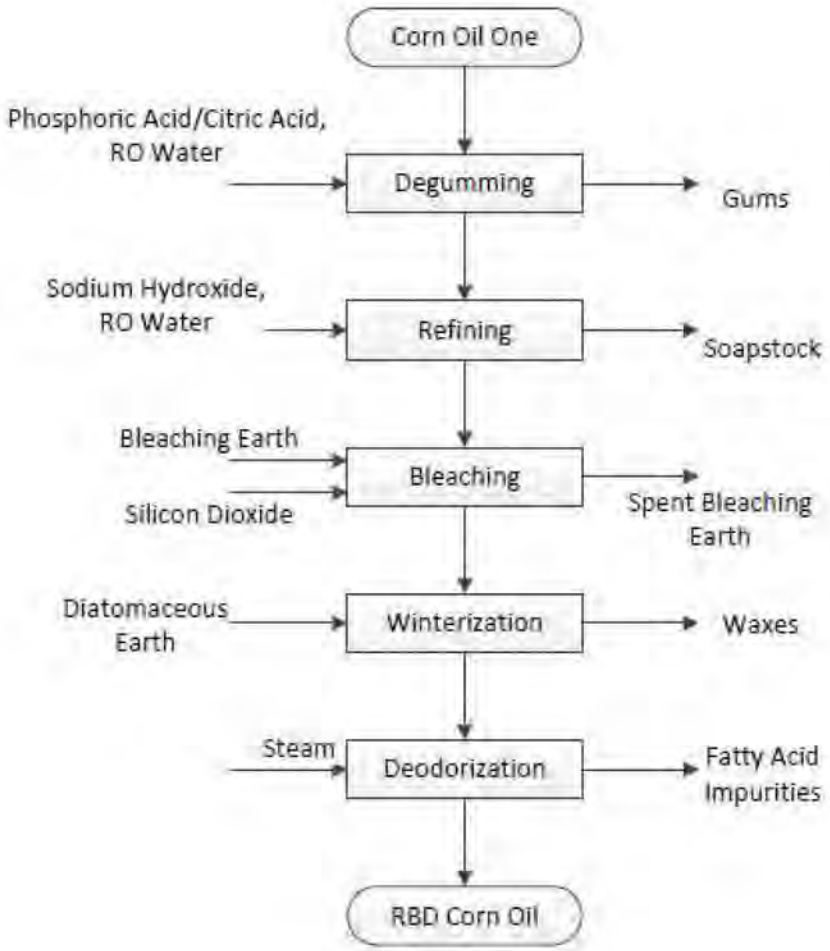


Table 4. Processing Aids in Conventional Oil RBD Steps Used by Corn Oil ONE

Chemicals	Function	Regulatory Approvals
Sodium Hydroxide	pH Control Agent	21 CFR § 184.1763
Citric Acid	pH Control Agent, Preservative	21 CFR § 184.1033
Phosphoric Acid	pH Control Agent	21 CFR § 182.1073
Bleaching Earth	Purification and Deodorization	21 CFR § 184.1155
Silicon Dioxide	Purification and Deodorization	21 CFR § 172.480
Diatomaceous earth	Filter Aid	SCOGS Report#61; ID Code:61790-53-2
Filters (Cellulose)	Various separation steps throughout the process	21 CFR § 177.2260

Removal of Impurities During Processing Steps

As earlier described, crude corn oil from the dry grind ethanol plant process contains non-oil impurities such as FFA, color pigments, trace metals, sterols, tocopherols, squalene and oxidation products that can adversely affect appearance, stability and flavor of the oil. These impurities can be removed by conventional RBD processes that are used on the production of conventional edible vegetable oil.

The CO1™ process (Phase 1), the steps prior to the conventional RBD process (Phase 2), removes much of the FFA content. Also, during the neutralization step of the CO1™ process, antibiotics and mycotoxins, if present, are unstable and will be removed. Given Corn Oil ONE's strict acceptance limit for incoming crude corn oil, the presence of chemical impurities is not expected. However, in the unlikely event that they are present in the crude corn oil, they will be completely removed from corn oil due to their thermophysical and chemical properties during the conventional RBD process The potential for removal of these contaminants, as described below, provides added assurance that the finished COZ corn oil would be free of unwanted contaminants and safe for consumption.

The thermophysical and chemical properties of mycotoxins and antibiotics and their fate through the processing steps of crude corn oil, i.e. the CO1™ and conventional RBD processing steps, are detailed in **Appendix E**. Below is a brief description of the removal of potential contaminants during key processing steps.

Crude Oil Neutralization: The first step in producing edible corn oil is neutralization where the FFAs present in the crude corn oil are removed by neutralizing them with a base such as sodium hydroxide to form soaps at a temperature between 155°F and 165°F. These soaps are insoluble in the oil and are readily separated from the corn oil through decantation. In this process the crude corn oil is mixed with a stoichiometric amount of sodium hydroxide in the presence of ethyl alcohol which serves as a solvent in aiding separation of soaps from the corn oil. Antibiotics and

mycotoxins, if present, will be removed in this separation step due to their selective solubility in the water and ethyl alcohol phase. Any residual soaps are removed by a water wash process or by treating with citric acid. Neutralized corn oil is then dried to remove any residual ethanol from the neutralization process at temperatures between 235°F and 245°F and a pressure of 200 mmHg. Final residues of ethanol are stripped from the oil with steam at a temperature of 265°F and pressure of 200 mmHg.

Degumming, Drying, Refining, and Water Wash: This step of processing involves the addition of phosphoric or citric acid at temperatures of 140-150°F, and usually requires a mixing residence time of 30-40 minutes. The degummed oil is then refined with an 11% caustic solution at 165°F with a residence time of 8-12 minutes. A centrifuge is often used to separate the soap and water solution from the oil. Lastly, the oil is then washed with 5-8 weight percent water for 8-10 minutes at a temperature of 190-195°F, and the wash water is separated from the oil. After the initial chemical treatment is complete, the oil is then dried at a temperature of 185-190°F and a pressure of 50 mmHg. Antibiotics, mycotoxins and other chemical impurities, if present, are purged in this water washing step due to their selective solubility in the water phase.

Winterization: An additional optional step that may be employed prior to bleaching and deodorization is fractioning, also known as winterization, in which the crude corn oil is cooled to a temperature of 40°F and centrifuged or filtered with nylon filters to obtain crude corn oil that flows easily at room temperature and maintains a transparent clear liquid appearance at low temperatures. Although usually preceding bleaching and deodorization, winterization can also be performed subsequent to any of those steps. The optional winterization step is customer-driven and conducted at the customer's request.

Bleaching: Neutralized corn oil from the step above is then bleached to remove any color pigments such as carotenoids, lutein, zeaxanthin, and chlorophyll. In this process the neutralized corn oil is heated to 235°F and then mixed with natural bleaching clays in amounts of 1 to 2 weight percent. Any residual mycotoxins are adsorbed into the bleaching clays at this step of processing. This mixture is then filtered through a filter press consisting of metal filter media to obtain bleached corn oil. In addition to the color pigments, bleaching also removes trace metals, phospholipids and oxidation products.

Deodorization: Deodorization is the final mandatory step in the process producing edible corn oil where the corn oil is subjected to steam distillation to remove odor-causing substances. In this process corn oil is subjected to high temperatures between 465°F and 485°F and vacuum at a maximum of 5 mmHg to evaporate all odoriferous substances. The high temperature conditions of deodorization will purge any remaining mycotoxins, antibiotics and other chemical impurities, if present, using a steam stripping process. Sparge steam is added at a rate of 1.0 to 1.5 weight percent of the oil feed. The resulting deodorized oil is bland and almost tasteless. Antioxidants can be optionally added at this step.

Effective removal of antibiotics via the processing steps as discussed above is documented in one sample of crude corn oil that contained erythromycin above the LOD. Although rejected as raw input material, it was subjected to the CO1™ and conventional RBD processes to show that these processes are effective in removing any residual antibiotics that may be present (see COA in **Appendix F**). From reviewing the molecular structures and physical and chemical properties, all the 5 antibiotics have high solubilities in polar solvents such as water, ethanol, methanol and low solubilities in non-polar solvents such as hexane. Erythromycin, Tylosin, Penicillin have higher

solubility in water and Virginiamycin and Tetracycline have higher solubility in ethanol. Ethanol and water are used as co-solvents in the CO1 process and further the oil from this process is subjected to a water wash step in the conventional refining process. Therefore, all the 5 antibiotics will be removed during the CO1 process and the conventional refining process to below their limits of detection. In addition to the above process steps, bleaching and deodorization processes can further remove any residues.

Specifications

Specifications for COZ corn oil are presented in Table 5. Specifications for COZ corn oil meet the Food Chemicals Codex specifications for corn oil (unhydrogenated) (FCC Vol 11).

Table 5. Specifications for COZ Corn Oil

Parameter	FCC*	COZ Corn Oil	Analytical Method
Color	NMT 5.0 red	NMT 5.0 red	AOCS-Wesson
Appearance	----------	Pale Yellow Liquid	Visual
Water	NMT 0.1%	NMT 0.1%	AOCS Ca 2c-25
Free Fatty Acids (as oleic)	NMT 0.1%	NMT 0.1%	AOCS Ca 5a-40
Iodine Value	120-130	120-130	AOCS Cd 1-25
Linolenic Acid	NMT 2%	NMT 2%	High Resolution Capillary Gas Chromatography
Peroxide Value	NMT 10 mEq /kg	NMT 10 mEq /kg	AOCS Cd 8b-90
Unsaponifiable Matter	NMT 1.5%	<1.5%	AOCS Ca 6a-40
Fatty Acid Composition			
<14	<0.1%	<0.1%	
14:0	<1.0%	<1.0%	AOAC996.06
16:0	8.0-19%	8.0-19%	
16:1	<0.5%	<0.5%	
18:0	0.5-4.0%	0.5-4.0%	
18:1	19-50%	19-50%	
18:2	38-65%	38-65%	
18:3	<2%	<2.0%	
20:0	<1%	<1.0%	
20:1	<0.5%	<0.5%	
22:0	<0.3%	<0.3%	
22:1	<0.1%	<0.1%	
24:0	<0.4%	<0.4%	
Impurities			
Arsenic	NMT 0.5 mg/kg	NMT 0.1 mg/kg	DIN EN 13805/14083/Atomic Absorption method
Cadmium	--		
Lead	NMT 0.1 mg/kg		
Mercury	--		
Microbiological			

Parameter	FCC*	COZ Corn Oil	Analytical Method
Total Aerobic Count	----------	< 10 cfu/g	AOAC 990.1
Yeasts	----------	< 10 cfu/g	AOAC 997.02
Molds	----------	< 10 cfu/g	AOAC 997.02
Escherichia Coli	----------	< 10 cfu/g	AOAC 991.14
Salmonella	----------	Absent/25g	AOAC 2003.09
Enterobacteriaceae	----------	< 10 cfu/g	ISO 21528-2
* *Food Chemicals Codex*, 11th Edition, corn oil (Unhydrogenated)			

COAs for three nonconsecutive batches of COZ corn oil meeting FCC and COZ corn oil specifications are presented in **Appendix G**. The data from these three batches confirming compliance with specifications are also summarized below in **Table 6.**

Table 6. Batch Data Confirming Compliance with Specifications for COZ Corn Oil

Parameter	Specification	Batch Data		
		Batch # 1 026303-01	Batch # 3 053502-02	Batch # 5 052468-02
Color	NMT 5.0 Red	4.2R	2.2R	1.1R
Water	NMT 0.1%	0.05%	0.07%	0.07%
Free Fatty Acids	NMT 0.1%	0.09%	0.06%	0.10%
Iodine Value	Between 120-130	121.9	123.5	123.3
Linolenic Acid	NMT 2.0%	1.08%	0.98%	0.97%
Peroxide Value	NMT 10 mEq/kg	1.8 mEq/kg	0.6 mEq/kg	0.4 mEq/kg
Unsaponifiable Matter	NMT 1.5%	1.25%	1.15%	1.14%
Fatty Acid Composition				
<14	<0.1%	<0.01%	<0.01%	<0.01%
14-0	<1.0%	0.03%	0.03%	0.03%
16-0	8.0-19%	10.34%	10.32%	10.37%
16-1	<0.5%	0.15%	0.14%	0.17%
18-0	0.5-4.0%	1.57%	1.59%	1.54%
18-1	19-50%	27.64%	27.77%	26.53%
18-2	38-65%	51.16%	51.07%	51.61%
18-3	<2.0%	1.08%	0.98%	0.97%
20-0	<1.0%	0.33%	0.33%	0.33%
20-1	<0.5%	0.37%	0.40%	0.38%
22-0	<0.3%	0.12%	0.13%	0.11%
22-1	<0.1%	0.01%	<0.01%	<0.01%
24-0	<0.4%	0.16%	0.17%	0.16%
Heavy Metals				
Lead	NMT 0.1 mg/kg	<0.01mg/kg	<0.01mg/kg	<0.01mg/kg
Arsenic		<0.01mg/kg	<0.01mg/kg	<0.01mg/kg
Cadmium		<0.01mg/kg	<0.01mg/kg	<0.01mg/kg

Parameter	Specification	Batch Data		
		Batch # 1 026303-01	**Batch # 3 053502-02**	**Batch # 5 052468-02**
Mercury		<0.01mg/kg	<0.01mg/kg	<0.01mg/kg
Microbiological Specifications				
Total Aerobic Count	< 10 cfu/g	<10 cfu/g	<10 cfu/g	<10 cfu/g
Yeasts	< 10 cfu/g	<10 cfu/g	<10 cfu/g	<10 cfu/g
Molds	< 10 cfu/g	<10 cfu/g	<10 cfu/g	<10 cfu/g
Escherichia Coli	< 10 cfu/g	<10 cfu/g	<10 cfu/g	<10 cfu/g
Salmonella	Absent/25g	Not detected	Not detected	Not detected
Enterobacteriaceae	< 10 cfu/g	<10 cfu/g	<10 cfu/g	<10 cfu/g

Part 3. Dietary Exposure

Proposed Use and Level

COZ corn oil derived from distillers corn oil using the CO1™ process and conventional refining processes is intended to be used as edible corn oil. Its use will be substitutional to other edible corn oil products in the US market.

Estimated Daily Intake

Since the use of COZ corn oil will be substitutional to other edible corn oil products in the US market, the estimated daily intake for corn oil based for the US population was developed and detailed in **Appendix H**.

Part 4. Self-Limiting Levels of Use

COZ corn oil is intended to be used as edible corn oil. Its use will be substitutional to other edible corn oil products in the US market. We are not aware of technological or palatable issues associated with the proposed use levels. Self-limiting levels of use are not applicable to this notice.

Part 5. Experience Based on Common Use in Food before 1958

The conclusion of GRAS status of COZ corn oil derived from distillers corn oil and intended to be used as edible corn oil was based upon scientific procedures. Experience based on common use in food before 1958 is not applicable to this notice.

Part 6. Narrative

Corn is indigenous to the western hemisphere. It is suggested that corn has been cultivated by man for over 5,000 years. Corn was refined beginning in the mid-1800's into starches, sweeteners and cooking oils. Corn oil was used or blended with animal fats for frying and baking in both the home and institutional business. Corn oil has been an accepted commodity by consumers for over 100 years. Its main use is in cooking where high smoke point makes refined oil a valuable frying oil. It is also the key ingredient in some margarine.

COZ corn oil is intended to be used as edible corn oil and its use will be substitutional to other edible corn oil products in the US market. The safety of COZ corn oil is established based on the suitability of the raw material ingredient, mainly the crude corn oil feedstock, the manufacturing process that removes all potential impurities, mainly the the CO1™ and conventional oil refining steps, resulting in COZ corn oil that is equivalent to edible corn oil.

COZ Corn Oil Equivalent to Edible Corn Oil

- **Safety of Edible Corn Oil**

Corn oil is a food with a long history of use in the U.S. food supply (Corn Refiners Association, 2006). Nearly all of the corn oil produced is refined for the food industry and direct use by consumers. The principal food uses of corn oil include salad and cooking oil, margarine, blends of butter, mayonnaise and emulsion type salad dressings. Corn oil is used as an oil ingredient in a variety of packaged and restaurant foods, including spaghetti sauce, potato chips and snack foods, French fries and breaded foods, baking mixtures, frosting and whipped toppings, crumb coating for meat and poultry, and baked goods (Corn Refiners Association, 2006).

While not as widely used as some vegetable oils, corn oil is also used in infant formulas globally and in select products available in the U.S. marketplace. The available literature also indicates that corn oil was commonly used in infant formulas in the U.S. as recently as the late 1990s. The LSRO Expert Report (1998), for example, lists corn oil, along with soy and high-oleic safflower and sunflower oils, as the most commonly used sources for unsaturated fatty acids in infant formula and is used in combination with coconut or palm oil. Corn oil was traditionally used rather than soy oil in powdered formulas as the lower concentration of α-linolenic acid in corn oil was less susceptible to oxidative degradation (Ponder et al., 1992). The recent published literature also includes references to use of corn oil in extensively hydrolyzed and reduced mineral infant formulas produced in the U.S. (summarized by Green Corkins and Shurley, 2016).

Corn oil is used as a vehicle to administer unpalatable or volatile chemicals to alter the dietary fat levels in long-term toxicity and carcinogenicity studies in rodents. Control male rats receiving a corn oil vehicle have been shown to have a higher incidence of pancreatic proliferative lesions and a lower incidence of mononuclear cell leukemia than untreated control males (NTP, 1994). Corn oil is not mutagenic in Salmonella typhimurium strains TA97, TA98, TA100, or TA1535, with or without S9 (NTP, 1994). Based on a study comparing the effects of various concentrations of safflower (very high in polyunsaturated fat), corn oil (high levels of

polyunsaturated and monounsaturated fats), and tricaprylin (high in saturated medium-chain fatty acids) (tricaprylin) on the incidence and pattern of neoplasms in the F344/N rat, it was concluded that safflower oil and tricaprylin do not offer significant advantages over corn oil as a gavage vehicle in long-term rodent studies (NTP, 1994).

In a large number of human studies corn oil diets have been shown to significantly lower elevated blood pressure. These observed beneficial effects of corn oil lead to a submission of a qualified health claim petition – Corn Oil and Corn Oil-Containing Products and a Reduced Risk of Heart Diseases (Docket No. 2006P-0243). In the petition, it was asserted that under 21 CFR§101.14(b)(3)(1), corn oil provides taste, aroma and nutritive value as established by compositional data from the USDA, a monograph for corn oil from FCC, and the presence of linolenic acid, an essential fatty acid, and that corn oil is GRAS because of its long history of widespread use. Based on the review of the scientific evidence in the petition, FDA concluded that there is sufficient scientific support for a qualified health claim for corn oil (FDA, 2007).

- **Coz Corn Oil is Equivalent to Edible Corn Oil**

As described earlier, COZ corn oil meets the FCC specifications for corn oil (unhydrogenated) (FCC Vol 11). Its specification limits for metals are well below the FCC specifications (see COAs in **Appendix G**).

Nutrient data

Fatty Acids

Corn oil is a mixture of triglycerides including saturated and unsaturated fatty acids. Typical corn oil processing includes refining, bleaching, and deodorizing steps which substantially remove free fatty acids, phospholipids, color, odor, and flavor components, as well as miscellaneous other non-oil components. Food grade specifications for corn oil include limits on physical and chemical properties of the oil as well as fatty acids.

The FCC specifications for the predominant fatty acids in corn oil (present at >1%), the CODEX standards for these fatty acids, the fatty acid composition of typical corn oil in the US food supply (per 100 g oil and per 100 g fatty acids), and mean concentrations of the fatty acids in COZ corn oil that is the subject of this GRAS evaluation are summarized below (Table 7). The predominant fatty acids in food-grade corn oil include linoleic acid and oleic acid, followed by palmitic acid, stearic acid, and linolenic acid. Collectively, these five fatty acids typically account for more than 90% of corn oil by weight. The composition of the COZ corn oil is consistent with that of typical corn oil.

Table 7. Fatty Acid Composition of Typical Corn Oil and COZ Corn Oil

Nutrient	USDA[a] per 100 g oil (04518)	USDA[a] per 100 g fatty acid (04518)	CODEX per 100 g fatty acid	FCC Specification	COZ Corn Oil Mean][b]
Total fat	100	-		-	-
Total fatty acids	95.201	100		-	92.91%
C16:0 (palmitic acid)	10.579	11.012	8.6-16.5	8.0-19.0%	10.34%
C18:0 (stearic acid)	1.848	1.924	ND-3.3	0.5-4.0%	1.57%
C18:1(oleic acid)	27.333	28.452	20.0-42.2	19-50%	27.31%
C18:2 (linoleic acid)	53.515	55.706	34.0-65.6	38-65%	51.28%
C18:3(linolenic acid)	1.161	1.209	ND-2.0	≤2.0%	1.01%

[a] USDA National Nutrient Database for Standard Reference, corn oil (04518). Total fatty acids represented by sum of saturated, monounsaturated, and polyunsaturated fatty acids. Values for C18:1, C18:2, and C18:3 correspond to data reported for undifferentiated form.
[b] Mean of three representative samples (see Table 4 for data from each sample)

Phytosterols

Vegetable oils typically contain phytosterols, which are compounds structurally similar to cholesterol. The most abundant phytosterols in both plants and the human diet are β-sitosterol, campesterol, and stigmasterol. Based on data from CODEX (CODEX 2017), typical corn oil contains 700 to 2210 mg total sterols per 100 g oil with cholesterol accounting for less than 1% of total sterols. The predominant sterols in typical corn oil include β-sitosterol, campesterol, and stigmasterol. Data from the USDA indicate that β-sitosterol, campesterol, and stigmasterol account for approximately 661, 241, and 80 mg per 100 g oil, respectively, or approximately 982 mg phytosterols (USDA 2018). Phytosterols in COZ corn oil are comparable to levels in conventional corn oil as summarized in Table 8

Table 8. Total Sterols and Percentages by Phytosterol in Typical Corn Oil as Compared to COZ Corn Oil

Phytosterol	Phytosterols per 100 g Oil and Percent Contribution by Type	
	Typical Corn Oil**	COZ Corn Oil*
Total sterols (mg/100 g)	700-2,210	1,410
Cholesterol, %	<1%	<1%
Campesterol, (mg/100g)	241	196
Stigmasterol (mg/100g)	80	74
Beta-sitosterol (mg/100g)	661	722
Others, %	ND-2.4	0.4%

Vitamins

Typical corn oil is a source of fat-soluble vitamins, including approximately 14.3 mg vitamin E (alpha-tocopherol) per 100 g oil and 1.9 µg vitamin K (phylloquinone) per 100 g oil (USDA,

2018). Similarly, COZ corn oil has 19.3 mg vitamin E (alpha-tocopherol) per 100 g oil and <1 µg vitamin K (phylloquinone) per 100 g oil (see **Appendix G** for certificate of analysis).

Stability data

There are numerous factors that influence the stability of oil including the fatty acid composition of the oils and storage temperature of the oil. Based on the fatty acid profile of the COZ corn oil, it is reasonable to assume that the COZ corn oil would have a stability profile similar to that of other edible corn oil in the marketplace. Stability testing for COZ corn oil was conducted under both accelerated and ambient conditions. The results showed that COZ corn oil is stable under ambient conditions. When exposed to heat under accelerated conditions, concentrations of oxidation products such as hydroperoxides (measured as peroxide value, PV) and decomposed hydroperoxides (measured as anisidine value, AV) in the oil increased, which is consistent with the response of corn oil subjected to heat as reported in the literature (Halvorsen and Blomhoff 2011). The complete stability study reports for the accelerated shelf-life condition for the duration of 91 days and for the ambient shelf-life condition for 273 days are provided in **Appendix I.** The available data demonstrate stability through 273 days at ambient condition.

Safety Conclusion

Corn Oil ONE has established acceptance criteria for the incoming crude corn oil (i.e., the distillers corn oil and starting material in the production of COZ corn oil) to ensure its suitability for further processing via the CO1™ and RBD process into edible corn oil. The unsaponifiables, insolubles, iodine value, and moisture acceptance criteria are consistent with characteristics of crude corn oil derived from conventional corn refineries. The FFA acceptance limit is higher than it is in crude corn oil from conventional corn refineries, but the CO1™ process is able to remove the FFA. In order to ensure that the crude corn oil is suitable for further processing, Corn Oil ONE has established strict acceptance limits for antibiotics, mycotoxins, metals and pesticides, as well as other chemical impurities in the incoming crude corn oil. Also, to assure compliance with its acceptance criteria, standard operating procedures for new supplier certification and periodic testing of crude corn oil are also implemented.

The CO1™ process, the steps prior to the conventional RBD process, remove much of the FFA content. Also, during the neutralization step of the CO1™ process, antibiotics and mycotoxins, if present, are unstable and will be removed. Given Corn Oil ONE's strict acceptance limit for incoming crude corn oil, the presence of chemical impurities is not expected. However, in the unlikely event that they are present in the crude corn oil, they will be completely removed from corn oil due to their thermophysical and chemical properties during the conventional RBD process. The removal of these contaminants during these processing steps provides added assurance that the finished COZ corn oil would be free of unwanted contaminants and safe.

Corn oil is a food; humans and animals consume corn oil as a component of the diet and it is safe. COZ corn oil derived from distillers corn oil by the CO1™ process and conventional RBD processes is equivalent to conventional corn oil. COZ corn oil meets FCC specifications. It is nutritionally equivalent to conventional corn oil based on fatty acid, phytosterol, and vitamin

profiles. The stability of COZ corn oil under both accelerated and ambient testing conditions is consistent with the stability of standard corn oil.

Thus, the proposed use of COZ corn oil as edible corn oil, as substitutional to other edible corn oil in the US market, is safe.

Discussion of Information Inconsistent with GRAS Determination

Corn Oil ONE is not aware of information that would be inconsistent with a finding that the proposed use of COZ corn oil as edible corn oil, meeting appropriate specifications specified herein and used according to cGMP, is safe and GRAS.

Basis for Conclusion that there is Consensus Regarding Safety

A GRAS Panel consisted of the following individuals: Richard W. Lane, Ph.D., DABT (Lane Consulting), Nadine R. Sahyoun, Ph.D. (Professor, Nutrition and Food Science, University of Maryland), and Stanley M. Tarka, Jr., Ph.D., FATS (The Tarka Group, Inc. and Adjunct Associate Professor, The Pennsylvania State University College of Medicine, critically evaluated Exponent's safety documentation (the dossier) and other available data and information that the members of the GRAS Panel believed to be pertinent to the safety of the proposed use of COZ Corn Oil. The GRAS Panel convened on April 25, 2019 via teleconference and independently, jointly, and unanimously concluded that COZ Corn Oil, produced consistent with current good manufacturing practice (cGMP) and meeting the specifications as presented in the supporting dossier described above, is safe for use as edible corn oil in conventional foods. The GRAS Panel further concluded unanimously that the intended use of COZ Corn Oil as edible corn oil in conventional foods is GRAS based on scientific procedures. It is also the unanimous consensus opinion of this GRAS Panel that other qualified experts would concur with these conclusions. The GRAS Panel Signed Consensus Statement is located in **Appendix J.**

The intended use of COZ corn oil as edible corn oil has been determined to be safe through scientific procedures as set forth in 21 CFR§170.30(b), thus satisfying the so-called "technical" element of the GRAS determination. Because this safety evaluation was based on generally available and widely accepted data and information, it also satisfies the so-called "common knowledge" element of a GRAS determination.

Part 7. List of Supporting Data and Information in GRAS Notice

AAFCO. 2017. Association of American Feed Control Officials — Official Publication. Champaign, Ill.

CODEX STANDARD 210-1999 for Named Vegetable Oils. Adopted in 1999. Revised in 2001, 2003, 2009, 2017. Amended in 2005, 2011, 2013, 2015. http://www.fao.org/fao-who-codexalimentarius/codex-texts/list-standards/en/ Accessed March 12, 2019.

Corn Refiners Association. Corn Oil. https://corn.org/wp-content/uploads/2018/10/CornOil.pdf 2006

Food and Drug Administration (FDA). Qualified Health Claims: Letter of Enforcement Discretion – Corn Oil and Corn Oil- Containing Products and a Reduced Risk of Heart Disease (Docket No. 2006P-0243). March 25, 2007.

Green Corkins K, Shurley T. What's in the Bottle? A Review of Infant Formulas. Nutr Clin Pract. 2016 Dec;31(6):723-729. doi: 10.1177/0884533616669362.

Guidance for Industry and FDA: Advisory Levels for Deoxynivalenol (DON) in Finished Wheat Products for Human Consumption and Grains and Grain By-Products used for Animal Feed. Document issued on: June 29, 2010; Revised July 7, 2010. Page Last Updated: 9/17/2018. https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm120184.htm

Guidance for Industry: Fumonisin Levels in Human Foods and Animal Feeds. Document issued on: June 6, 2000; Revised November 9, 2001. https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm109231.htm

Guidance for Industry: Action Levels for Poisonous or Deleterious Substances in Human Food and Animal Feed. August 2000. Page Last Updated: 9/20/2018. https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm077969.htm

Halvorsen BL, Blomhoff R. Determination of lipid oxidation products in vegetable oils and marine omega-3 supplements. Food Nutr Res. 2011;55.

Joint FAO/WHO Expert Committee on Food Additives (JECFA). 1998. PROCAINE BENZYLPENICILLIN. TRS 888-JECFA 50/25. Tox monograph: See FAS 27-JECFA 36/105 (BENZYLPENICILLIN, 1990). http://www.inchem.org/documents/jecfa/jeceval/jec_2002.htm

Joint FAO/WHO Expert Committee on Food Additives (JECFA). 2006. Evaluation: Erythromycin. TRS 939-JECFA 66/33. Tox monograph: See FAS 57-JECFA66/31. http://apps.who.int/food-additives-contaminants-jecfa-database/chemical.aspx?chemID=39...

Joint FAO/WHO Expert Committee on Food Additives (JECFA). 2008. Seventieth meeting (Residues of veterinary drugs).Summary report of the seventieth meeting of JECFA. Tylosin Antimicrobial Agent (page 5).

Life Sciences Research Office (LSRO) Expert Panel Report. Raiten DJ, Talbot JM, Waters JH, Eds. Assessment of nutrient requirements for infant formulas. J Nutr. 1998 Nov;128(11 Suppl):i-iv, 2059S-2293S. Review. No abstract available. Erratum in: J Nutr 1999 May;129(5):1090.

National Center for Health Statistics (NCHS). 2016. National Health and Nutrition Examination Survey Data 2013-2014. Hyattsville, MD: US Department of Health and Human Services, Centers for Disease Control and Prevention. Available via: https://wwwn.cdc.gov/nchs/nhanes/continuousnhanes/default.aspx?BeginYear=2013.

National Center for Health Statistics (NCHS). 2018. National Health and Nutrition Examination Survey Data 2013-2014. Hyattsville, MD: US Department of Health and Human Services, Centers for Disease Control and Prevention. Available via: https://wwwn.cdc.gov/nchs/nhanes/continuousnhanes/default.aspx?BeginYear=2015.

National Toxicology Program (NTP). Comparative Toxicology Studies of Corn Oil, Safflower Oil, and Tricaprylin (CAS Nos. 8001-30-7, 8001-23-8, and 538-23-8) in Male F344/N Rats as Vehicles for Gavage. Natl Toxicol Program Tech Rep Ser. 1994 Apr;426:1-314.

Ponder DL, Innis SM, Benson JD, Siegman JS. Docosahexaenoic acid status of term infants fed breast milk or infant formula containing soy oil or corn oil. Pediatr Res. 1992 Dec;32(6):683-8.

US Department of Agriculture (USDA). 2017. Food Patterns Equivalents Database (FPED) 2013-2014. Beltsville, MD: US Department of Agriculture, Agricultural Research Service, Food Surveys Research Group. Available via: https://www.ars.usda.gov/northeast-area/beltsville-md-bhnrc/beltsville-human-nutrition-research-center/food-surveys-research-group/docs/fped-overview/.

US Department of Agriculture (USDA). 2018a. Food Patterns Equivalents Database (FPED) 2015-2016. Beltsville, MD: US Department of Agriculture, Agricultural Research Service, Food Surveys Research Group. Available via: https://www.ars.usda.gov/northeast-area/beltsville-md-bhnrc/beltsville-human-nutrition-research-center/food-surveys-research-group/docs/fped-overview/.

US Department of Agriculture (USDA). 2018b. USDA Food and Nutrient Database for Dietary Studies 2015-2016. Beltsville, MD: US Department of Agriculture, Agricultural Research Service, Food Surveys Research Group. Available via: https://www.ars.usda.gov/northeast-area/beltsville-md-bhnrc/beltsville-human-nutrition-research-center/food-surveys-research-group/docs/fndds/.

US FDA. 2006. Guidance for Industry: Estimating Dietary Intake of Substances in Food. Available at: https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/IngredientsAdditivesGRASPackaging/ucm074725.htm.

US FDA. Guidance for Industry: Fumonisin Levels in Human Foods and Animal Feeds. June 6, 2000; Revised November 9, 2001. Page Last Updated: 9/20/2018. https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm109231.htm

USDA 2018. US Department of Agriculture, Agricultural Research Service, Nutrient Data Laboratory. USDA National Nutrient Database for Standard Reference, Legacy. Version Current: April 2018. https://ndb.nal.usda.gov/ndb/.

Appendices

Appendix A. Crude Corn Oil Acceptance Criteria Rationale

Antibiotics Residue

The acceptance criteria for antibiotics are **non-detects** based on the limit of detection (LOD) of 0.05 ppm. (FDA LIB 4438). The following assessment was conducted to provide support that a **non-detection** at the LOD 0.05 ppm is safe:

- Based on 21 CFR §556.750, the ADI for **virginiamycin** is 250 µg/kg bw/day.
- JECFA (2006) established an ADI of 0–0.7 µg/kg bw for **erythromycin**
- JECFA (1998) established an ADI of 30 µg/p/d for **penicillin G.**
- Based on 21CFR §556.750, the ADI for **tetracycline** is 25 µg/kg bw/day
- JECFA (2008) established an ADI of 0–30 µg/kg bw for **tylosin.**

Assuming that the daily intake of corn oil of 6g/day (see EDI in **Appendix H)** is exposed at the LOD of 0.05 ppm, for a 60 kg bw the EDI would be 0.005 µg/kg bw/day. This is well below the ADIs for these antibiotics. Therefore, there is an ample margin of safety when there is no detection at the LOD of 0.05 ppm in the crude corn oi.

Mycotoxins

The acceptance criteria for mycotoxins were based on US FDA guidance levels (FDA 2001, FDA 2000, FDA 2010) and limits for mycotoxins:

Fumonisin (B1, B2, B3) (FDA 2001)[4]	**Guidance Level (ppb)**
Degermed dry milled corn products (e.g. flaking grits, corn meal, corn flour with fat content of <2.25 %, dry weight basis)	2000
Cleaned corn intended for popcorn	3000
Whole or partially degermed dry milled corn products (e.g. flaking grits, corn meal, corn flour with fat content of <2.25 %,dry weight basis); dry milled corn bran; cleaned corn intended for mass production	4000
Aflatoxin (total) (FDA 2001)[5]	**Maximum Level (ppb)**
All foods except milk	20
Deoxynivalenol (DON) (FDA 2010)[6]	**Guidance level (ppb)**
Finished wheat product consumed by humans	1000

[4] https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm109231.htm

[5] https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm077969.htm

[6] https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm120184.htm

Metals

The acceptance criteria for metal impurities (arsenic, cadmium, lead and mercury) in the crude corn oil were established to be the same as the specification limits for the finished edible COZ corn oil, which are well below FCC specifications.

Other Chemical Impurities

The acceptance criterion for other chemical impurities is derived based on the concept of threshold of toxicological concern (TTC). The TTC approach as currently applied is a science-based screening tool useful for preliminary screening assessment. Based on the recent comprehensive review by EFSA and the WHO (2016),[7] the TTC approach is a valid screening tool, based on scientific risk assessment principles, to assess low dose chemical exposures, and to distinguish those for which further data are required to assess the human health risk from those with no appreciable risk. The following TCC values were summarized by in the 2016 report by the EFSA and WHO:

Type of TTC value	TTC value in µg/person per day
With structural alert for genotoxicity	0.15
OPs and carbamates	18
Cramer Class III	90
Cramer Class II	540
Cramer Class I	1800

As such the lowest TCC value of 0.15 µg/day as described in the EFSA/WHO report is used as the basis for deriving the acceptance limit for chemical impurities in crude corn oil.

Based on the TCC of 0.15 µg/day. the acceptance limit for crude corn oil was derived as follows:

- 90th percentile per user intake of corn oil being more than 6 g/day (see EDI in **Appendix H**)
- Acceptance limit in crude corn oil: $= \frac{0.15\ \mu g/day}{6 g/day} = 0.025\ \mu g/g$ or 25 ppb

[7] European Food Safety Authority (EFSA) and World Health Organization (WHO), 2016. Review of the Threshold of Toxicological Concern (TTC) approach and development of new TTC decision tree;; PUBLISHED: 10 March 2016

Appendix B. Corn Oil One Standard Operating Procedure – Acceptance Criteria, Sampling and Testing Procedure for Crude Corn Oil

Standard Operating Procedure (Corn Oil One Acceptance Criteria)

1. Purpose

The purpose of this procedure is to define the acceptance criteria and testing protocols for raw materials at the Corn Oil One plant in Council Bluffs.

2. Scope

This procedure is applicable to Corn Oil One operations and laboratory personnel.

3. Responsibilities

Quality Management is required to:
- Determine the extent and scope of testing
- Review tolerances levels annually
- Ensure that the program is adhered to

Operations is required to:
- Follow the regular testing protocol and probation testing protocol for receiving material
- Receive the material and document their checks and inspections

Lab is required to:
- Follow testing protocol for pesticides, antibiotic residues, and mycotoxins
- Communicate results of probation testing to Operations and Purchasing
- Communicate non-conformances to Quality Management and Purchasing

Purchasing is required to:
- Ensure suppliers are aware of acceptance criteria and tolerance levels
- Communicate any non-conformances of the acceptance criteria to suppliers
- Re-evaluate suppliers based on performance and adherence to acceptance criteria

4. Procedure

I. Acceptance criteria

a) Corn Oil One has established acceptance criteria for its suppliers and maintains a list of approved suppliers who verify that they meet these criteria.
b) A sample is provided and inspected prior to the supplier being approved and added to the normal testing protocol.
c) Acceptance criteria is outlined in Tables 1 and 2.

Table 1 Acceptance criteria for Crude Corn Oil

Criteria	Corn Oil One's acceptance criteria for crude corn oil
Free fatty acids (as Oleic)	Max 20%
Unsaponifiables	Max 2.5%
Insoluble Matter	Max 0.5%
Iodine Value	Min 115
Moisture	Max 1%

Table 2 Crude Corn Oil – Contaminant Acceptance limit

Criteria	Acceptance Limit*	Method
Antibiotic Residues		
Virginiamycin	Not detected (LOD = 0.05 ppm)	FDA LIB (4438)
Erythromycin	Not detected (LOD = 0.05 ppm)	
Penicillin G	Not detected (LOD = 0.05 ppm)	
Tetracycline	Not detected (LOD = 0.05 ppm)	
Tylosin	Not detected (LOD = 0.05 ppm)	
Mycotoxins		
Aflatoxin (total)	< 20 ppb	AOAC 2008.2
Fumonisin (total)	< 2 ppm	
Deoxynivalenol (DON)	< 1 ppm	
Metals Arsenic Cadmium Lead Mercury	<0.1 ppm	ICP-MS
Pesticides	40 CFR 180: Tolerances and exemptions for pesticide and chemical residues in food.	USDA FSIS method CLG_HEC1
Other chemical impurities	<0.025ppm (or 25 ppb)	Mass Balance Calculation

*see Appendix A of GRN. Crude Corn Oil Acceptance Criteria Rationale

d) Prior to approving a supplier, specific chemical impurities identified through the supplier verification process shall have their regulatory status confirmed. If they do not have proper regulatory status, the chemical properties, thermophysical properties, inclusion rates, and plant addition location will be identified for each disclosed compound by the supplier. This shall only include compounds that come into contact with processing streams that predicate corn oil separation in their production process.

e) Once identified, the inclusion (addition) rates for chemical impurities shall be used to perform a by-difference, steady-state, compositionally conservative material balance calculation on the supplier's distillers corn oil process. This calculation shall assume a proportional split of chemical impurities based exclusively on the mass fractions and stream ratios around process unit operations that contact distillers corn oil production streams. The final chemical impurity concentration calculated from this will be compared to the acceptance limit of 25 ppb in the crude corn oil.

f) The thermophysical and chemical properties of the identified chemical impurities shall then be vetted through a compound specific process fate (whether the specific impurity changes its chemical form) and purge (whether the specific impurity is removed and/or concentrated via a process step) assessment.

g) The analysis from the mass balance and fate and purge assessment for the supplier's process shall be permanently associated with the supplier and recorded in plant's Quality Control and Quality Assurance information on the secured company controlled documents drive. Through the supplier verification program, suppliers understand, and are responsible for contacting Corn Oil One in the event that there is a change to their distillers corn oil process. Additionally, suppliers are re-evaluated on an annual basis to verify that there has been no update to their distillers corn oil process.

II. Raw material inspection

a) All purchased material which influences the manufacture of, or is intended for use as part of, deliverable products is subject to inspection and testing by receiving personnel.
b) Upon receipt of raw material; receiving personnel verify the origin quantity, and inspect all trailers for signs of tampering or damage.
c) If all checks and inspections are satisfactory, receiving personnel signs the delivery receipt. All shortages or damage is documented on all copies of the delivery receipts.
d) Raw materials are verified against the purchase order, packing slips, and are visually examined.
e) All receiving inspections are logged and filed along with provided supplier paperwork.

III. Regular testing protocol

a) A combination of on-site and off-site testing is performed to verify that the acceptance criteria listed in Table 1 and Table 2 is being met as part of the regular testing protocol.
b) Samples retained from incoming raw material will be used in conjunction with monthly and yearly feedstock tank testing to identify suppliers that are not in conformance with acceptance criteria.
c) On a monthly and yearly basis a random feedstock tank sample is taken before the tank is processed. This sample is sent for third party analysis. See table 3.
d) The feedstock tank selected for random sampling will not be currently in process
e) If one or more criteria is out of the acceptance specification, retained samples of the individual shipments are sent for third party analysis.

Table 3 Regular testing Protocol

Sample	Tests
Every incoming Feedstock load	FFA, Moisture, screen for insolubles & unsaponifiables
Monthly Random sampling of feedstock	Chemical Impurities, Iodine value, Antibiotic Residues, Mycotoxins, total MIU
Yearly Random sampling of feedstock	Metals, Pesticides

f) Corn Oil One utilizes its Process Inventory Management System (PIMS) to trace the contents of its feedstock holding tanks to individual incoming raw material loads.
g) Retained samples from individual raw material loads are tracked and managed by the Laboratory Information Management System (LIMS). Testing results are also recorded using the LIMS software.
h) After third party analysis of the retained samples, individual supplier(s) found to be outside of specification for pesticides, and/or mycotoxins, and/or antibiotic residues will be reported as a non-conformance. A non-conformance report will be filled out and action will be explained in the report. This supplier will also be on probation, and be subjected to the probation testing protocol.

IV. Probation testing protocol

a) All new materials are sent in for 3rd party testing for pesticides, Antibiotic residues, and mycotoxins.
b) If the sample conforms to Corn Oil One acceptance criteria, the supplier will move into the regular testing protocol.
c) If a sample fails Corn Oil Ones acceptance criteria for pesticides, antibiotic

residues, or mycotoxins, the supplier will be on probation.

d) When a supplier goes on probation:
   1. Purchasing will communicate to supplier they are on probation for the specification not in conformance.
   2. Operations will unload material directly into off spec tank.
   3. Operations or lab will send in a sample for 3rd party testing of the violated specification
   4. Lab personnel will communicate to Operations and Purchasing the results
      i. Below acceptance criteria- approved to be processed
      ii. Above acceptance criteria- hold for non-conformance & further instruction by upper management.

e) For pesticide probation, supplier cannot be removed from the probation testing protocol until the supplier receives 5 consecutive reports for 3rd party lab with no pesticides detected.

f) For antibiotic and mycotoxin probation, supplier cannot be removed until the supplier receives 5 consecutive reports for 3rd party lab meeting Corn Oil One acceptance criteria.

5. Revision History

Log ALL revisions into the sections of the table.

Description of Revision	Date Revised	New Revision #
New	**17 FEB 2019**	**1**
Content edits for clarity	**5 MAR 2019**	**2**
Content edits for clarity	**20 MAR 2019**	**3**
Content edits for clarity	**26 MAR 2019**	**4**
Grammar/Layout Update	**3 OCT 2019**	**5**
Grammar/Layout Update	**8 OCT 2019**	**6**

Appendix C. Certificates of Analysis for Crude Corn Oil

"Corn oil" samples tested are the crude corn oil (distillers corn oil) prior to being processed via CO1 and RBD process into edible corn oil (COZ corn oil).

Sample no. 434604/13204954

DIVERSIFIED LABORATORIES, INC.

4150 LAFAYETTE CENTER DRIVE * CHANTILLY, VIRGINIA 20151 * (703) 222-8700

Certificate of Analysis

Submitted by: CORN OIL ONE
Sample: CORN OIL
Client Date: 03/19/2019
Date Received: 03/20/2019
Analysis Requested: LIPID ANALYSIS

FREE FATTY ACIDS (%)	11.78
MOISTURE (%)	0.38
INSOLUBLE MATTER (%)	0.10
UNSAPONIFIABLE (%)	2.17
TOTAL MIU (%)	2.65
IODINE VALUE (#)	123.26

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Date Processed: 03/20/2019
Date Reported: 3/21/2019

Control Number: 434604

Thomas Scott
Director of Laboratory Services

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"Service Through Science"

DIVERSIFIED LABORATORIES, INC.

4150 LAFAYETTE CENTER DRIVE * CHANTILLY, VIRGINIA 20151 * (703) 222-8700

Certificate of Analysis

Submitted by: CORN OIL ONE
Sample: CORN OIL
Client Date: 03/19/2019
Date Received: 03/20/2019
Analysis Requested: PESTICIDE/PCB SCREEN (mg/kg) CLG_HEC1 (Modified)

ALDRIN	N.D.	HEPTACHLOR	N.D.
CHLORDANE		HEPTACHLOR EPOXIDE	N.D.
alpha-CHLORDANE	N.D.	HEXACHLOROBENZENE	N.D.
gamma-CHLORDANE	N.D.	LINURON	N.D.
OXYCHLORDANE	N.D.	LINDANE	N.D.
TRANS-NONACHLOR	N.D.	METHOXYCHLOR	N.D.
BIFENTHRIN	N.D.	METHYL CHLORPYRIFOS	N.D.
BHC		MIREX	N.D.
alpha-BHC	N.D.	DDT	
beta-BHC	N.D.	p,p'-DDD	N.D.
delta-BHC	N.D.	o,p'-DDD	N.D.
TOTAL BHC	N.D.	p,p'-DDE	N.D.
CARBOPHENOTHION	N.D.	o,p'-DDE	N.D.
CHLORDENE	N.D.	p,p'-DDT	N.D.
CHLORPYRIFOS	N.D.	o,p'-DDT	N.D.
DELTAMETHRIN	N.D.	TOTAL DDT	N.D.
DICHLOFENTHION	N.D.	PARATHION	N.D.
DIELDRIN	N.D.	PERMETHRIN (SUM OF ALL ISOMERS)	N.D.
ENDOSULFAN I	N.D.	PCB	N.D.
ENDOSULFAN II	N.D.	1016,1221, 1232, 1242, 1248, 1254, 1260, 1262, 1268	
ENDOSULFAN SULFATE	N.D.		
ENDRIN	N.D.	RONNEL	N.D.
ENDRIN ALDEHYDE	N.D.	TOXAPHENE	N.D.
ENDRIN KETONE	N.D.	TRANS-NONACHLOR	N.D.
FONOPHOS (DYFONATE)	N.D.		
HBB	N.D.		

Note: Parts per million, ppm = mg/kg.

Accredited by ISO/IEC 17025 (Accreditation #67126) and the USDA-FSIS Accredited Laboratory Program for Pesticides and PCBs.

Date Processed: 3/20/2019
Date Reported: 3/20/2019

Control Number: 434604

Thomas Scott
Director of Laboratory Services

REPORT NUMBER
19-086-9014 v4

REPORT DATE
Jun 05, 2019

SEND TO
36293

RECEIVED DATE
Mar 20, 2019

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ISSUE DATE
Jun 05, 2019

CORN OIL ONE
WILL ATKISSON
4400 E UNIVERSITY AVE
PLEASANT HILL IA 50327

REPORT OF ANALYSIS

For: (36293) CORN OIL ONE
CORN OIL
CORN OIL

Analysis	Level Found As Received	Units	Reporting Limit	Method	Analyst-Date	Verified-Date
Sample ID: **NO ID** Lab Number: **13204954**						
Aflatoxin B1	n.d.	ppb	1.00	AOAC 2008.02 (mod)	kmc4-2019/03/23	tjp8-2019/03/25
Aflatoxin B2	n.d.	ppb	1.00	AOAC 2008.02 (mod)	kmc4-2019/03/23	tjp8-2019/03/25
Aflatoxin G1	n.d.	ppb	1.00	AOAC 2008.02 (mod)	kmc4-2019/03/23	tjp8-2019/03/25
Aflatoxin G2	n.d.	ppb	1.00	AOAC 2008.02 (mod)	kmc4-2019/03/23	tjp8-2019/03/25
Aflatoxin summation	n.d.	ppb	1.00	Calculation	Auto-2019/03/25	Auto-2019/03/27
DON (Vomitoxin)	n.d.	ppm	0.1	AOAC 2008.02 (mod)	kmc4-2019/03/22	tjp8-2019/03/25
Fumonisin B1	n.d.	ppm	0.1	AOAC 2008.02 (mod)	kmc4-2019/03/23	tjp8-2019/03/25
Fumonisin B2	n.d.	ppm	0.1	AOAC 2008.02 (mod)	kmc4-2019/03/23	tjp8-2019/03/25
Fumonisin B3	n.d.	ppm	0.1	AOAC 2008.02 (mod)	kmc4-2019/03/23	tjp8-2019/03/25
Fumonisin summation	n.d.	ppm	0.10	Calculation	Auto-2019/03/25	Auto-2019/03/27
Chlorotetracycline (CTC) residue	n.d.	ppm	0.05	FDA LIB 4438	akj2-2019/03/27	tjp8-2019/03/27
Doxycycline (residue)	n.d.	ppm	0.050	FDA LIB 4438	akj2-2019/03/22	tjp8-2019/03/22
Oxytetracycline (OTC) residue	n.d.	ppm	0.05	FDA LIB 4438	akj2-2019/03/27	tjp8-2019/03/27
Penicillin residue	n.d.	ppm	0.05	FDA LIB 4438	akj2-2019/03/22	tjp8-2019/03/22
Tetracycline (residue)	n.d.	ppm	0.050	FDA LIB 4438	akj2-2019/03/27	tjp8-2019/03/27
Tylosin (Tylan)	n.d.	ppm	0.05	FDA LIB 4438	akj2-2019/03/22	tjp8-2019/03/22
Virginiamycin residue	n.d.	ppm	0.05	FDA LIB 4438	akj2-2019/03/22	tjp8-2019/03/22
Erythromycin residue	n.d.	ppm	0.05	FDA LIB 4438	akj2-2019/03/22	tjp8-2019/03/22
Arsenic (total)	n.d.	mg/kg	10.0	EPA 6010	ery3-2019/03/21	bab2-2019/03/26

The result(s) issued on this report only reflect the analysis of the sample(s) submitted.

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CORN OIL ONE
WILL ATKISSON
4400 E UNIVERSITY AVE
PLEASANT HILL IA 50327

REPORT OF ANALYSIS

For: (36293) CORN OIL ONE
CORN OIL
CORN OIL

Analysis		Level Found As Received	Units	Reporting Limit	Method	Analyst-Date	Verified-Date
Sample ID: NO ID	Lab Number: **13204954** (con't)						
Mercury (total)		n.d.	mg/kg	0.010	EPA 7471	ccm2-2019/03/26	bab2-2019/03/26
Cadmium (total)		n.d.	mg/kg	0.50	EPA 6010	ery3-2019/03/21	bab2-2019/03/26
Lead (total)		n.d.	mg/kg	5.0	EPA 6010	ery3-2019/03/21	bab2-2019/03/26
Antimony (total)		n.d.	mg/kg	10	EPA 6010	ery3-2019/03/21	bab2-2019/03/26

This report was reissued on 2019-06-05 11:09:03 by hlr3 for the following reason:
removed strepto per Will request.
All results are reported on an AS RECEIVED basis., n.d. = not detected , ppm = parts per million, ppm = mg/kg , ppb = parts per billion

For questions please contact:

Craig Ebel
Feed Coordinator
cebel@midwestlabs.com (402)590-2962

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CORN OIL ONE
WILL ATKISSON
4400 E UNIVERSITY AVE
PLEASANT HILL IA 50327

REPORT OF ANALYSIS

For: (36293) CORN OIL ONE
CORN OIL
CORN OIL

Detailed Method Description(s)

Mycotoxin extraction and analysis

Sample analysis follows MWL LCMS 020 which is based on AOAC 2008.02 (modified). Samples are ground to a homogenous consistency and placed in an extraction solution. The extract is allowed to equilibrate and then an aliquot passed through an immunoaffinity column which contains antibodies that are specific for the mycotoxins. The mycotoxins are released from the affinity column and then analyzed by either LC/MS and/or LC/MS/MS which allows identification of the mycotoxins using mass spectrometery and retention time.

ME 042

Analysis follows MWL ME 042 which is based on EPA 6010b, Inductively Coupled Plasma (ICP). A light emission technique where prepared samples are injected into a high energy plasma that forces the elements in the injected sample to emit light energies which are proportional to the level of minerals and metals present. The light is then detected and correlated to the levels of minerals and metals in the original sample.

Full Antibiotic

Sample analysis follows MWL LCMS 011 which is based on FDA LIB 4438. Submitted samples for antibiotics measurement are extracted with trichloroacetic acid and EDTA solutions, reagent water, and methanol. The extracts are cleaned and concentrated using solid phase extraction (SPE). The extracts are injected into a LC/MS/MS for separation and quantification.

ME 067

Samples are analyzed for mercury using MWL ME 067 which is based upon EPA 7471, cold vapor atomic absorption (CVAA).

Samples are prepared via MWL ME 037 that uses a series of digestion steps involving hot mineral acids and oxidizers so as to destroy organic matter and solubilize mercury. The mercury is reduced by use of stannous chloride to elemental mercury that is then aerated to the light path of a mercury light of an atomic absorption spectrometer (AAS). The absorption of the mercury light at 253.7 nm is then correlated to the level of mercury present in the original sample.

Calculation

Analytical results are entered into applicable formulas to provide a calculated result which is reported.

Sample No. 436991/13219931

DIVERSIFIED LABORATORIES, INC.

4150 LAFAYETTE CENTER DRIVE * CHANTILLY, VIRGINIA 20151 * (703) 222-8700

Certificate of Analysis

Submitted by: CORN OIL ONE
Sample: CORN OIL
Client Date: 04/15/2019
Date Received: 04/16/2019
Analysis Requested: LIPID ANALYSIS

FREE FATTY ACIDS (%)	12.44
MOISTURE (%)	0.46
INSOLUBLE MATTER (%)	<0.01
UNSAPONIFIABLE (%)	1.66
TOTAL MIU (%)	2.12
IODINE VALUE (#)	121.02

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Date Processed: 04/16/2019
Date Reported: 4/17/2019

Control Number: 436991

Thomas Scott
Director of Laboratory Services

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DIVERSIFIED LABORATORIES, INC.

4150 LAFAYETTE CENTER DRIVE * CHANTILLY, VIRGINIA 20151 * (703) 222-8700

Certificate of Analysis

Submitted by: CORN OIL ONE
Sample: CORN OIL
Client Date: 04/15/2019
Date Received: 04/16/2019
Analysis Requested: PESTICIDE/PCB SCREEN (mg/kg) CLG_HEC1 (Modified)

ALDRIN	N.D.	HEPTACHLOR	N.D.
CHLORDANE		HEPTACHLOR EPOXIDE	N.D.
alpha-CHLORDANE	N.D.	HEXACHLOROBENZENE	N.D.
gamma-CHLORDANE	N.D.	LINURON	N.D.
OXYCHLORDANE	N.D.	LINDANE	N.D.
TRANS-NONACHLOR	N.D.	METHOXYCHLOR	N.D.
BIFENTHRIN	N.D.	METHYL CHLORPYRIFOS	N.D.
BHC		MIREX	N.D.
alpha-BHC	N.D.	DDT	
beta-BHC	N.D.	p,p'-DDD	N.D.
delta-BHC	N.D.	o,p'-DDD	N.D.
TOTAL BHC	N.D.	p,p'-DDE	N.D.
CARBOPHENOTHION	N.D.	o,p'-DDE	N.D.
CHLORDENE	N.D.	p,p'-DDT	N.D.
CHLORPYRIFOS	N.D.	o,p'-DDT	N.D.
DELTAMETHRIN	N.D.	TOTAL DDT	N.D.
DICHLOFENTHION	N.D.	PARATHION	N.D.
DIELDRIN	N.D.	PERMETHRIN (SUM OF ALL ISOMERS)	N.D.
ENDOSULFAN I	N.D.	PCB	N.D.
ENDOSULFAN II	N.D.	1016,1221, 1232, 1242, 1248, 1254, 1260, 1262, 1268	
ENDOSULFAN SULFATE	N.D.		
ENDRIN	N.D.	RONNEL	N.D.
ENDRIN ALDEHYDE	N.D.	TOXAPHENE	N.D.
ENDRIN KETONE	N.D.	TRANS-NONACHLOR	N.D.
FONOPHOS (DYFONATE)	N.D.		
HBB	N.D.		

Note: Parts per million, ppm = mg/kg.

Accredited by ISO/IEC 17025 (Accreditation #67126) and the USDA-FSIS Accredited Laboratory Program for Pesticides and PCBs.

Date Processed: 4/16/2019
Date Reported: 4/16/2019

Control Number: 436991

Thomas Scott
Director of Laboratory Services

REPORT NUMBER
19-114-9607 v2

REPORT DATE
Apr 25, 2019

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36293

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Apr 16, 2019

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ISSUE DATE
Apr 25, 2019

CORN OIL ONE
WILL ATKISSON
4400 E UNIVERSITY AVE
PLEASANT HILL IA 50327

REPORT OF ANALYSIS

For: (36293) CORN OIL ONE
CORN OIL
CORN OIL

Analysis	Level Found As Received	Units	Reporting Limit	Method	Analyst-Date	Verified-Date
Sample ID: **DC03** Lab Number: **13219931**						
Penicillin residue	n.d.	ppm	0.05	FDA LIB 4438	akj2-2019/04/18	tjp8-2019/04/18
Tetracycline (residue)	n.d.	ppm	0.050	FDA LIB 4438	akj2-2019/04/18	tjp8-2019/04/18
Tylosin (Tylan)	n.d.	ppm	0.05	FDA LIB 4438	akj2-2019/04/18	tjp8-2019/04/18
Virginiamycin residue	n.d.	ppm	0.05	FDA LIB 4438	akj2-2019/04/18	tjp8-2019/04/18
Erythromycin residue	n.d.	ppm	0.05	FDA LIB 4438	akj2-2019/04/22	tjp8-2019/04/22
Aflatoxin B1	n.d.	ppb	1.00	AOAC 2008.02 (mod)	kmc4-2019/04/18	tjp8-2019/04/19
Aflatoxin B2	n.d.	ppb	1.00	AOAC 2008.02 (mod)	kmc4-2019/04/18	tjp8-2019/04/19
Aflatoxin G1	n.d.	ppb	1.00	AOAC 2008.02 (mod)	kmc4-2019/04/18	tjp8-2019/04/19
Aflatoxin G2	n.d.	ppb	1.00	AOAC 2008.02 (mod)	kmc4-2019/04/18	tjp8-2019/04/19
Aflatoxin summation	n.d.	ppb	1.00	Calculation	Auto-2019/04/19	Auto-2019/04/24
DON (Vomitoxin)	n.d.	ppm	0.1	AOAC 2008.02 (mod)	kmc4-2019/04/18	tjp8-2019/04/19
Fumonisin B1	n.d.	ppm	0.1	AOAC 2008.02 (mod)	kmc4-2019/04/18	tjp8-2019/04/19
Fumonisin B2	n.d.	ppm	0.1	AOAC 2008.02 (mod)	kmc4-2019/04/18	tjp8-2019/04/19
Fumonisin B3	n.d.	ppm	0.1	AOAC 2008.02 (mod)	kmc4-2019/04/18	tjp8-2019/04/19
Fumonisin summation	n.d.	ppm	0.10	Calculation	Auto-2019/04/19	Auto-2019/04/24
Arsenic (total)	n.d.	mg/kg	10.0	EPA 6010	ery3-2019/04/19	bab2-2019/04/23
Mercury (total)	n.d.	mg/kg	0.010	EPA 7471	ccm2-2019/04/24	bab2-2019/04/24
Cadmium (total)	n.d.	mg/kg	0.50	EPA 6010	ery3-2019/04/19	bab2-2019/04/23
Lead (total)	n.d.	mg/kg	5.0	EPA 6010	ery3-2019/04/19	bab2-2019/04/23

The result(s) issued on this report only reflect the analysis of the sample(s) submitted.

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CORN OIL ONE
WILL ATKISSON
4400 E UNIVERSITY AVE
PLEASANT HILL IA 50327

REPORT OF ANALYSIS

For: (36293) CORN OIL ONE
CORN OIL
CORN OIL

Analysis	Level Found As Received	Units	Reporting Limit	Method	Analyst-Date	Ver Dat	d-

This report was reissued on 2019-04-25 08:50:13 by hlr3 for the following reason:
amended report.
All results are reported on an AS RECEIVED basis., n.d. = not detected , ppm = parts per million, ppm = mg/kg , ppb = parts per billion

For questions please contact:

Craig Ebel
Feed Coordinator
cebel@midwestlabs.com (402)590-2962

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WILL ATKISSON
4400 E UNIVERSITY AVE
PLEASANT HILL IA 50327

REPORT OF ANALYSIS

For: (36293) CORN OIL ONE
CORN OIL
CORN OIL

Detailed Method Description(s)

Full Antibiotic

Sample analysis follows MWL LCMS 011 which is based on FDA LIB 4438. Submitted samples for antibiotics measurement are extracted with trichloroacetic acid and EDTA solutions, reagent water, and methanol. The extracts are cleaned and concentrated using solid phase extraction (SPE). The extracts are injected into a LC/MS/MS for separation and quantification.

Mycotoxin extraction and analysis

Sample analysis follows MWL LCMS 020 which is based on AOAC 2008.02 (modified). Samples are ground to a homogenous consistency and placed in an extraction solution. The extract is allowed to equilibrate and then an aliquot passed through an immunoaffinity column which contains antibodies that are specific for the mycotoxins. The mycotoxins are released from the affinity column and then analyzed by either LC/MS and/or LC/MS/MS which allows identification of the mycotoxins using mass spectrometery and retention time.

Calculation

Analytical results are entered into applicable formulas to provide a calculated result which is reported.

ME 042

Analysis follows MWL ME 042 which is based on EPA 6010b, Inductively Coupled Plasma (ICP). A light emission technique where prepared samples are injected into a high energy plasma that forces the elements in the injected sample to emit light energies which are proportional to the level of minerals and metals present. The light is then detected and correlated to the levels of minerals and metals in the original sample.

ME 067

Samples are analyzed for mercury using MWL ME 067 which is based upon EPA 7471, cold vapor atomic absorption (CVAA).

Samples are prepared via MWL ME 037 that uses a series of digestion steps involving hot mineral acids and oxidizers so as to destroy organic matter and solubilize mercury. The mercury is reduced by use of stannous chloride to elemental mercury that is then aerated to the light path of a mercury light of an atomic absorption spectrometer (AAS). The absorption of the mercury light at 253.7 nm is then correlated to the level of mercury present in the original sample.

Sample No. DC04-440670/13236636

DIVERSIFIED LABORATORIES, INC.

4150 LAFAYETTE CENTER DRIVE * CHANTILLY, VIRGINIA 20151 * (703) 222-8700

Certificate of Analysis

Submitted by: CORN OIL ONE
Sample: DC04
Client Date: 05/29/2019
Date Received: 05/30/2019
Analysis Requested: LIPID ANALYSIS

FREE FATTY ACIDS (%)	11.92
MOISTURE (%)	0.41
INSOLUBLE MATTER (%)	<0.01
UNSAPONIFIABLE (%)	1.71
TOTAL MIU (%)	2.12
IODINE VALUE (#)	120.37

Date Processed: 05/30/2019
Date Reported: 5/31/2019

Control Number: 440670

Thomas Scott
Director of Laboratory Services

"Service Through Science"

DIVERSIFIED LABORATORIES, INC.

4150 LAFAYETTE CENTER DRIVE * CHANTILLY, VIRGINIA 20151 * (703) 222-8700

Certificate of Analysis

Submitted by: CORN OIL ONE
Sample: SAMPLE ID: DC04
Client Date: 05/17/2019
Date Received: 05/22/2019
Analysis Requested: PESTICIDE/PCB SCREEN (mg/kg) CLG_HEC1 (Modified)

ALDRIN	N.D.	HEPTACHLOR	N.D.
CHLORDANE		HEPTACHLOR EPOXIDE	N.D.
alpha-CHLORDANE	N.D.	HEXACHLOROBENZENE	N.D.
gamma-CHLORDANE	N.D.	LINURON	N.D.
OXYCHLORDANE	N.D.	LINDANE	N.D.
TRANS-NONACHLOR	N.D.	METHOXYCHLOR	N.D.
BIFENTHRIN	N.D.	METHYL CHLORPYRIFOS	N.D.
BHC		MIREX	N.D.
alpha-BHC	N.D.	DDT	
beta-BHC	N.D.	p,p'-DDD	N.D.
delta-BHC	N.D.	o,p'-DDD	N.D.
TOTAL BHC	N.D.	p,p'-DDE	N.D.
CARBOPHENOTHION	N.D.	o,p'-DDE	N.D.
CHLORDENE	N.D.	p,p'-DDT	N.D.
CHLORPYRIFOS	N.D.	o,p'-DDT	N.D.
DELTAMETHRIN	N.D.	TOTAL DDT	N.D.
DICHLOFENTHION	N.D.	PARATHION	N.D.
DIELDRIN	N.D.	PERMETHRIN (SUM OF ALL ISOMERS)	N.D.
ENDOSULFAN I	N.D.	PCB	N.D.
ENDOSULFAN II	N.D.	1016,1221, 1232, 1242, 1248, 1254, 1260, 1262, 1268	
ENDOSULFAN SULFATE	N.D.		
ENDRIN	N.D.	RONNEL	N.D.
ENDRIN ALDEHYDE	N.D.	TOXAPHENE	N.D.
ENDRIN KETONE	N.D.	TRANS-NONACHLOR	N.D.
FONOPHOS (DYFONATE)	N.D.		
HBB	N.D.		

Note: Parts per million, ppm = mg/kg.

Accredited by ISO/IEC 17025 (Accreditation #67126) and the USDA-FSIS Accredited Laboratory Program for Pesticides and PCBs.

Date Processed: 5/22/2019
Date Reported: 5/23/2019

Control Number: 440670

Thomas Scott
Director of Laboratory Services

REPORT NUMBER
19-144-9780 v3

REPORT DATE
Jun 05, 2019

SEND TO
36293

RECEIVED DATE
May 20, 2019

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ISSUE DATE
Jun 05, 2019

CORN OIL ONE
WILL ATKISSON
4400 E UNIVERSITY AVE
PLEASANT HILL IA 50327

REPORT OF ANALYSIS

For: (36293) CORN OIL ONE
CORN OIL
CORN OIL

Analysis	Level Found As Received	Units	Reporting Limit	Method	Analyst-Date	Verified-Date
Sample ID: **DCO 4** Lab Number: **13236636**						
Aflatoxin B1	n.d.	ppb	1.00	AOAC 2008.02 (mod)	kmc4-2019/05/22	tjp8-2019/05/23
Aflatoxin B2	n.d.	ppb	1.00	AOAC 2008.02 (mod)	kmc4-2019/05/22	tjp8-2019/05/23
Aflatoxin G1	n.d.	ppb	1.00	AOAC 2008.02 (mod)	kmc4-2019/05/22	tjp8-2019/05/23
Aflatoxin G2	n.d.	ppb	1.00	AOAC 2008.02 (mod)	kmc4-2019/05/22	tjp8-2019/05/23
Aflatoxin summation	n.d.	ppb	1.00	Calculation	Auto-2019/05/23	Auto-2019/05/24
DON (Vomitoxin)	n.d.	ppm	0.1	AOAC 2008.02 (mod)	kmc4-2019/05/22	tjp8-2019/05/23
Fumonisin B1	n.d.	ppm	0.1	AOAC 2008.02 (mod)	kmc4-2019/05/22	tjp8-2019/05/23
Fumonisin B2	n.d.	ppm	0.1	AOAC 2008.02 (mod)	kmc4-2019/05/22	tjp8-2019/05/23
Fumonisin B3	n.d.	ppm	0.1	AOAC 2008.02 (mod)	kmc4-2019/05/22	tjp8-2019/05/23
Fumonisin summation	n.d.	ppm	0.10	Calculation	Auto-2019/05/23	Auto-2019/05/24
Penicillin residue	n.d.	ppm	0.05	FDA LIB 4438	akj2-2019/05/24	tjp8-2019/05/24
Tetracycline (residue)	n.d.	ppm	0.050	FDA LIB 4438	akj2-2019/05/24	tjp8-2019/05/24
Tylosin (Tylan)	n.d.	ppm	0.05	FDA LIB 4438	akj2-2019/05/24	tjp8-2019/05/24
Virginiamycin residue	n.d.	ppm	0.05	FDA LIB 4438	akj2-2019/05/24	tjp8-2019/05/24
Erythromycin residue	n.d.	ppm	0.05	FDA LIB 4438	akj2-2019/05/24	tjp8-2019/05/24
Arsenic (total)	n.d.	mg/kg	10.0	EPA 6010	ery3-2019/05/22	kkh9-2019/05/23
Mercury (total)	n.d.	mg/kg	0.010	EPA 7471	ccm2-2019/05/23	kkh9-2019/05/23
Cadmium (total)	n.d.	mg/kg	0.50	EPA 6010	ery3-2019/05/22	kkh9-2019/05/23
Lead (total)	n.d.	mg/kg	5.0	EPA 6010	ery3-2019/05/22	kkh9-2019/05/23

The result(s) issued on this report only reflect the analysis of the sample(s) submitted.

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CORN OIL ONE
WILL ATKISSON
4400 E UNIVERSITY AVE
PLEASANT HILL IA 50327

REPORT OF ANALYSIS

For: (36293) CORN OIL ONE
CORN OIL
CORN OIL

Analysis	Level Found As Received	Units	Reporting Limit	Method	Analyst-Date	Verified-Date
Sample ID: DCO 4 Lab Number: **13236636** (con't)						
Antimony (total)	n.d.	mg/kg	10	EPA 6010	ery3-2019/05/22	kkh9-2019/05/23

This report was reissued on 2019-06-05 11:10:04 by hlr3 for the following reason:
removed strepto per WIll.
All results are reported on an AS RECEIVED basis., n.d. = not detected , ppm = parts per million, ppm = mg/kg , ppb = parts per billion

For questions please contact:

Craig Ebel
Feed Coordinator
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PLEASANT HILL IA 50327

REPORT OF ANALYSIS

For: (36293) CORN OIL ONE
CORN OIL
CORN OIL

Detailed Method Description(s)

Mycotoxin extraction and analysis

Sample analysis follows MWL LCMS 020 which is based on AOAC 2008.02 (modified). Samples are ground to a homogenous consistency and placed in an extraction solution. The extract is allowed to equilibrate and then an aliquot passed through an immunoaffinity column which contains antibodies that are specific for the mycotoxins. The mycotoxins are released from the affinity column and then analyzed by either LC/MS and/or LC/MS/MS which allows identification of the mycotoxins using mass spectrometery and retention time.

Calculation

Analytical results are entered into applicable formulas to provide a calculated result which is reported.

Full Antibiotic

Sample analysis follows MWL LCMS 011 which is based on FDA LIB 4438. Submitted samples for antibiotics measurement are extracted with trichloroacetic acid and EDTA solutions, reagent water, and methanol. The extracts are cleaned and concentrated using solid phase extraction (SPE). The extracts are injected into a LC/MS/MS for separation and quantification.

ME 042

Analysis follows MWL ME 042 which is based on EPA 6010b, Inductively Coupled Plasma (ICP). A light emission technique where prepared samples are injected into a high energy plasma that forces the elements in the injected sample to emit light energies which are proportional to the level of minerals and metals present. The light is then detected and correlated to the levels of minerals and metals in the original sample.

ME 067

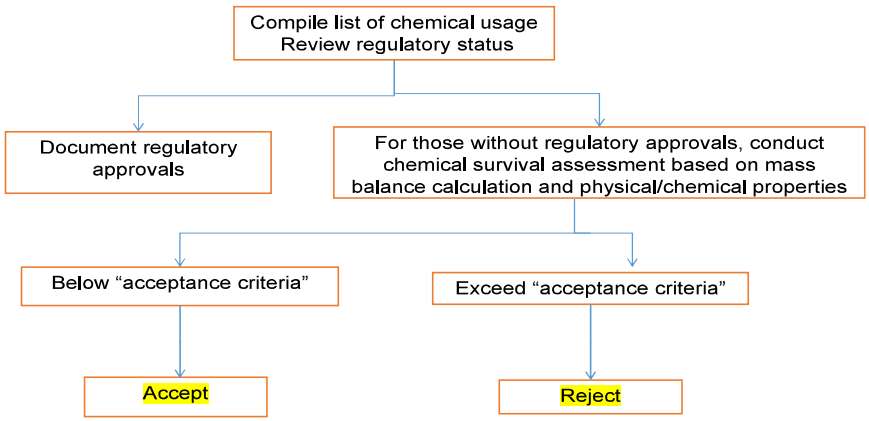
Samples are analyzed for mercury using MWL ME 067 which is based upon EPA 7471, cold vapor atomic absorption (CVAA).

Samples are prepared via MWL ME 037 that uses a series of digestion steps involving hot mineral acids and oxidizers so as to destroy organic matter and solubilize mercury. The mercury is reduced by use of stannous chloride to elemental mercury that is then aerated to the light path of a mercury light of an atomic absorption spectrometer (AAS). The absorption of the mercury light at 253.7 nm is then correlated to the level of mercury present in the original sample.

Appendix D. Compliance Assessment Procedure For Chemical Impurities

For the "other chemical" impurity parameter, to ensure that the crude oil is suitable for further refinement with the CO1™ and conventional RBD processes to produce edible corn oil, a chemical use inventory at the dry grind ethanol plant is first carried out. Then a regulatory compliance check is conducted to identify chemicals present in the corn-ethanol production that have the appropriate regulatory approvals (i.e., approved for use as food additive, GRAS for its intended uses, prior-sanctioned, etc.). For chemicals present in the production of corn-ethanol production that do not pass the regulatory check and they are subject to a chemical survival assessment based on mass balance calculation and physical/chemical properties to determine a hypothetical worst-case concentration that could be present in the crude corn oil. These hypothetical worst-case concentrations are compared to the acceptance limit of 25 ppb for these chemical impurities. Figure D-1 outlines this stepwise assessment process.

Figure D-1. Compliance Assessment Approach



Corn Oil ONE's crude corn oil supplier and partner, ICM Biofuels, followed the above assessment step. Starting with a chemical inventory, ICM Biofuels documented the regulatory status of each chemical used in its production plant (see Table D-1).

Table D-1. Substances in Crude Corn Oil with Regulatory Approval for Use in Food

Function	Substances	Regulatory Status
Enzyme	Alpha Amylase	21 CFR §172.892 Food starch-modified - includes reference to enzymes
Enzyme	Glucoamylase	21 CFR §172.892 Food starch-modified - includes reference to enzymes; 21 CFR §173.357 Materials used as fixing agents in the immobilization of

Function	Substances	Regulatory Status
		enzyme preparations - includes reference to glucoamylase
Enzyme	Protease	21 CFR §184.1027 Mixed carbohydrase and protease enzyme product
Additives	Sulfuric Acid	21 CFR §184.1095 Sulfuric acid
Additives	Caustic Soda	21 CFR §184.1763 Sodium hydroxide (caustic soda)
Additives	Urea	21 CFR §184.1923 Urea
Yeast	Ethanol Red Active Dry Yeast	21 CFR §172.896 Dried yeasts
Feedstock	City Water	-
Feedstock	Corn	-
Feedstock	Hominy	-
Feedstock	Masa Water	-

Source: ICM Biofuels

For the chemicals used that do not have the appropriate regulatory status (see Table D-2), ICM, Inc. conducted a mass balance calculation at ICM Biofuels taking into account physical/chemical properties where appropriate. All theoretical worst-case concentrations meet Corn Oil ONE's acceptance limit (below 25 ppb). It should be noted that these mass balance calculations coupled with physical/chemical properties provide conservative worst-case estimates based on mass flow splits at the various points in the process.

Table D-2. Substances in Crude Corn Oil with Mass Balance Calculation

Label	Substances	Theoretical Maximum Conc. In Crude Corn Oil (ppb)
A	VOxOUT 70C CO2 Scrubber Chemical	12
B	Boiler MP Plus Scale Inhibitor Boiler Chemical	4
C	BWT 200 B Alkalinity Builder Boiler Chemical	10
D	Oxigon 200 Oxygen Scavenger Boiler Chemical	7
E	RLT 19 Condensate Treatment Boiler Chemical	10
F	Bulab 8170GR Evaporator Anti-Scalant	20
G	FermaSure XL	14
J	ProClean PC 106 CO2 Scrubber Cleaner	(only used to clean in shutdown)
K	PhiBro AC Clean-in-Place Chemical	1
L	PhibroBreak Corn Oil Additive	3

Source: ICM, Inc.

Theoretical mass balance calculation conducted by ICM Biofuels

Additive A is introduced in the CO2 Scrubber. The CO2 Scrubber bottoms are sent to the Cook Water Tank, which is then used to hydrate corn into mash. The mash is sent to Fermentation. In the case of poor fermentation, additive G is introduced to the process in a Fermentation Tank. Once the fermenting process is complete, the contents of the Fermentation Tank (now called

beer) are sent to the Beer Column. The Beer Column bottoms are sent to centrifuges and the separated liquid portion, called Centrate, is split between Backset and Thin Stillage. The Thin Stillage is processed in the Evaporators and part of it is drawn off to extract Corn Oil. So, through this process flow path, Additive A and G can enter the Corn Oil.

Additive F is introduced to the steam side of the Evaporators. The steam condensate is then sent to the Boiler. At the Boiler, additives B, C, D, and E are introduced. Steam condensate from the Evaporators and from other sections of the plant is re-vaporized in the Boiler into steam and sent back to the process. A portion of the steam is directly injected into the mash in the Cook section of the plant. The mash then is sent to Fermentation and the process flow path continues the same as written above, which allows additives B, C, D, E, and F to enter the Corn Oil.

Through the process flow calculation, the additive amount has been determined by using ratios alongside the process mass flow splits. For example, the Centrate flow is 211,300 lb/hr with Additive A flow of 9.62 lb/hr. The Centrate splits between Backset and Thin Stillage. The Thin Stillage has a flow of 137,300 lb/hr. So, Additive A flow in the Thin Stillage will be determined through the following calculation:

$$Additive\ A_{TS} = \frac{Thin\ Stillage\ Flow}{Centrate\ Flow} * Additive\ A_C = \frac{137{,}300}{211{,}300} * 9.62 = 6.25\ lb/hr$$

There are also recycle loops in the process flow. For example, the Backset ends up being sent to Fermentation and thus recycles the Additives, causing some concentration build up. This has been accounted for in the calculations.

Additive J is used with the Clean In Place (CIP) fluid during shutdown to clean the CO2 Scrubber. After cleaning, the CIP with additive is routed away before startup of the regular production process and does not have a flow path to enter the corn oil.

Additive K is used with CIP in concentrations up to 4%. It can be transferred to the Beer Well, then to the Beer Column and thus can follow the same flow path to the corn oil as above.

Additive L is introduced to the thin stillage as it enters Evaporation, so some can end up in the corn oil.

Conclusions

Corn Oil ONE's acceptance criteria require additive concentration to be under 25 ppb. All additives are below the limit.

It should also be noted that these calculations were based on mass balance calculation and physical/chemical properties of the additives where appropriate. For instance, the hydrophilic nature of many of these additives are expected to result in their partitioning into the water phase instead of the oil phase.

For example, the above VOxOUT 70C CO2 Scrubber Chemical is highly soluble in water and does not go with the oil phase. The calculation incorporated experts in the field of water chemistry taking a conservative expert opinion that more than 95% of the product would go with the water phase, so that was taken into account as well as that the oil is separated at the most concentrated evaporator providing the highest concentration of residual water and therefore additive in the oil as the assumption. For example, if the oil was separated in a previous

evaporator as most facilities are; then the concentration would be reduced by 35% reducing the "worst case" table calculation from 12 to 8 ppb. These conservative assumptions show that the theoretical maximum concentration in the oil stream remain well below the acceptance limit..

Appendix E. Thermophysical and Chemical Properties of Mycotoxin and Antibiotics, and Their Fate Through CO1™ and Conventional RBD Processing Steps

Thermo-physical and Chemical Characteristics

			Stability					Solubility						
		Melting Point (°F)	**Decomposition Temperature (°F, unless noted)**	**Acidic**	**Alkaline**	**Ultraviolet**	**Alcohol**	**Water (mg/L @ 25°C)**	**Ethanol (mg/L @ 25°C)**	**Acetone (mg/L @ 25°C)**	**Ethyl Ether (mg/L @ 25°C)**	**Vapor Pressure (mmHg @ 25 °C)**	**Adsorption Potential**	**Boiling Point (°F @ SP)**
Mycotoxins	Aflatoxin	515	<515, partial @ 482, 64% reduction @ 176	Unstable	Unstable	Unstable	Stable	16.14	Soluble			2.65E-10	Bentonite: Near complete Adsorption	982.4
	Deoxynivalenol (DON)	305	Degradation in the presence of sugar and starch at 392 F. In frying applications, 28 to 20% reduction between 336 and 469 C	DON sulfonate 3: Stable	DON sulfonate 1 & 2: Stable, DON sulfonate 3: Unstable			55000	10			1.73E-09	Bentonite: 20% Adsorption	
	Fumonisin	258.8	347, dependent on the process material and method		Unstable	Stable		25000				3.06E-11	Adsoption range is 30% to 100%.	
Antibiotics	Virginiamycin	239 to 248	280-284, Rapid inactivation at >9.5 pH		Unstable			Soluble	Soluble			9.6E-22 @ 22C	Adsorps in soil at approx. Koc = 980	
	Penicilin			Unstable	Unstable		Unstable in alcohol fermentation (35 deg. C)	Penicillin G: 100000	Soluble		Soluble		Adsorps in soil at approx Koc = 570	
	Erythromycin	375.8	pH < 4, over heating			Stable		2000	Soluble	Soluble	Soluble	2.12E-25		
	Tylosin	262.4 to 269.2	over heating	Unstable @ < pH = 2	Unstable			5000	Soluble	Soluble	Soluble	1.98E-34	Adsorps in sandy loam at approx. Koc = 79880, 5664, 553 and 771, and silty clay, clay, sand soils Koc = 1350-95532	
	Tetracycline	338	Decomposition upon heating	Unstable @ < pH = 2	Unstable	Unstable		231	20000		Insoluble			

Processing Steps - CO1 Process Steps

		Neutralization	Acidification	Oil Drying	Oil Stripper	Crystallization	Wax Separation
		Ethanol, Sodium Hydroxide, RO water	Sulfuric Acid or Citric Acid				
		160	163	230	260	45	75
		755	755	206	206	755	755
		552	17	54	9	1332	10
Mycotoxins	Aflatoxin	50:50 Fractionation by Mass Fraction; Unstable	Unstable	Will not Vaporize	Will not Vaporize	No Effect	50:50 Fractionation by Mass Fraction
	Deoxynivalenol (DON)	50:50 Fractionation by Mass Fraction	Stable	Will not Vaporize	Will not Vaporize	No Effect	50:50 Fractionation by Mass Fraction
	Fumonisin	0:100; Oil:H2O/ETOH Fractionation; Unstable		Will not Vaporize	Will not Vaporize	No Effect	50:50 Fractionation by Mass Fraction
Antibiotics	Virginiamycin	0:100; Oil:H2O/ETOH Fractionation; Unstable		Will not Vaporize	Will not Vaporize	No Effect	50:50 Fractionation by Mass Fraction
	Penicilin	0:100; Oil:H2O/ETOH Fractionation; Unstable	Unstable			No Effect	50:50 Fractionation by Mass Fraction
	Erythromycin	0:100; Oil:H2O/ETOH Fractionation		Will not Vaporize	Will not Vaporize	No Effect	50:50 Fractionation by Mass Fraction
	Tylosin	0:100; Oil:H2O/ETOH Fractionation; Unstable	Unstable	Will not Vaporize	Will not Vaporize	No Effect	50:50 Fractionation by Mass Fraction
	Tetracycline	0:100; Oil:H2O/ETOH Fractionation; Unstable	Unstable	Will not Vaporize	Will not Vaporize	No Effect	50:50 Fractionation by Mass Fraction

Color code indicates a compound will be completely removed in this processing step by mean of physical or chemical means

Processing Steps - RBD Process Steps

		Degumming	Dryer	Caustic Refining	Water Wash	Bleaching	Winterization	Deodorization
		Phosphoric Acid, Citric Acid		11% NaOH solution	5-8 w% Water	0.5% Bleaching earth, 0.2% DE		0.5-2% steam
		140-150	185-190	165	190-195	230-250		480-500
			50			<36		3 to 6
		30-40		8-12	8-10	30-45		20-30
Mycotoxins	Aflatoxin	Unstable	Will not Vaporize	Unstable	50:50 Fractionation by Mass Fraction	Near 100% Adsorbed	No Effect	
	Deoxynivalenol (DON)	Stable	Will not Vaporize	Stable	0:100; Oil:H20 Fractionation	Near 20% Adsorbed	No Effect	
	Fumonisin		Will not Vaporize		0:100; Oil:H2O Fractionation	30% Adsoption		
Antibiotics	Virginiamycin		Will not Vaporize	Unstable	0:100; Oil:H20 Fractionation			100% Will vaporize
	Penicilin	Unstable		Unstable	0:100; Oil:H20 Fractionation			
	Erythromycin		Will not Vaporize		0:100; Oil:H20 Fractionation			
	Tylosin		Will not Vaporize	Unstable	0:100; Oil:H20 Fractionation			
	Tetracycline			Unstable	0:100; Oil:H20 Fractionation			

Color code indicates a compound will be completely removed in this processing step by mean of physical or chemical means

Appendix F. Removal of Impurities– Certificate of Analysis for Pre and Post- Processing

A) Crude corn oil sample –Prior to Processing

REPORT NUMBER
19-091-9203 v2
REPORT DATE
Apr 02, 2019
SEND TO
36293
RECEIVED DATE
Mar 22, 2019

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ISSUE DATE
Apr 02, 2019

CORN OIL ONE
WILL ATKISSON
4400 E UNIVERSITY AVE
PLEASANT HILL IA 50327

REPORT OF ANALYSIS
For: (36293) CORN OIL ONE
CORN OIL
CORN OIL

Analysis	Level Found As Received	Units	Reporting Limit	Method	Analyst-Date	Verified-Date
Sample ID: NO ID Lab Number: **13206616** (con't)						
Tetracycline (residue)	n.d.	ppm	0.050	FDA LIB 4438	akj2-2019/04/01	tp6-2019/04/01
Tylosin (Tylan)	n.d.	ppm	0.05	FDA LIB 4438	akj2-2019/03/29	tp6-2019/04/01
Virginiamycin residue	n.d.	ppm	0.05	FDA LIB 4438	akj2-2019/03/29	tp6-2019/04/01
Streptomycin residue	n.d.	ppm	0.05	FDA LIB 4438 (mod)	akj2-2019/03/28	tp6-2019/03/28
Erythromycin residue	0.09	ppm	0.05	FDA LIB 4438	akj2-2019/03/29	tp6-2019/04/01

This report was reissued on 2019-04-02 16:12:51 by hlr3 for the following reason:
edited report per client request.
All results are reported on an AS RECEIVED basis., n.d. = not detected , ppm = parts per million, ppm = mg/kg , ppb = parts per billion

For questions please contact:
[redacted]
Craig Ebel
Feed Coordinator
cebel@midwestlabs.com (402)590-2962

The result(s) noted on this report only reflect the analysis of the sample(s) submitted.

B) After processing through the CO1 and Conventional RBD Process

REPORT NUMBER
19-209-9020
REPORT DATE
Jul 28, 2019
SEND TO
36293
RECEIVED DATE
Jul 18, 2019

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PAGE 1/2
ISSUE DATE
Jul 28, 2019

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PLEASANT HILL IA 50327

REPORT OF ANALYSIS
For: (36293) CORN OIL ONE
LIQUID ANALYSIS
LIQUID

Analysis	Level Found As Received	Units	Reporting Limit	Method	Analyst-Date	Verified-Date
Sample ID: **COZ BATCH 1** Lab Number: **13267319** Date Sampled: **2019-07-15**						
Penicillin residue	n.d.	ppm	0.05	FDA LIB 4438	kmc4-2019/07/28	ak|2-2019/07/28
Tetracycline (residue)	n.d.	ppm	0.050	FDA LIB 4438	kmc4-2019/07/28	ak|2-2019/07/28
Tylosin (Tylan)	n.d.	ppm	0.05	FDA LIB 4438	kmc4-2019/07/22	ak|2-2019/07/22
Virginiamycin residue	n.d.	ppm	0.05	FDA LIB 4438	kmc4-2019/07/22	ak|2-2019/07/22
Erythromycin residue	n.d.	ppm	0.05	FDA LIB 4438	kmc4-2019/07/22	ak|2-2019/07/22

All results are reported on an AS RECEIVED basis.. n.d. = not detected . ppm = parts per million. ppm = mg/kg

For questions please contact:

Sara Sterkel-Colombo
Account Manager
scolombo@midwestlabs.com ()-

Appendix G. Certificates of Analysis for COZ Corn Oil

Eurofins Scientific Inc.
Nutrition Analysis Center
2200 Rittenhouse Street, Suite 150
Des Moines, IA 50321
Tel:+1 515 265 1461
Fax:+1 515 266 5453

Eurofins Sample Code: 464-2018-02140638
Sample Description: Corn Oil
Client Sample Code: COZ-Batch 1
PO Number:
Client Code: QD0006388

Entry Date: 02/14/2018
Reporting Date: 02/22/2018

Corn Oil One
attn: Mohan Dasari
10868 189th St. Bldg 13
Council Bluffs, IA 51503

Corn Oil One
Attn: Lab Reports
10868 189th St. Bldg 13
Council Bluffs, IA 51503

CERTIFICATE OF ANALYSIS

AR-18-QD-026303-01

Test	Result	
QD143 - Moisture & Volatiles By Air Oven		**Completed: 02/20/2018**
AOCS Ca 2c-25		
Moisture & Volatiles By Air Oven	0.05 %	
QD06S - Lead (Mwd-ICP-MS)		**Completed: 02/17/2018**
J. AOAC vol. 90 (2007) 844-856 (Mod)		
* Lead (Pb)	<0.010 mg/kg	
QD06Q - Arsenic (Mwd-ICP-MS)		**Completed: 02/17/2018**
J. AOAC vol. 90 (2007) 844-856 (Mod)		
* Arsenic (As)	<0.010 mg/kg	
QD239 - Unsaponifiable Matter		**Completed: 02/16/2018**
AOCS Ca 6a-40		
* Unsaponifiable matter	1.25 %	
QD094 - Free Fatty Acids (FFA)		**Completed: 02/17/2018**
AOCS Ca 5a-40		
* FFA (Free Fatty Acids)	0.09 %	
QD103 - Peroxide Value (PV)		**Completed: 02/16/2018**
AOCS Cd 8-53		
* Peroxide Value - Initial	1.8 meq/kg	
QD106 - Iodine Value		**Completed: 02/19/2018**
AOCS Cd 1d-92		
* Iodine value	121.9	
QD04J - Lovibond Color - Lovibond Scale		**Completed: 02/16/2018**
AOCS Cc 13j-97, Cc 13e-92		
Lovibond Color - Lovibond Scale	4.2R, 70.0Y, 0.0B, 2.0N	
QA216 - Cold Test		**Completed: 02/20/2018**
AOCS Cc 11-53		
Cold test, 0°C	Pass, >8 Hours	
QD05C - Fatty Acids-Full Omega 9,6&3 & Trans %W/W (AOCS)		**Completed: 02/22/2018**
AOAC 996.06		
* Fatty Acid Profile	Reported as Fatty Acids	
* C4:0 (Butyric Acid)	<0.01 %	
* C6:0 (Caproic acid)	<0.01 %	
* C8:0 (Caprylic acid)	<0.01 %	
* C10:0 (Capric acid)	<0.01 %	
* C11:0 (Undecanoic acid)	<0.01 %	

Eurofins Sample Code: 464-2018-02140638
Client Sample Code: COZ-Batch 1

Test	Result
QD05C - Fatty Acids-Full Omega 9,6&3 & Trans %W/W (AOCS) (Cont.)	**Completed: 02/22/2018**
AOAC 996.06	
* C12:0 (Lauric Acid)	<0.01 %
* C14:0 (Myristic acid)	0.03 %
* C14:1 (Myristoleic acid)	<0.01 %
* C15:0 (Pentadecanoic acid)	0.01 %
* C15:1 (Pentadecenoic acid)	<0.01 %
* C16:0 (Palmitic Acid)	10.34 %
* C16:1 Omega 7	0.10 %
* C16:1 Total (Palmitoleic Acid + isomers)	0.15 %
* C16:2 (Hexadecadienoic Acid)	<0.01 %
* C16:3 (Hexadecatrienoic Acid)	<0.01 %
* C 16:4 (Hexadecatetraenoic Acid)	<0.01 %
* C17:0 (Margaric Acid)	0.06 %
* C17:1 (Heptadecenoic Acid)	0.03 %
* C18:0 (Stearic Acid)	1.57 %
* C18:1 (Vaccenic acid)	0.57 %
* C18:1 Omega 9 (Oleic Acid)	27.02 %
* C18:1, Total (Oleic Acid + isomers)	27.64 %
* C18:2 Omega 6 (Linoleic Acid)	50.79 %
* C18:2, Total (Linoleic Acid + isomers)	51.16 %
* C18:3 Omega 3 (Alpha Linolenic Acid)	1.08 %
* C18:3 Omega 6 (Gamma Linolenic Acid)	<0.01 %
* C18:3, Total (Linolenic Acid + isomers)	1.08 %
* C18:4 Omega 3 (Octadecatetraenoic Acid)	<0.01 %
* C18:4 Total (Octadecatetraenoic Acid)	<0.01 %
* C20:0 (Arachidic Acid)	0.33 %
* C20:1 Omega 9 (Gondoic Acid)	0.23 %
* C20:1 Total (Gondoic Acid + isomers)	0.37 %
* C20:2 Omega 6	0.04 %
* C20:2 Total (Eicosadienoic Acid)	0.04 %
* C20:3 Omega 3	<0.01 %
* C20:3 Omega 6	<0.01 %
* C20:3, Total (Eicosatrienoic Acid)	<0.01 %
* C20:4 Omega 3	<0.01 %
* C20:4 Omega 6 (Arachidonic Acid)	<0.01 %
* C20:4, Total (Eicosatetraenoic Acid)	<0.01 %
* C20:5 Omega 3 (Eicosapentaenoic Acid)	<0.01 %
* C21:5 Omega 3 (Heneicosapentaenoic Acid)	<0.01 %
* C22:0 (Behenic Acid)	0.12 %
* C22:1 Omega 9 (Erucic Acid)	0.01 %
* C22:1 Total (Erucic Acid + isomers)	0.01 %
* C22:2 Docosadienoic Omega 6	<0.01 %
* C22:3 Docosatrienoic, Omega 3	0.02 %
* C22:4 Docosatetraenoic Omega 6	<0.01 %
* C22:5 Docosapentaenoic Omega 3	<0.01 %
* C22:5 Docosapentaenoic Omega 6	<0.01 %
* C22:5 Total (Docosapentaenoic Acid)	<0.01 %
* C22:6 Docosahexaenoic Omega 3	<0.01 %
* C24:0 (Lignoceric Acid)	0.16 %
* C24:1 Omega 9 (Nervonic Acid)	<0.01 %
* C24:1 Total (Nervonic Acid + isomers)	0.01 %
* Total Omega 3 Isomers	1.10 %
* Total Omega 5 Isomers	<0.01 %
* Total Omega 6 Isomers	50.83 %

Eurofins Sample Code: 464-2018-02140638
Client Sample Code: COZ-Batch 1

Test	Result	
QD05C - Fatty Acids-Full Omega 9,6&3 & Trans %W/W (AOCS) (Cont.)		**Completed: 02/22/2018**
AOAC 996.06		
* Total Omega 7 Isomers	0.67 %	
* Total Omega 9 Isomers	27.43 %	
* Total Monounsaturated Fatty Acids	28.17 %	
* Total Polyunsaturated Fatty Acids	52.27 %	
* Total Saturated Fatty Acids	12.63 %	
* Total Trans Fatty Acids	0.07 %	
* Total Fat as Triglycerides	97.39 %	
* Total Fatty Acids	93.15 %	
UM0B1 - Escherichia coli - AOAC 991.14		**Completed: 02/20/2018**
AOAC 991.14		
* E. coli	< 10 cfu/g	
UMABD - Enterobacteriaceae - AOAC 2003.01		**Completed: 02/20/2018**
AOAC 2003.01		
* Enterobacteriaceae	< 10 cfu/g	
UMAEK - Salmonella - AOAC 2003.09		**Completed: 02/20/2018**
AOAC 2003.09		
* Salmonella spp.	Not Detected /25 g	
UMFPA - Moulds - AOAC 997.02		**Completed: 02/20/2018**
AOAC 997.02		
Mold	< 10 cfu/g	
Yeast	< 10 cfu/g	
UMHY9 - Aerobic Plate Count - AOAC 990.12		**Completed: 02/20/2018**
AOAC 990.12		
* Aerobic Plate Count	< 10 cfu/g	

**The test result is covered by our current A2LA accreditation.*

Respectfully Submitted,
Eurofins Scientific Inc.

David Gross
Support Services Manager

Biological Testing
Cert:3329:01

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Eurofins Scientific, Inc. Measurement of Uncertainty can be obtained upon request.

Eurofins Scientific Inc.
Nutrition Analysis Center
2200 Rittenhouse Street, Suite 150
Des Moines, IA 50321
Tel:+1 515 265 1461
Fax:+1 515 266 5453

Eurofins Sample Code: 464-2018-04050457
Sample Description: Corn Oil
Client Sample Code: COZ - Batch 5
PO Number:
Client Code: QD0006388

Entry Date: 04/05/2018
Reporting Date: 05/18/2018

Corn Oil One
attn: Mohan Dasari
10868 189th St. Bldg 13
Council Bluffs, IA 51503

Corn Oil One
Attn: Lab Reports
10868 189th St. Bldg 13
Council Bluffs, IA 51503

CERTIFICATE OF ANALYSIS

AR-18-QD-052468-02

This analytical report supersedes AR-18-QD-052468-01.

Test	Result	
QD143 - Moisture & Volatiles By Air Oven		**Completed: 04/11/2018**
AOCS Ca 2c-25		
Moisture & Volatiles By Air Oven	0.07 %	
QD06T - Cadmium (Mwd-ICP-MS)		**Completed: 05/18/2018**
J. AOAC vol. 90 (2007) 844-856 (Mod)		
* Cadmium (Cd)	<0.010 mg/kg	
QD06S - Lead (Mwd-ICP-MS)		**Completed: 04/10/2018**
J. AOAC vol. 90 (2007) 844-856 (Mod)		
* Lead (Pb)	<0.010 mg/kg	
QD06R - Mercury (Mwd-ICP-MS, Most Matrices)		**Completed: 05/18/2018**
J. AOAC vol. 90 (2007) 844-856 (Mod)		
* Mercury (Hg)	<0.010 mg/kg	
QD06Q - Arsenic (Mwd-ICP-MS)		**Completed: 04/10/2018**
J. AOAC vol. 90 (2007) 844-856 (Mod)		
* Arsenic (As)	<0.010 mg/kg	
QD239 - Unsaponifiable Matter		**Completed: 04/09/2018**
AOCS Ca 6a-40		
* Unsaponifiable matter	1.14 %	
QD094 - Free Fatty Acids (FFA)		**Completed: 04/10/2018**
AOCS Ca 5a-40		
* FFA (Free Fatty Acids)	0.10 %	
QD103 - Peroxide Value (PV)		**Completed: 04/09/2018**
AOCS Cd 8-53		
* Peroxide Value - Initial	0.4 meq/kg	
QD106 - Iodine Value		**Completed: 04/07/2018**
AOCS Cd 1d-92		
* Iodine value	123.3	
QD04J - Lovibond Color - Lovibond Scale		**Completed: 04/09/2018**
AOCS Cc 13j-97, Cc 13e-92		
Lovibond Color - Lovibond Scale	1.1R, 22.0Y, 0.0B, 0.0N	
QA216 - Cold Test		**Completed: 04/10/2018**
AOCS Cc 11-53		
Cold test, 0°C	Pass. >8 Hours	

Eurofins Sample Code: 464-2018-04050457
Client Sample Code: COZ - Batch 5

Test	Result
QD05C - Fatty Acids-Full Omega 9,6&3 & Trans %W/W (AOCS)	**Completed: 04/12/2018**
AOAC 996.06	
* Fatty Acid Profile	Reported as Fatty Acids
* C4:0 (Butyric Acid)	<0.01 %
* C6:0 (Caproic acid)	<0.01 %
* C8:0 (Caprylic acid)	<0.01 %
* C10:0 (Capric acid)	<0.01 %
* C11:0 (Undecanoic acid)	<0.01 %
* C12:0 (Lauric Acid)	<0.01 %
* C14:0 (Myristic acid)	0.03 %
* C14:1 (Myristoleic acid)	<0.01 %
* C15:0 (Pentadecanoic acid)	0.01 %
* C15:1 (Pentadecenoic acid)	<0.01 %
* C16:0 (Palmitic Acid)	10.37 %
* C16:1 Omega 7	0.10 %
* C16:1 Total (Palmitoleic Acid + isomers)	0.17 %
* C16:2 (Hexadecadienoic Acid)	<0.01 %
* C16:3 (Hexadecatrienoic Acid)	<0.01 %
* C 16:4 (Hexadecatetraenoic Acid)	<0.01 %
* C17:0 (Margaric Acid)	0.06 %
* C17:1 (Heptadecenoic Acid)	0.03 %
* C18:0 (Stearic Acid)	1.54 %
* C18:1 (Vaccenic acid)	0.55 %
* C18:1 Omega 9 (Oleic Acid)	25.91 %
* C18:1, Total (Oleic Acid + isomers)	26.53 %
* C18:2 Omega 6 (Linoleic Acid)	51.15 %
* C18:2, Total (Linoleic Acid + isomers)	51.61 %
* C18:3 Omega 3 (Alpha Linolenic Acid)	0.97 %
* C18:3 Omega 6 (Gamma Linolenic Acid)	<0.01 %
* C18:3, Total (Linolenic Acid + isomers)	0.97 %
* C18:4 Omega 3 (Octadecatetraenoic Acid)	<0.01 %
* C18:4 Total (Octadecatetraenoic Acid)	<0.01 %
* C20:0 (Arachidic Acid)	0.33 %
* C20:1 Omega 9 (Gondoic Acid)	0.22 %
* C20:1 Total (Gondoic Acid + isomers)	0.38 %
* C20:2 Omega 6	0.04 %
* C20:2 Total (Eicosadienoic Acid)	0.04 %
* C20:3 Omega 3	<0.01 %
* C20:3 Omega 6	<0.01 %
* C20:3, Total (Eicosatrienoic Acid)	<0.01 %
* C20:4 Omega 3	<0.01 %
* C20:4 Omega 6 (Arachidonic Acid)	<0.01 %
* C20:4, Total (Eicosatetraenoic Acid)	<0.01 %
* C20:5 Omega 3 (Eicosapentaenoic Acid)	<0.01 %
* C21:5 Omega 3 (Heneicosapentaenoic Acid)	<0.01 %
* C22:0 (Behenic Acid)	0.11 %
* C22:1 Omega 9 (Erucic Acid)	<0.01 %
* C22:1 Total (Erucic Acid + isomers)	<0.01 %
* C22:2 Docosadienoic Omega 6	<0.01 %
* C22:3 Docosatrienoic, Omega 3	0.02 %
* C22:4 Docosatetraenoic Omega 6	<0.01 %
* C22:5 Docosapentaenoic Omega 3	<0.01 %
* C22:5 Docosapentaenoic Omega 6	<0.01 %
* C22:5 Total (Docosapentaenoic Acid)	<0.01 %
* C22:6 Docosahexaenoic Omega 3	<0.01 %

Eurofins Sample Code: 464-2018-04050457
Client Sample Code: COZ - Batch 5

Test	Result	
QD05C - Fatty Acids-Full Omega 9,6&3 & Trans %W/W (AOCS) (Cont.)		**Completed: 04/12/2018**
AOAC 996.06		
* C24:0 (Lignoceric Acid)	0.16 %	
* C24:1 Omega 9 (Nervonic Acid)	<0.01 %	
* C24:1 Total (Nervonic Acid + isomers)	0.03 %	
* Total Omega 3 Isomers	1.00 %	
* Total Omega 5 Isomers	<0.01 %	
* Total Omega 6 Isomers	51.19 %	
* Total Omega 7 Isomers	0.65 %	
* Total Omega 9 Isomers	26.35 %	
* Total Monounsaturated Fatty Acids	27.10 %	
* Total Polyunsaturated Fatty Acids	52.63 %	
* Total Saturated Fatty Acids	12.63 %	
* Total Trans Fatty Acids	0.08 %	
* Total Fat as Triglycerides	96.64 %	
* Total Fatty Acids	92.43 %	
UM0B1 - Escherichia coli - AOAC 991.14		**Completed: 04/10/2018**
AOAC 991.14		
* E. coli	< 10 cfu/g	
UMABD - Enterobacteriaceae - AOAC 2003.01		**Completed: 04/10/2018**
AOAC 2003.01		
* Enterobacteriaceae	< 10 cfu/g	
UMAEK - Salmonella - AOAC 2003.09		**Completed: 04/10/2018**
AOAC 2003.09		
* Salmonella spp.	Not Detected /25 g	
UMFPA - Moulds - AOAC 997.02		**Completed: 04/10/2018**
AOAC 997.02		
Mold	< 10 cfu/g	
Yeast	< 10 cfu/g	
UMHY9 - Aerobic Plate Count - AOAC 990.12		**Completed: 04/10/2018**
AOAC 990.12		
* Aerobic Plate Count	< 10 cfu/g	

**The test result is covered by our current A2LA accreditation.*

Respectfully Submitted,
Eurofins Scientific Inc.

David Gross
Support Services Manager

Biological Testing
Cert:3329:01

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eurofins | Nutrition Analysis Center

Eurofins Scientific Inc.
Nutrition Analysis Center
2200 Rittenhouse Street, Suite 150
Des Moines, IA 50321
Tel:+1 515 265 1461
Fax:+1 515 266 5453

Eurofins Sample Code: 464-2018-04060233
Sample Description: Corn Oil
Client Sample Code: COZ- Batch 3
PO Number:
Client Code: QD0006388

Entry Date: 04/06/2018
Reporting Date: 05/18/2018

Corn Oil One
attn: Mohan Dasari
10868 189th St. Bldg 13
Council Bluffs, IA 51503

Corn Oil One
Attn: Lab Reports
10868 189th St. Bldg 13
Council Bluffs, IA 51503

CERTIFICATE OF ANALYSIS

AR-18-QD-053502-02

This analytical report supersedes AR-18-QD-053502-01.

Test	Result	
QD143 - Moisture & Volatiles By Air Oven		**Completed: 04/ 11/2018**
AOCS Ca 2c-25		
Moisture & Volatiles By Air Oven	0.07 %	
QD06T - Cadmium (Mwd-ICP-MS)		**Completed: 05/ 18/ 2018**
J. AOAC vol. 90 (2007) 844-856 (Mod)		
* Cadmium (Cd)	<0.010 mg/kg	
QD06S - Lead (Mwd-ICP-MS)		**Completed: 04/ 10/ 2018**
J. AOAC vol. 90 (2007) 844-856 (Mod)		
* Lead (Pb)	<0.010 mg/kg	
QD06R - Mercury (Mwd-ICP-MS, Most Matrices)		**Completed: 05/ 18/ 2018**
J. AOAC vol. 90 (2007) 844-856 (Mod)		
* Mercury (Hg)	<0.010 mg/kg	
QD06Q - Arsenic (Mwd-ICP-MS)		**Completed: 04/ 10/ 2018**
J. AOAC vol. 90 (2007) 844-856 (Mod)		
* Arsenic (As)	<0.010 mg/kg	
QD239 - Unsaponifiable Matter		**Completed: 04/ 11/2018**
AOCS Ca 6a-40		
* Unsaponifiable matter	1.15 %	
QD094 - Free Fatty Acids (FFA)		**Completed: 04/ 12/ 2018**
AOCS Ca 5a-40		
* FFA (Free Fatty Acids)	0.06 %	
QD103 - Peroxide Value (PV)		**Completed: 04/ 10/ 2018**
AOCS Cd 8-53		
* Peroxide Value - Initial	0.6 meq/kg	
QD106 - Iodine Value		**Completed: 04/ 11/2018**
AOCS Cd 1d-92		
* Iodine value	123.5	
QD04J - Lovibond Color - Lovibond Scale		**Completed: 04/ 10/ 2018**
AOCS Cc 13j-97, Cc 13e-92		
Lovibond Color - Lovibond Scale	2.2R, 27.0Y, 0.0B, 1.3N	
QA216 - Cold Test		**Completed: 04/ 12/ 2018**
AOCS Cc 11-53		
Cold test, 0°C	Pass, >8 Hours	

Eurofins Sample Code: 464-2018-04060233
Client Sample Code: COZ- Batch 3

Test	Result
QD05C - Fatty Acids-Full Omega 9 , 6&3 & Trans %W/ W (AOCS)	
AOAC 996.06	
* Fatty Acid Profile	Reported as Fatty Acids
* C4:0 (Butyric Acid)	<0.01 %
* C6:0 (Caproic acid)	<0.01 %
* C8:0 (Caprylic acid)	<0.01 %
* C10:0 (Capric acid)	<0.01 %
* C11:0 (Undecanoic acid)	<0.01 %
* C12:0 (Lauric Acid)	<0.01 %
* C14:0 (Myristic acid)	0.03 %
* C14:1 (Myristoleic acid)	<0.01 %
* C15:0 (Pentadecanoic acid)	0.01 %
* C15:1 (Pentadecenoic acid)	<0.01 %
* C16:0 (Palmitic Acid)	10.32 %
* C16:1 Omega 7	0.10 %
* C16:1 Total (Palmitoleic Acid + isomers)	0.14 %
* C16:2 (Hexadecadienoic Acid)	<0.01 %
* C16:3 (Hexadecatrienoic Acid)	<0.01 %
* C 16:4 (Hexadecatetraenoic Acid)	<0.01 %
* C17:0 (Margaric Acid)	0.07 %
* C17:1 (Heptadecenoic Acid)	0.03 %
* C18:0 (Stearic Acid)	1.59 %
* C18:1 (Vaccenic acid)	0.56 %
* C18:1 Omega 9 (Oleic Acid)	27.14 %
* C18:1, Total (Oleic Acid + isomers)	27.77 %
* C18:2 Omega 6 (Linoleic Acid)	50.63 %
* C18:2, Total (Linoleic Acid + isomers)	51.07 %
* C18:3 Omega 3 (Alpha Linolenic Acid)	0.98 %
* C18:3 Omega 6 (Gamma Linolenic Acid)	<0.01 %
* C18:3, Total (Linolenic Acid + isomers)	0.98 %
* C18:4 Omega 3 (Octadecatetraenoic Acid)	<0.01 %
* C18:4 Total (Octadecatetraenoic Acid)	<0.01 %
* C20:0 (Arachidic Acid)	0.33 %
* C20:1 Omega 9 (Gondoic Acid)	0.23 %
* C20:1 Total (Gondoic Acid + isomers)	0.40 %
* C20:2 Omega 6	0.03 %
* C20:2 Total (Eicosadienoic Acid)	0.03 %
* C20:3 Omega 3	<0.01 %
* C20:3 Omega 6	0.02 %
* C20:3, Total (Eicosatrienoic Acid)	0.02 %
* C20:4 Omega 3	<0.01 %
* C20:4 Omega 6 (Arachidonic Acid)	<0.01 %
* C20:4, Total (Eicosatetraenoic Acid)	<0.01 %
* C20:5 Omega 3 (Eicosapentaenoic Acid)	<0.01 %
* C21:5 Omega 3 (Heneicosapentaenoic Acid)	<0.01 %
* C22:0 (Behenic Acid)	0.13 %
* C22:1 Omega 9 (Erucic Acid)	<0.01 %
* C22:1 Total (Erucic Acid + isomers)	<0.01 %
* C22:2 Docosadienoic Omega 6	<0.01 %
* C22:3 Docosatrienoic, Omega 3	<0.01 %
* C22:4 Docosatetraenoic Omega 6	<0.01 %
* C22:5 Docosapentaenoic Omega 3	<0.01 %
* C22:5 Docosapentaenoic Omega 6	<0.01 %
* C22:5 Total (Docosapentaenoic Acid)	<0.01 %
* C22:6 Docosahexaenoic Omega 3	<0.01 %

Eurofins Sample Code: 464-2018-04060233
Client Sample Code: COZ- Batch 3

Test	Result	
QD05C - Fatty Acids-Full Omega 9 , 6&3 & Trans %W/ W (AOCS) (Cont.)		**Completed: 04/ 13/ 2018**
AOAC 996.06		
* C24:0 (Lignoceric Acid)	0.17 %	
* C24:1 Omega 9 (Nervonic Acid)	<0.01 %	
* C24:1 Total (Nervonic Acid + isomers)	0.02 %	
* Total Omega 3 Isomers	0.99 %	
* Total Omega 5 Isomers	<0.01 %	
* Total Omega 6 Isomers	50.69 %	
* Total Omega 7 Isomers	0.66 %	
* Total Omega 9 Isomers	27.58 %	
* Total Monounsaturated Fatty Acids	28.33 %	
* Total Polyunsaturated Fatty Acids	52.10 %	
* Total Saturated Fatty Acids	12.66 %	
* Total Trans Fatty Acids	0.06 %	
* Total Fat as Triglycerides	97.38 %	
* Total Fatty Acids	93.14 %	
UM0B1 - Escherichia coli - AOAC 991.14		**Completed: 04/ 12/ 2018**
AOAC 991.14		
* E. coli	< 10 cfu/g	
UMABD - Enterobacteriaceae - AOAC 2003. 01		**Completed: 04/ 12/ 2018**
AOAC 2003.01		
* Enterobacteriaceae	< 10 cfu/g	
UMAEK - Salmonella - AOAC 2003. 09		**Completed: 04/ 12/ 2018**
AOAC 2003.09		
* Salmonella spp.	Not Detected /25 g	
UMFPA - Moulds - AOAC 997. 02		**Completed: 04/ 12/ 2018**
AOAC 997.02		
Mold	< 10 cfu/g	
Yeast	< 10 cfu/g	
UMHY9 - Aerobic Plate Count - AOAC 990. 12		**Completed: 04/ 12/ 2018**
AOAC 990.12		
* Aerobic Plate Count	< 10 cfu/g	

**The test result is covered by our current A2LA accreditation.*

Respectfully Submitted,
Eurofins Scientific Inc.

David Gross
Support Services Manager

Biological Testing
Cert:3329:01

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Phytosterol analysis

eurofins | Food Integrity & Innovation

Report Number:	**2399945-0**
Report Date:	**19-Feb-2019**
Report Status:	**Final**

Certificate of Analysis

Feed Energy Company

3121 Dean Ave
Des Moines Iowa 50035 United States

Sample Name:	**Corn Oil**	**Eurofins Sample:**	**8140721**
Project ID	FEED_ENERG-20190211-0001	**Receipt Date**	08-Feb-2019
PO Number	CVD	**Receipt Condition**	Ambient temperature
Sample Serving Size		**Login Date**	11-Feb-2019
Description	Lab 839		

Analysis	Result
Sterol	
Cholesterol	0.0105 mg/g
Campesterol	1.96 mg/g
Stigmasterol	0.736 mg/g
Beta Sitosterol	7.22 mg/g
Brassicasterol	0.0322 mg/g
Other Sterols/Stanols	4.10 mg/g
Total Sterols	14.1 mg/g

Method References	**Testing Location**
Sterol (STOL_S)	**Food Integrity Innovation-Madison**
Official Methods of Analysis, Method 2007.03, AOAC INTERNATIONAL, Gaithersburg, MD, (Modified)	

Testing Location(s)	**Released on Behalf of Eurofins by**
Food Integrity Innovation-Madison	**Edward Ladwig - Director**

Eurofins Food Chemistry Testing US, Inc.
3301 Kinsman Blvd
Madison WI 53704
800-675-8375

Eurofins Food Integrity and Innovation accepts all liability for work conducted as of 01 Aug 2018.

eurofins | Eurofins Craft Technologies

Eurofins Craft Technologies

4344 Frank Price Church Road
Wilson, NC 27893
252-206-7071
Craft_ClientServices@EurofinsUS.com

Feed Energy Company

John Norgaard
4400 E. University Ave
Pleasant Hill, IA 50327

Analytical Report

AR-19-YI-000396-01

Client Code: YI0000382

Received On: 01/30/2019
Reported On: 02/05/2019

Eurofins Sample Code:	129-2019-01300015	**Sample Registration Date:**	01/30/2019
Client Sample Code:		**Condition Upon Receipt:**	20.6 °C acceptable
Sample Description:	Lab 839 Corn Oil	**Sample Reference:**	Oil

YI006 - Vitamin E (alpha, beta, gamma, delta tocopherols)	**Reference**	**Analysis Completed**
	Encyclopedia of Food and Health; (5) 309-318	02/05/2019

Parameter	**Result**	**LOQ**
Alpha-Tocopherol	193 µg/g	10.00 µg/g
Beta-Tocopherol	<10.0 µg/g	10.00 µg/g
Delta-Tocopherol	<10.0 µg/g	10.00 µg/g
Gamma-Tocopherol	294 µg/g	10.00 µg/g
Total Tocopherols	498 µg/g	10.00 µg/g

YI008 - Vitamin K Profile Low Level (HPLC with PCRFD)	**Reference**	**Analysis Completed**
	AOAC 999.15, mod.	02/05/2019

Parameter	**Result**	**LOQ**
Phylloquinone (Vitamin K1)	ND µg/g	0.01 µg/g
Menaquinone-4 (MK-4)(Vitamin K2)	ND µg/g	0.01 µg/g
trans-Menaquinone-7 (MK-7)(Vitamin K2)	ND µg/g	0.01 µg/g

Respectfully Submitted,

Jeffrey Whaley
Senior Scientist